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Influenza illness is a vaccine-preventable disease, yet seasonal outbreaks occur yearly and vaccination coverage rates remain suboptimal. Given that childhood vaccination is dependent on parental decision-making processes, parental beliefs about influenza vaccination are important for elucidating the underlying factors contributing to suboptimal influenza vaccination coverage rates of young children. Furthermore, the 2009 H1N1 influenza pandemic was well-publicized in the media, yet the lack of increased vaccination coverage among pediatric populations during the pandemic may reflect insufficient concern regarding the threat of influenza. Our study aimed to evaluate the effect of social and behavioral factors that may influence parental decision making and subsequently influenza vaccination of children attending daycare during the 2010 – 2011 influenza season in Tarrant County, Texas. Our study involved the administration of a one-time self-administered paper survey to parents of children aged 6 months to 59 months attending home- or center-based daycare. One-hundred sixty six parents from twenty-three daycares completed the survey. Logistic regression was used to estimate odds ratios for total associations and

corresponding 95% confidence limits (CL) of each factor on influenza vaccine uptake. Our results suggest that physician recommendation (OR=16.4, 95% CL: 5.5, 48.6) and parents with high levels of preventive behaviors (High: OR=7.1, 95% CL: 1.9, 26.4; Moderate: OR=1.4, 95% CL: 0.4, 5.3) influence influenza vaccination of children in daycare. Parents with a high perceived threat of the 2009 H1N1 pandemic influenza strain had greater odds of vaccinating their children than parents with high perceived threat of influenza illness compared to parents with a low perceived threat of influenza illness (High: OR=3.3, 95% CL: 2.1, 5.1; Moderate: OR=1.2, 95% CL: 0.8, 1.8) and this association varied by race/ethnicity. Although preliminary, our findings suggest the potential relation of physician recommendation and parental preventive behaviors, with limited effect of the 2009 H1N1 influenza pandemic, as influential factors in the relation between health beliefs and behaviors and vaccination decision-making for children attending daycare. Future research may benefit from continued exploration of social and behavioral factors that influence influenza vaccination of children in pediatric populations with consideration of the measurement of social and health behavior constructs.

INDIVIDUAL CHILD AND PARENTAL FACTORS THAT INFLUENCE
INFLUENZA VACCINATION IN CHILDREN 6 MONTHS TO 59 MONTHS OF
AGE

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AGE

DISSERTATION

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By

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LIST OF ABBREVIATIONS

ACIP: Advisory Committee on Immunization Practices

CL: confidence limit;

DAG: directed acyclic graph;

Flu: influenza;

HBM: Health Belief Model

IQR: inter-quartile range;

NHFS: National 2009 H1N1 Flu Survey

TDFPS: Texas Department of Family and Protective Services

CHAPTER 1

BACKGROUND

Influenza illness continues to cause a significant disease burden in pediatric populations in the United States. [1, 2] Young children (less than five years of age) experience the greatest morbidity and mortality from influenza epidemics each year.[3] The highest attack rates of influenza illness[2, 4-6] and the highest rates of infection[2, 7] occur among children less than three years of age[8] ranging from 23% to 48% annually.[9, 10] Furthermore, children under five years of age are at greatest risk of developing influenza-associated complications leading to hospitalization and death.[2, 3, 11]

Extensive research shows that children play a significant role in the transmission cycle of influenza because of the nature of the virus and the means by which it spreads.[12] Infected children shed the influenza virus in greater quantities and for more days than adults. [13] Furthermore, daycare environments are conducive to transmission of the influenza virus, permitting the spread of the virus from children to others in their shared environments.[14, 15] Therefore, measures to reduce or prevent the spread of influenza in daycare environments, such as vaccination, have utility.

Annual influenza vaccination is the most effective tool for preventing influenza illness and its associated complications and sequelae.[3, 16] In April 2002, the Advisory Committee on Immunization Practices (ACIP) recommended

influenza immunization of children aged 6 months to 23 months of age.[17] Subsequently, these recommendations were expanded to children aged 24 months through 59 months during the 2006 – 2007 influenza season.[18] Although a few years have passed since the ACIP recommendations were released, national seasonal influenza vaccination coverage estimates from sentinel sites across the United States revealed a lack of increased vaccination coverage in children aged 6 to 23 months (2009-2010 coverage=55.7%), marginal increases among children aged 24 months to 59 months (2009-2010 coverage=38.4%), and low full vaccination coverage of children less than 5 years of age.[19] Furthermore, interim results of state-specific seasonal influenza vaccine coverage reported 40.5% of children aged 6 months to 17 years in Texas were vaccinated for seasonal influenza during the 2009 – 2010 influenza season.[20] Although these estimates represent an increase in influenza vaccination coverage compared to previous influenza seasons, influenza vaccine coverage remains suboptimal to infer herd immunity.[3, 21, 22] Research suggests that increased vaccination coverage of children may reduce the overall burden of influenza to those at highest risk of influenza-associated complications. Nonetheless, suboptimal vaccination for influenza in children continues to threaten the community and warrants further research that explicates and elucidates the magnitude of the underlying etiologies of those factors that influence influenza vaccination.

Existing research on factors that influence influenza vaccination of children provides predominantly descriptive findings (e.g. prevalence of influenza vaccination or vaccine coverage rates).[3, 23] These studies provide an indication of who is and who is not getting the influenza vaccine. Descriptive studies, such as those that estimate influenza vaccination coverage in socio-demographic subgroups, have utility for public health program planning and health services resource allocation but have limited application for elucidating the underlying factors that contribute to the disproportionate vaccine uptake in subgroups of the population.[24] Understanding *why* there are fewer people in certain subgroups of the population getting the influenza vaccine each year requires inferential studies, which elucidate the underlying mechanisms and structural (i.e., causal) relations among factors that contribute to the quantification or enumeration of influenza vaccination coverage rates. Subsequently, inferential research requires that confounding be addressed, which is not a concern in descriptive studies.[24]

Factors that influence parental decision to vaccinate their children against influenza involve inherently social and behavioral concepts and underpinnings. Research on influenza vaccine uptake has begun to use social behavioral models, although inconsistently. [1] Regardless of *what* factors influence a parent's decision to vaccinate, valid measurement of these factors is an integral component of appropriately identifying and elucidating the magnitude of the associations between the individual and group-level risk factors and flu

vaccination of young children. Cumulative evidence from previous studies supports the application of a conceptualized framework such as the Health Belief Model (HBM) to describe and explain the influence of individual behaviors on health behaviors.[25, 26] The HBM is used in health behavior research to elucidate the constructs of individual perceptions of threat (defined as susceptibility and severity of disease), benefit, barriers, and self-efficacy that affect, for example, the acceptance and uptake of influenza vaccine

The evidence regarding the effect of parental risk perception of influenza on influenza vaccination of children has focused broadly on pediatric populations (i.e. children aged 6 months to 18 years). Previous research used primarily descriptive analyses to present differences in vaccination coverage by socio-demographic and parental factors. Limited information is available regarding health behaviors and constructs that influence parental decision making of influenza vaccination of children attending daycare. Exploring factors that influence parental decision making of children attending daycares provides a unique opportunity to target a population in a high risk environment for influenza transmission. Therefore, we focused our investigation on children aged 6 months to 59 months attending home- or center-based daycare in Tarrant County, Texas. We framed this research in the form of a pilot study given the limited resources to conduct the proposed study. Our study was designed to better describe and understand the underlying health behaviors and constructs that lead to parental decision making of influenza vaccination for young children by using inferential

methods and behavioral models to inform construct and survey development.

Subsequently, the primary objectives of this dissertation were:

1. To systematically review the literature to identify parental factors associated with influenza vaccine uptake in children.
2. To estimate the magnitude of the association of individual child and parental factors on influenza vaccine uptake in children aged 6 months to 59 months attending daycare in Tarrant County, Texas.
3. To evaluate the effect of the 2009 H1N1 influenza pandemic on parental decisions to vaccinate children with the influenza vaccine during the 2010 – 2011 influenza season in Tarrant County, Texas.

CHAPTER 2

SYSTEMATIC REVIEW

Introduction

Annual influenza vaccination is the most effective public health measure for preventing influenza illness and its associated complications and sequelae.[3, 16] The expansion of the Advisory Committee on Immunization Practices (ACIP) recommendations for influenza vaccination to children aged 24 months through 59 months during the 2006 – 2007 influenza season resulted in the universal recommendation for influenza immunization of all children 6 months to 18 years of age.[18] Although a few years have passed since the ACIP recommendations were released, national seasonal influenza vaccination coverage estimates from sentinel sites across the United States reveal a lack of increased vaccination coverage in children aged 6 to 23 months (2009-2010 coverage=55.7%), marginal increases among children aged 24 months to 59 months (2009-2010 coverage=38.4%), and low full vaccination coverage of children less than 5 years of age.[19] Although these estimates represent an increase in influenza vaccination coverage compared to previous influenza seasons, influenza vaccine coverage remains suboptimal.[3, 21, 22] Furthermore, these coverage estimates are insufficient to meet the Healthy People 2020 objectives[27] for improving influenza vaccination coverage levels among young children (target = 80 percent vaccination coverage (Objectives IID-7, IID-12.1, and IID-12.2)[28].

Influenza illness continues to cause a significant burden on the community, particularly in pediatric populations.[1, 2] Children are a considerable source of influenza virus transmission to those in their household and persons at increased risk of influenza complications, particularly infants, elderly, and immune compromised individuals.[3] Although elderly populations have the greatest risk of mortality during seasonal influenza outbreaks, children are responsible for transmission of the virus to these high-risk populations.[16] Therefore, increasing vaccination coverage of pediatric populations should reduce the burden of influenza illness on other at-risk populations. Nonetheless, childhood vaccinations are dependent on surrogate decisions by parents or caregivers at which time risks and benefits associated with influenza vaccination are assessed. Factors that influence parental decision to vaccinate their children against influenza involve inherently social and behavioral concepts and underpinnings. Parents and caregivers are thus influenced by internal (e.g. family environment, personal beliefs regarding use of preventive health services) and external factors (e.g. social norms, information from health professionals and media outlets).

Although studies have begun to evaluate social and behavioral factors that influence influenza vaccination in pediatric populations using health behavior theories and models, no review on social and behavioral factors that influence pediatric influenza vaccination that summarizes the empirical evidence from this research exists. Therefore, the purpose of this systematic review is to describe

and summarize the findings of published literature on social and behavioral factors and determinants that influence parental decision to vaccinate children with the influenza vaccine.

Methods

Literature search strategy

We searched peer-reviewed literature in PubMed/MEDLINE, CINAHL, PsychInfo, and ISI Web of Science Citation Index Expanded databases published in English through April 2011 that investigated social and behavioral factors that influence influenza vaccination in pediatric populations. No starting date limitations were imposed. Broad search terms included keywords related to influenza (and variants such as flu), vaccin*, immunization, child*, and parent* (where * is a Boolean operator that searches permutations of the base word, e.g. vaccination) to allow specificity in our search.

Study eligibility criteria

Articles identified using the search strategy were merged into a collective database of potentially eligible studies. These potentially eligible studies were screened for eligibility. Studies of hypothetical scenarios or simulations were excluded from the systematic review. Basic science studies, case reports, case series, editorials, and letters to the editor, which essentially functioned as case reports, were ineligible. Only original studies were eligible for critical review.

However, backward citation tracking of review articles (including systematic reviews and meta-analyses) was conducted to search for any potentially eligible studies not previously identified. Studies of populations outside the United States were ineligible for inclusion because of differences between the United States and other countries in health care system infrastructure and utilization, immunization mandates, and potential social and cultural differences in beliefs and motivations related to the use of preventive health services such as influenza vaccination. Studies were eligible if influenza vaccination coverage was assessed in children aged 6 months to 18 years of age in which parents or caregivers made the decision to vaccinate the child. Social and behavioral determinants were defined broadly as those described in Health Belief Model constructs including perceived risk, perceived effectiveness of the influenza vaccine, perceived barriers to vaccination, and cues to action. To be included in the final study for critical review, studies had to meet the following criteria: (1) *actual* influenza vaccination was measured; studies in which influenza vaccination intention only was measured were excluded; and (2) social and behavioral determinants defined by the Health Belief Model constructs were measured using either qualitative (e.g. focus group) or quantitative data ascertainment methods (e.g. survey questions).

Data abstraction

Descriptive characteristics of eligible studies included in the final critical review were abstracted. These characteristics included influenza season as defined by the two year overlapping seasonal cycle of influenza spread in North America (e.g.1999-2000). Study design, study location, age categories of children included in each study, sample size, site location, and health status of study population were described. The outcome of interest in this systematic review was influenza vaccination. Information regarding outcome measurement (e.g. self-report) and validation methods used (e.g. medical records, immunization registry data) were abstracted from eligible studies. ACIP recommendations for universal childhood influenza immunization were effective during the 2006-2007 influenza season. Studies that were conducted post-ACIP recommendations were indicated. Overall percentage of children vaccinated for influenza was recorded and calculated if not explicitly reported. Statistical methods used to analyze study data were reported for each study. Covariate selection method and model covariates were reported for studies using regression analyses. Factors that influence influenza vaccination in children were abstracted from eligible studies and categorized for descriptive purposes as broad social behavioral determinants or more specifically as HBM constructs when appropriate. Directionality of the association was reported and defined as positive, negative, or null association (i.e., relative risk = 1.0). For those studies in

which confidence limits were reported, uncertainty of the estimates was reported using durability estimates.

Results

The systematic literature search yielded 3,398 articles, of which 124 abstracts and full articles were identified for further examination. From these 124 studies, 10 studies met our inclusion criteria and were included in the systematic review[29-38]. The screening and selection process of the studies in this review is illustrated in *Figure 1*. The included studies and their characteristics are described in *Table 1*. Briefly, studies that evaluated social and/or behavioral influencing factors were conducted on influenza vaccination during the 1999-2000 influenza season through the 2009-2010 influenza season. The majority of studies were conducted during the 2003-2004 influenza season (n=5, 50%). Nearly all studies were cross-sectional using varying survey administration modes (i.e. telephone, mail, internet, interview) to ascertain information (cross-sectional: n=9; focus group: n=1). Sample sizes ranged from 54 mothers (focus group) to 794 parents. Populations studied included healthy children (n=6, 60%), hospitalized children (n=1, 10%), children with asthma (n=1, 10%), and sick or high-risk populations, such as children with chronic medical conditions (n=2, 20%). Few studies were conducted in healthy pediatric populations outside a clinic or institutional setting (n=2, 33%). The majority of studies included in this review measured influenza vaccination through self-report (self-report: n=9

(90%). Of these studies, half validated self-reported influenza vaccination using medical records or immunization registries (validated self-report: n=5 (50%)). Reported and calculated vaccination coverage estimates ranged from 7% - 82%. Vaccination coverage estimates could not be calculated in 3 studies because there were insufficient data available in the manuscript. Influenza vaccination measurement methods and vaccination coverage percentages are reported in *Table 2*.

Various statistical methods for analysis of study data were utilized in the studies included in this literature review. Although regression methods were the most commonly used analytical tool to assess the association between social/behavioral factors and influenza vaccine uptake of children, covariate selection methods and model adjustment variables varied between studies. Furthermore, more than half of studies did not specify a covariate selection method used (n=6, 60%) in regression analyses. A summary of analytic and covariate selection methods with model covariates included in the analyses is presented in *Table 3*.

A summary of sociodemographic and behavioral health constructs with direction of the association reported for studied factors that influence influenza vaccination uptake in pediatric populations is detailed in *Table 4*. We briefly describe the key results of the included studies below.

Demographic characteristics

Demographic variables such as age, gender, and race/ethnicity were reported to modestly influence influenza vaccination of children, although confidence intervals for the estimates were imprecise [29, 30] (i.e. wide confidence intervals most likely caused by overadjustment and or unnecessary adjustment[39]). Increasing age of the child had a modest to no association on influenza vaccination.[29, 30, 36, 40, 41] Overall, ethnic minority groups were less likely to have their children vaccinated against influenza compared to parents of White children.[40, 41]

Social and behavioral constructs

There were different methods used to measure and assess the social and behavioral constructs of influenza vaccination. These methods included the development of composite scales [40, 41], importance ratings [38], and reporting of percentage of the parents that responded to a specific question or series of questions.[29-31, 33, 36, 38] Some studies used descriptive statistics and percentages to describe the association between behavioral constructs on influenza vaccination.[29, 30, 33, 38] Lack of knowledge regarding the influenza vaccine [29, 30] was identified as a barrier to vaccination in some studies. The role of cues to action, such as physician recommendation[29-32, 36, 38, 40, 41] and reminder postcards and letters[32, 40], positively influenced parental decisions to vaccinate their children. Studies which assessed concerns regarding

vaccine safety as a barrier to influenza vaccination found a modest to strong association between vaccination status.[30, 32, 36, 38, 40] Susceptibility to influenza [38], the severity of the disease [38], and the benefits [36, 38], risks, and barriers to vaccination in addition to the social norms regarding vaccination were suggested to influence parental decisions to vaccinate their children against influenza.[40, 41]

Discussion

This systematic review identified and summarized published studies that reported parental behavioral and socio-demographic factors that influenced influenza vaccination of young children in their study populations. Based on the results of the included studies, cues to action, specifically physician recommendation, may be considered an important factor that influences parent decision making regarding influenza vaccination of children. Some evidence supports parental perceived threat of influenza illness, its severity, and whether a child is susceptible to the virus, as factors that may affect a parent's intent uptake of the influenza vaccine. Personal experiences with previous influenza vaccinations of the child and social norms regarding its acceptability provide an indication of whether a parent will likely vaccinate his/her child during the current influenza season. Nonetheless, given the still poorly defined nature of the topic and limited use of health behavior models, this review provides researchers with a pulse of the evolving literature regarding social and behavioral factors that

influence influenza vaccination in pediatric populations. Furthermore, our findings may be limited by the information available in the published articles. Article length and type (e.g. brief report, original report) may restrict the authors from providing detail regarding survey questions and responses. Therefore, this information is omitted from our findings. Incomplete retrieval of identified research may result in non-representativeness of studies published on the topic.

Existing research on factors that influence influenza vaccination of children provides predominantly descriptive findings (e.g. prevalence of social/behavioral factors by vaccination status).[3, 23] These studies provide an indication of who is and who is not getting the influenza vaccine. Descriptive studies, such as those that estimate influenza vaccination coverage in socio-demographic subgroups, have utility for public health program planning and health services resource allocation but have limited application for elucidating the underlying factors that contribute to the disproportionate vaccine uptake in subgroups of the population.[24] Nonetheless, our results indicate that published studies have primarily reported imprecise results regarding influenza vaccination in pediatric populations.[30] Heterogeneity of study populations, questions asked, and varying statistical models used to assess associations preclude conclusions regarding the health beliefs and behaviors that are likely to influence influenza vaccination of young children.

Although we provide a summary of “significant” factors that influenced influenza vaccination of children, it is uncertain whether the analytic methods

used in these previous studies provides evidence that can be used to inform further research that directs intervention development. Given marginal incremental increases in influenza vaccination coverage, there is a continued need for research that identifies factors that influence vaccine uptake in children. As more studies incorporate social behavioral models [1], such as the HBM, in their research to measure health behavior constructs and to identify factors that influence vaccine uptake, efforts should be made to ensure the reliability and validity of the questions and scales used to measure the health behavior and belief constructs. Future research may benefit from continued exploration of social and behavioral factors that influence influenza vaccination of children in pediatric populations with consideration of the measurement of social and health behavior constructs.

Figure 1. Flow diagram for the search and selection of studies, systematic review of behavioral factors that influenza vaccination of children.

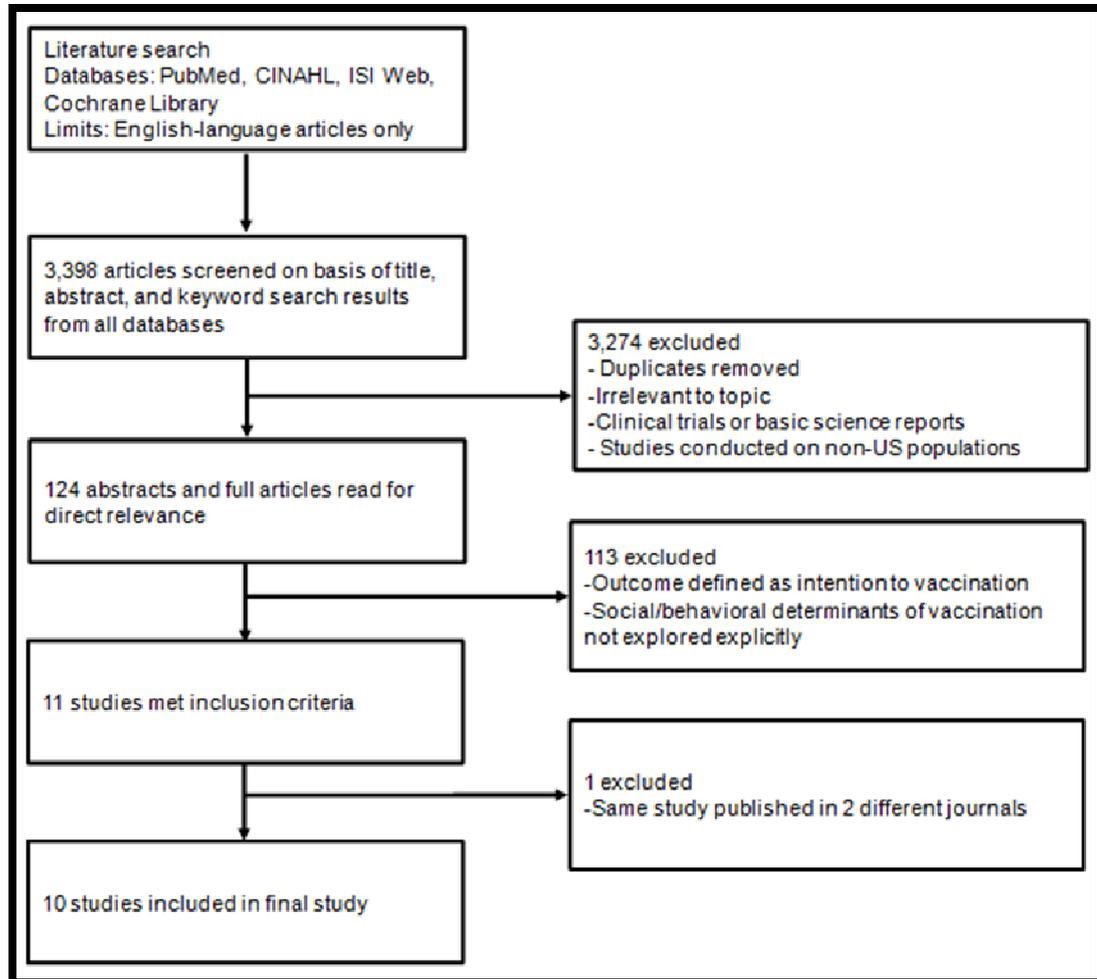


Table 1. Characteristics of observational studies that explored social and behavioral factors that influence influenza vaccination in pediatric populations.

First author	Flu season	Study design	Mode	Study location(s)	Age category	Site location type	Sample size	Health status ^a
Poehling[29]	1999-2000	cross-sectional	survey	Tennessee	6 mos – 3 yrs	children's hospital	189	Hospitalized
Hemingway[30]	2002-2003	cross-sectional	survey	Tennessee	6 mos - 59 mos	pediatric clinic	249 in 2002; 329 in 2003	Healthy
Lin[31]	2002-2003	cross-sectional	survey-mail	Pennsylvania	2 yrs – 13 yrs	health center	183	High risk
Nowalk[32]	2002-2003; 2003-2004	cross-sectional-	survey-mail	Pennsylvania	6 mos – 23 mos	health center	417 in 2003 266 in 2004	Healthy
Mirza[33]	2002-2003; 2003-2004	cross-sectional	survey-self administered or mailed	Southeastern US	not specified (pediatric)	pediatric subspecialty clinics	794	Chronic medical condition
Daley[34]	2003-2004	cross-sectional	Survey-phone	Colorado	6 mos - 21 mos	private pediatric practices	472	Healthy
Daley[35]	2003-2004	longitudinal	pre and post surveys	Colorado	6 mos - 21 mos	private pediatric practices	316	Healthy
Gnanasekaran[36]	2003-2004	cross-sectional	survey-phone	Massachusetts	5 yrs - 18 yrs	managed care organization	295	Asthma
Gazmararian[37]	2005-2006	cross-sectional	focus group	Georgia	5 yrs – 12 yrs		54	Healthy
Flood[38]	2009-2010	cross-sectional	Web-based	USA	2 yrs – 12 yrs	Across US	500	healthy

^aHealth status= healthy, ill, hospitalized, or high risk medical condition for flu complications

Table 2. Summary of influenza vaccination outcome measurement of studies that discussed factors that influence influenza vaccination in children.

First author	Measurement ^a	Influenza vaccination	Validation method	Outcome measurement misclassification	% vaccinated
Poehling[29]	Self-report		----		22
Hemingway[30]	Self-report and Validated	Tennessee State Immunization Registry		Potential misclassification of flu vaccination (underestimating number of children vaccinated) because the registry doesn't capture flu vaccinations from "most other clinics in the region"	7 (2002) 18 (2003)
Lin[31]	Self-report, Validated	Medical record		Potential misclassification of flu vaccination (underestimating number of children vaccinated) because children may have received vaccine at another location or medical provider	31
Nowalk[32]	Self-report		----		48
Mirza [33]	Self-report		----		NR
Daley[34]	Self-report, Validated	Immunization registry and billing data			NR
Daley[35]	Self-report, Validated	Immunization registry and billing data			82
Gnanasekaran[36]	Validated	Computerized medical records		Potential misclassification of flu vaccination (underestimating number of children vaccinated) because children may have received vaccine at another location or medical provider	43
Gazmararian[37]	Self-report		----		NR ^b
Flood[38]	Self-report		----		44 (every year) 22 (sometimes)

^aSelf-report or validated;

^bNR=Not reported or unable to calculate based on available information in manuscript

Table 3. Summary of analytic methods used in studies to assess the influence of social and behavioral factors on influenza vaccination of pediatric populations.

First author	Statistical analysis reported		Covariate selection method		Model covariates for regression analyses									
	X ²	Logistic regression		method	Age	Sex	Race	Health Plan1	High risk condition	No. children in family	Vaccinated family member	Physician recommendation	Fall continuity appointment	Health belief factors3
Poehling[29]		✓		Not specified	✓	✓	✓		✓		✓			
Hemingway[30]	✓	✓		Not specified	✓	✓	✓		✓		✓	✓	✓	
Lin[31]	✓	✓		Significant X ²			✓			✓				
Nowalk[32]	✓	✓		Not specified										
Mirza[33]	✓	✓		Not specified					✓					
Daley[34]	✓	✓		Not specified	✓		✓	✓			✓			✓
Daley[35]	M4	✓		Variables significant (p< 0.20) in bivariable analyses were entered in multivariable logistic model; final model covariates were selected if p<0.05										✓
Gnanasekaran[36]	✓	✓		Variables significant (p< 0.20) in bivariable analyses were entered in multivariable logistic model; final model covariates were selected if p<0.10	✓							✓		✓
Gazmararian[37]		✓												
Flood[38]	✓	ANOVA												

Table 4. Summary of sociodemographic and behavioral health constructs; direction of the association reported for studied factors that influence influenza vaccination uptake in pediatric populations.

Factors that influence vaccine uptake	Study reference number									
	[29]	[30]	[31]	[32]	[33]	[34]	[35]	[36]	[37]	[38]*
SOCIODEMOGRAPHIC VARIABLES										
Age	+ ^a	+/0 ^c				0	-	-		
Gender	- ^b	+/- ^b								
Race/ethnicity	+	+/- ^b				-	-			
Parental education							-			
PERCEIVED SUSCEPTIBILITY										
Perceived susceptibility of child to flu			-			+				
High risk condition	+	+/+								
PERCEIVED SEVERITY OF FLU										
Severity of flu						-				
PERCEIVED BENEFITS										
Benefits of vaccination						+				+
PERCEIVED BARRIERS										
Barriers to vaccination							-			-
Lack of knowledge about flu or vaccine		+								-
Risks of vaccination (safety)		+					-			-
CUES TO ACTION										
Intent to vaccinate										-
Prior vaccination of caregiver/family	+	-/+					+			
Physician recommendation	+	+/+	+	+	+	+	+	+	+	
Family supports vaccination			+							
Reminder postcard				+					+	
Fall continuity appointment										
Social norms regarding vaccination		-/+							+	+

*Flood et al analyses used a p-value < 0.008 to indicate a significant difference between subgroups; mean agreement and importance ratings were reported;

^a + (positive association: more likely to vaccinate);

^b - (negative association: less likely to vaccinate);

^c null (0); | = imprecise with wide confidence intervals

Reference groups: age (younger), gender (female), race (white); parental education level (college graduate), persistent asthma (asthma), recent hospitalization (no recent hospitalization), general health scale (fair or poor); fall continuity appointment (no); *Used reported crude estimate; benefits of vaccination (prevent spread to elderly); barriers to vaccination (e.g. convenience), intent to vaccinate (planned to vaccinate)

CHAPTER 3

INFLUENZA VACCINATION OF DAYCARE CHILDREN

Introduction

Influenza illness is a vaccine-preventable disease, yet seasonal outbreaks occur yearly and vaccination coverage rates remain suboptimal. The lack of increased influenza vaccination coverage of pediatric populations during the influenza season may reflect insufficient concern regarding the illness and its severity;^[42] an “it happens every year” attitude. Pediatric deaths from influenza illness, many of those prevented by vaccination, occur each year. Most recently during the 2010 – 2011 influenza season, more than half of the influenza-associated pediatric deaths occurred in children less than 5 years of age.^[43] Unfortunately, only 23% of those children received the influenza vaccine.^[43] The Morbidity and Mortality Weekly Report that provides data regarding pediatric deaths from influenza illness should not be understated. Of note, more than one-third of the children died at home or in the emergency department and more than half of those children were non-Hispanic White.^[43] Given that childhood vaccination is dependent on parental decision-making processes, parental beliefs about influenza vaccination are important for elucidating the underlying factors contributing to suboptimal influenza vaccination coverage rates of young children. Such beliefs may offer potentially modifiable targets for future intervention studies attempting to increase influenza vaccination of children.

Reducing the gap between influenza vaccine recommendations and current vaccination status in children requires knowledge about factors that encourage families to vaccinate children.[29] Few studies have addressed the underlying contributory and influencing factors for suboptimal influenza vaccination coverage in daycare-aged children. Although influenza vaccination is universally recommended for all children, influenza vaccination for children is not mandatory for daycare or for this specific age group and not considered a requirement for pediatricians to administer during well-child visits. Voluntary adherence to influenza vaccination of children is dependent on an understanding of underlying causal relations that incorporates health behavior theories and considers public perceptions and attitudes. Furthermore, there is a paucity of inferential studies to explicate the factors that influence influenza vaccine uptake in young children or studies that address suboptimal vaccination coverage levels by explicating the underlying causal mechanisms for these rates. Few studies have incorporated health behavior theory with causal diagrams to assess the relation between factors that influence influenza vaccination of young children.[24, 44] To expand our understanding of influenza vaccination status in children, we assessed factors that may influence parental decision making of their children using constructs based on the Health Belief Model (HBM).

Methods

The current study was designed to investigate factors that influence influenza vaccine decision making by caregivers for young children. The study employed a self-administered paper survey to parents of children aged 6 months to 59 months attending home- or center-based daycare in Tarrant County, Texas, to obtain parental perceptions of the influenza vaccine, influenza vaccination of their children, and personal preventive behaviors.

Participants

The study population consisted of parents or primary caregivers (18 years of age or older) of children 6 months to 59 months of age attending daycare in Tarrant County, Texas. All daycares (home and center) listed in the Texas Department of Family and Protective Services (TDFPS) database[45] that care for children aged 6 months through 59 months were eligible for inclusion. Parents of children less than 6 months of age were excluded from the survey because the influenza vaccine is not indicated or approved for use in children less than 6 months of age. In Texas, there are four classifications of child care settings including licensed daycare centers and three types of daycare homes (licensed child care homes, registered child care homes, and listed family homes).[46] Licensed child care centers provide care for seven or more children under 14 years old for less than 24 hours per day and are located outside of the home. They are routinely monitored and inspected by the TDFPS to ensure that

minimum standards, as outlined by the state, are met. Licensed child care homes follow similar licensing requirements but care is limited to a maximum of 12 children. Registered homes provide care for up to six children and are inspected less frequently than licensed homes. Listed family homes provide care for one to three unrelated children and are not inspected unless a report or complaint is received.[46] Our sample included the four types of child care facilities; specifically, licensed child care centers, licensed child care homes, registered child care homes, and listed family homes.

Sampling and recruitment

A weighted sampling scheme using probability proportionate to size sampling method (i.e. dependent on the size and daycare type) was used to sample child care providers (home- and center-based) and ascertain responses from parents. Analyses were weighted to account for sampling scheme. Daycares included in the sample were contacted via phone to inform them of the study using a telephone script and to obtain informed consent. Gift card incentives were provided to daycares for participating in the study. Participating daycares provided estimates for the number of families with children aged 6 months to 5 years of age. Families with more than one child meeting the age eligibility requirement were asked to complete one survey with responses applicable to the oldest child in the household aged between 6 months and 5

years. Parents were offered an opportunity to enter their name into a drawing to receive a gift card to a local store.

Theoretical framework

A multitude of health behavior theories have been developed to better understand and explain health behaviors such that researchers may “suggest ways to achieve health behavior change”[47] to improve health outcomes. The HBM is one of the most widely used theoretical frameworks for understanding individual health behavior and has been previously applied to influenza vaccination research. Current evidence suggests that health beliefs and behaviors regarding perceived risk of vaccine-related adverse events, perceived threat of influenza (i.e. susceptibility and severity), and parental preventive behaviors contribute to parental decision making regarding childhood influenza vaccination.[1, 26, 48] Empirical research applying the HBM has shown that perceived barriers is the most powerful single predictor of the HBM dimensions for all behaviors; and although both perceived susceptibility and perceived benefits were important overall, perceived susceptibility was more strongly related to preventive health behavior.[47, 49] Previous research on the use of the HBM for vaccine uptake and measurement of relevant constructs suggests that the use of this model may provide a strong theoretical framework from which to base our research. We selected the HBM to inform the measurement of our survey questions because this model incorporates the nuances of individual

behaviors that influence individual decision-making regarding preventive health services.[26, 47]

Survey instrument

The survey included both modified questions from the National 2009 H1N1 Flu Survey (NHFS)[50] and questions that measure factors identified using current evidence from the literature. To the best of our knowledge, there is no publicly available validated survey that ascertains responses to questions that assess the HBM constructs relevant to the uptake of influenza vaccine in child populations. Therefore, we constructed a survey with questions from previous studies and newly created questions.

The self-administered survey consisted of 39 questions. Twelve questions addressed individual and socio-demographic characteristics of the child and respondent. Child's age was measured as a continuous variable ascertained from adult respondents as age in months. The race/ethnicity of the child was categorized and reported by the respondent as non-Hispanic White, non-Hispanic Black, Hispanic, or Asian using two questions: "Is your child Hispanic or Latino?" and "Which of the following categories best describes your child's race?". Insurance coverage was defined as a dichotomous variable indicating whether the child had any kind of health care coverage, which included private insurance and government subsidized coverage such as Medicaid. Two questions were used to measure socioeconomic status; the education of the

respondent and the total combined family income before taxes for the prior year. The remainder of the questions addressed measurement of the HBM constructs and other relevant variables. Briefly, child's previous flu vaccination was measured as a dichotomous variable. Two questions were used to assess medical indication: "Has a doctor ever told you that your child has asthma?" and "The following is a list of health conditions. Please indicate whether a doctor, nurse, or other health professional has ever said that your child has the condition by placing an 'X' in the appropriate box (i.e. heart problem, including congenital heart disease; blood problems such as anemia or sickle cell disease; cerebral palsy; muscular dystrophy; kidney problems; liver problems; cancer; diabetes; lung problems; weakened immune system caused by chronic illness or by medicines; difficulty breathing or respiratory problems (other than asthma)."

Medical contraindication was a dichotomous variable measured by the parent responding to the question "Is your child allergic to eggs?". Physician recommendation was categorized as a dichotomous variable. Additionally, we asked parents questions regarding their preventive health behaviors (i.e., flu vaccination status, seen by physician in past year).

Measures

Our outcome of interest was influenza vaccination defined as received at least one dose of the influenza vaccine during the current influenza season, August 2010 through May 2011. Influenza vaccination status was ascertained

from responses to the question, “Has your child gotten a flu shot this year (August 2010 to April 2011)?” and coded as a dichotomous variable. Primary exposures of interest were four factors identified in our review of the literature that have been suggested in previous study populations to influence influenza vaccine uptake in young children. Questions used to assess health behaviors and beliefs constructs for our four primary exposures of are detailed in the following section.

Scale development

There were four main constructs measured in our study: parental preventive behaviors, perceived risk of vaccine-related adverse events [1, 44, 51, 52], perceived threat of influenza illness (includes susceptibility and severity) [1, 15, 53-56], and the effect of physician recommendation [1, 33, 54, 57-59]. We created a scale for each construct except for physician recommendation (measured using one question) that consisted of multiple items using questions aimed to reflect the scale’s overall purpose and underlying latent variables.[60] Questions in each construct used redundancy to capture aspects that differ within the constructs across questions.[60] We included items in each scale with numerous response categories to encourage discrimination among the differences in the underlying construct and to increase precision in our measurement of the scale.[60]

We briefly describe each construct and its intended measurement. We measured parental preventive behaviors by asking parents four successive questions. Briefly, we ascertained information on parent's prior year's flu vaccination status, current flu vaccination status, and whether the parent visited a health professional about his/her health within the past year for preventive services (e.g., check-up). We measured parents' perceived risk of vaccine-related adverse events by asking parents whether they agree or disagree with statements regarding vaccine safety and whether the flu vaccine caused the flu or other side effects. The final question of the five-item scale asked for parent's overall level concern with the flu shot making his/her child sick. Five questions measured the third construct, parents' perceived threat of flu, which incorporated questions to assess parent's perception of his/her child's susceptibility and severity of influenza illness. Two questions assessed the extent to which a parent perceived his/her child to be susceptible to the flu without vaccination. Two questions assess the parent's perception of the severity of the flu if the child were to become ill. The final question asked the parent "Overall, how likely is your child to get the flu this year?" ("Not at all possible," "Possible but not likely," "Possible," "Very likely," or "Will definitely").

Data analysis

Survey-item scales for measurement of constructs

We conducted an exploratory factor analysis of the 13 influenza vaccine belief and behavior items using principal components analysis with direct oblimin rotation. The oblique rotation method was used to address correlation of underlying factors. Kaiser criterion of eigenvalues ≥ 1.0 and Cattells scree test were used to select factors for the final scale. We retained factors with loadings larger than 0.4. Reverse coding was performed for items with negative correlations. Cronbach's coefficient α was used to evaluate the internal reliability of each individual factor. We used a Cronbach's alpha reliability estimate of ≥ 0.70 to consider the reliability of each subscale as satisfactory for inclusion in the construct measure.[61] Principal components analyses were unweighted. Resulting scale-reliability estimates were generated.

Factor assessment

Descriptive characteristics of our study population were evaluated by influenza vaccination status and weighted to address the sampling scheme. Continuous variables were evaluated to determine whether mean and corresponding standard deviation or median and interquartile range (IQR) were reported. The distribution of categorical variables between each factor and influenza vaccination was evaluated using proportions and frequency distributions. Logistic regression was used estimate prevalence odds ratios and

corresponding 95% confidence limits (CL) of each factor on influenza vaccine uptake. The analyses excluded participants with missing values for any of the variables in the model (i.e., complete subject analyses). All statistical analyses and data management were performed using SAS 9.2 (SAS Institute, Cary, NC).

Variables identified for adjustment

Variables identified for adjustment were those covariates that confound or create a spurious statistical association between the exposure and outcome of interest.[62] Briefly, a potential confounder in our study was a risk factor for influenza vaccination in the unexposed group (dependent on which factor we were assessing), a factor or covariate that influenced the exposure in the base or source population, and was not an intermediate in a pathway between the exposure and influenza vaccination.[62] A minimal sufficient set of covariates for which to adjust in the analyses (i.e. confounders) was identified *a priori* using the backdoor criterion for d-separation in a directed acyclic graph (DAG) [63, 64]. When the backdoor criterion is met, it is possible to estimate the *total average association* between an exposure and an outcome because the back doors where spurious statistical associations can occur are closed by a sufficient set of covariates.[65] Because DAGs require qualitative determinations of factors to include in the causal structure, an in-depth critical review of the evidence was required. *Table 5* provides a list of covariates identified for adjustment for each exposure-outcome relation.

Results

Our sample consisted of 224 home- and center-based daycares from a sampling frame of 1,069 recorded facilities in Tarrant County, Texas, made available through the Texas DFPS searchable database. A total of 100 home- and center-based daycares were contacted for recruitment. Nineteen daycares agreed to participate in the research study (licensed child care center=11, licensed child care home=4, registered child care home=3, listed family home=1). Additional details regarding the study sampling selection process are illustrated in *Figure 2*. There were 1,261 surveys distributed to daycares. Daycares were responsible for disseminating the self-administered 39-question surveys to their parents. Although one hundred sixty-eight surveys were returned for a response rate of 13.3%, response rates varied widely by daycare (median=29%, IQR=6.7%, 50%; see *Table 6*).

Our study population consisted of 166 parents of children with a median age of 42 months (IQR=28, 56). Slightly more than half of the children in the sample were male (male=53.6%, female=46.4%). Children of racial/ethnic minorities comprised nearly 40% of our study population (Non-Hispanic White: n=93 (60.8%), Hispanic White: n=23 (15.0%), Black: n=19 (12.4%), Other: n=18 (11.8%)). Adult respondents were primarily the child's mother (adult respondent: mother=144 (86.7%), father=16 (9.6%), other=6 (3.6%)). The median age of adult respondents was 35 years (IQR=31, 39) with ages ranging from 19 years to 65 years. More than three quarters of the adult respondents had at least some

college education or a college degree (less than high school=1.8%, high school graduate/GED=13.3%, vocational or trade school=3.6%, some college=23.5%, college degree or higher=57.8%). A large proportion of adult respondents reported family total combined incomes over \$50,000, with more than one third of families reporting combined incomes of more than \$100,000 (\$0-\$34,999=16.9%, \$35,000-\$49,999=6.6%, \$50,000-74,999=20.5%, \$75,000-\$99,999=15.1%, ≥ \$100,000=34.9%). Nearly all children were covered by some type of insurance (including government subsidized programs) (insured=97.6%, uninsured=2.4%).

Characteristics of sample children stratified by daycare type are reported in *Table 6* and were weighted to address complex survey sampling methods. Briefly, children attending licensed daycare centers were older than those attending licensed or registered homes. A greater proportion of children attending registered homes were female than children attending licensed centers or licensed homes. A large proportion of families with household incomes greater than \$100,000 had children attending licensed centers (42.6%), while total combined incomes of families with children in registered or licensed home were unevenly distributed among the other income categories. Parents of children in registered homes reported a minimum of at least some college education. Although more than 75% of parents with children in licensed centers or licensed homes reported at least some college, there was an uneven, but relatively similar, distribution of parents within the other educational categories.

Characteristics of sample children stratified by child's influenza

vaccination status are reported in *Table 7* and were weighted to address complex survey sampling methods. In general, children who had received the influenza vaccination for the current influenza season (2010-2011) were younger than those who were not vaccinated (median age in months (IQR): no doses=49 (38, 60); initiation=40 (26, 52). A greater proportion of unvaccinated children were male (no dose=60.6%; initiation=51.4%). A large proportion of families with a vaccinated child had a household income greater than \$100,000, while total combined incomes of families with an unvaccinated child were more homogeneously distributed among the other income categories with a greater proportion of families with incomes under \$35,000 than families of vaccinated children. The education level of the adult respondents was higher for vaccinated children compared with adult respondents of unvaccinated children. A larger proportion of adults of unvaccinated children reported high school as the highest completed level of education. Vaccination status of children varied by daycare type. Although the largest proportion of unvaccinated children and vaccinated attended licensed child care centers, a larger proportion of vaccinated children attended registered child care homes.

We identified 5 possible factors by examining factor eigenvalues in the exploratory factor analysis. Three factors were selected after evaluating the scree plot and considering the conceptual framework of the HBM constructs of interest. Factor loadings with associated survey questions are detailed in *Table*

7. Briefly, the perceived threat of influenza construct initially contained 5 questions including items that were intended to measure perceived susceptibility to influenza and perceived severity of influenza illness. All but one question, “If my child gets the flu then he/she will be very ill”, met satisfactory factor loading values that were equal to or greater than 0.40. Factor loadings for perceived threat of vaccine-related adverse events were satisfactory to create a score for perceived threat of vaccine-related adverse events and parental prevention behaviors. Internal consistency was generally acceptable (Cronbach’s $\alpha = 0.70$) for 2 of 3 constructs (threat: $\alpha=0.39$; risk of vaccine-related adverse events: $\alpha=0.54$; parental prevention behaviors: $\alpha=0.67$).

The prevalence of influenza vaccination was 64.7% (95% CI: 55.1%, 69.8%) in our study population, relatively higher than population-based estimates of vaccination coverage in children of the same age group (i.e., 2009 – 2010 U.S. estimates: aged 6 to 23 months= 55.7%, aged 24 months to 59 months= 38.4%); state-specific estimates for Texas in children 6 months to 17 years of age= 40.5%).^[19] Total associations for the relations between HBM factors and influenza vaccination are detailed in *Table 8*. Specifically, the odds of a child’s influenza vaccination was considerably higher among parents who have a high level of parental preventive behaviors compared to those parents with low levels of parental preventive behaviors (High: OR=7.1, 95% Confidence Limits (CL):1.9, 26.4; Moderate: OR=1.4, 95% CL: 0.4, 5.3). Parents describing beliefs consistent with a moderate or low perceived risk of vaccine-related adverse events were

more likely to vaccinate their children compared to parents with a high perceived threat of vaccine-related adverse events (Low: OR=7.0, 95% CL: 0.9, 51.9; Moderate: OR=5.1, 95% CL: 0.7, 38.2). In contrast, parents with a moderate perceived threat of influenza illness had greater odds of vaccinating their children than parents with high perceived threat of influenza illness compared to parents with a low perceived threat of influenza illness (High: OR=0.8, 95% CL: 0.2, 3.1; Moderate: OR=1.9, 95% CL: 0.5, 7.0). The odds of a child's influenza vaccination was considerably higher among parents who reported a physician's recommendation compared to those parents who did not report that a physician had recommended influenza vaccination for their children (OR=16.4, 95% CL: 5.5, 48.6).

Discussion

Our results suggest that physician recommendation and parents with high levels of preventive behaviors may influence influenza vaccination of children in daycare although these findings are preliminary given imprecise estimates. Certain limitations of our study should be considered when interpreting our results. An inverse association between parents' perceived threat of flu and child's flu vaccination was not consistent with prior knowledge of health belief model theory. A potential explanation for the inverse association is failure to condition two of the five questions in the perceived threat of flu construct on the risk of getting the flu given the child had not received the flu vaccine.[66]

Responses from parents who had vaccinated their children may have been influenced by a sense of reduced risk or threat of flu from vaccination; more than half of these parents responded that their children had a low chance of getting the flu (data not shown). Therefore, estimates for the perceived threat of flu may under- and inaccurately estimate the influence of risk perception regarding the threat of flu and parental decisions to vaccinate children.

Our study population may not necessarily represent the population from which we are interested in drawing inferences; a large proportion of daycares did not participate, particularly listed homes. Specifically, national estimates are available to provide a general description of the distribution of characteristics regarding parents who use different types of daycare, whereas there are few data available describing characteristics of parents who do not use home or center-based daycares.[67] Nearly half of all children under five years of age are placed in organized child care, including home and center-based daycares.[67] Forty percent of children under age five are cared for in informal child care (relative care only) arrangements; 29.5 percent with grandparents.[67] Parents of children who are in organized daycares differ from parents of children in informal daycare environments with respect to certain characteristics (i.e. income, education, occupation, health insurance coverage, etc.). Furthermore, the differences in population characteristics of parents who do not have their children in daycare, which may influence influenza vaccine uptake, may also differ between exposure group depending on the factor-outcome relation under

investigation. Overall, parents with a high school education or less use informal childcare more than other daycare settings.[67] Rural parents are less likely to use center-based care and more likely to use family child care providers compared to all other parents.[67] Half of all parents indicated cost as the primary reason for not staying home with their children (women \geq 35 years without a college degree, working mothers). As household income rises, children of middle-income and high-income parents are more likely to spend greater numbers of hours in child care than children of lower-income families.[67] Parents who do not use daycare are part of a particularly heterogeneous population regarding demographic characteristics; and thus it is more difficult to provide an accurate description of how these parents differ from parents who use daycare. Regardless, the above information provides an overview of some of the differences between parents who use formal daycare compared to parents who use informal types of daycare.

Selection bias is a potential concern in our study. If selection into the study sample is based on a child being in out-of-home care, parents who participate in the study may differ with regards to certain characteristics that influence factors associated with vaccine uptake. Concerns regarding self-selection bias occur because there may be differences in health beliefs between persons who participate in the study from parents who did not participate and subsequently result in biased effect measures of influenza vaccination. We attempted to reduce the potential for selection bias in the design stage by including home-based child

care providers in addition to center-based child care providers. Nonetheless, differential participation of parents by daycare type will result in biased estimates. Furthermore, selection bias may also occur from unmeasured characteristics that differ between parents of children who are not in a home or center-based daycare and that may also be associated with flu vaccine uptake.

Imprecise estimates resulting from small sample size was a concern in our study; therefore, we focused our study on the evaluation of four factors that have shown the greatest magnitude of effect in previously published studies. We restricted the number of questions in each construct but included multiple response categories to differentiate within levels of the item.[60] Scales with fewer response items typically reduce the burden on respondents, although longer scales tend to be more reliable. We subsequently included more response categories within selected questions and constructs to increase discrimination of differences within each level of the item. To ensure the reliability and validity of our survey constructs, we used multiple items to measure our constructs. This is intended to result in a more reliable test of that construct rather than the individual items or survey questions.[60] Furthermore, our use of standard regression methods is only sufficient to convey the total association (combined direct and indirect association) between HBM constructs and influenza vaccination. Further analyses (e.g. marginal structural models, structural equation modeling) are necessary to elucidate the magnitude of the direct and

indirect pathways, which may provide additional evidence for policy-related public health program decisions.

Measurement error and information bias may be a concern in our study. Biased estimates from misclassification may be more likely to occur with the measurement and classification of our exposure constructs more so than our outcome variable. In this study we assume that our outcome variable, influenza vaccination, is unlikely to be reported incorrectly and less susceptible to recall bias.[68] We ascertained vaccination status during the height of the typical flu season; therefore, we anticipate that most parents would be likely to recall the administration of a non-mandatory vaccination that most often requires a scheduled visit with a medical provider or health clinic. If information bias occurred, misclassification of influenza vaccination would most likely be non-differential. Non-differential misclassification typically biases estimates toward the null for a dichotomous outcome, in which case our estimates may underestimate the 'true' magnitude of the association between our exposure and outcome.[62] Misclassification of our exposures, the HBM factor constructs, may lead to biased estimates but the direction and magnitude of the bias is unknown.

A strength of our research is the use of causal diagrams. Causal diagrams provide a uniform framework for evaluating design and analysis strategies for any causal question under any set of causal assumptions (parametric and non-parametric) and enables researchers to evaluate multiple biases (e.g. confounding, selection bias).[62, 69] They are particularly useful for guiding

model specification because the simultaneous relations between multiple covariates can be evaluated. The conventional criteria for assessing confounding can be unreliable because they may lead to the specification of a regression model with covariates that increase bias. Adjusting for certain covariates may introduce conditional associations that are not evident when using these criteria.[62, 69]

Influenza-associated pediatric deaths are preventable. Increasing influenza vaccination coverage in pediatric populations, especially those in children attending daycare, will impact the morbidity and mortality associated with influenza outbreaks. The focus and breadth of our study intended to better describe and understand the underlying health behaviors and constructs that lead to parental decision making of influenza vaccination for young children, in particular for children in daycare. Our study was designed to pilot a survey in a target population for increasing influenza vaccination coverage. In particular, recruitment of daycares and parental participation was challenging in daycare settings with limited oversight from state agencies (e.g., listed child care homes). Although preliminary, our findings suggest the potential relation between physician recommendation and parental preventive behaviors are influential factors in the relation between health beliefs and behaviors with vaccination decision-making for children attending daycare in Tarrant County, Texas. Further research in this population, in a larger cohort of participating daycares and parents, that elucidates the underpinnings of physician recommendation and

parental preventive behaviors may provide insight regarding the pathways to increase influenza vaccination of children in daycare. Nonetheless, conducting research that involves social and behavioral variables as components in the assessment of an exposure-outcome relation should be theoretically grounded. Future studies that address these issues may improve inference regarding the parental health beliefs and behaviors and influenza vaccination of children attending daycare.

Figure 2. Survey sample flow diagram, study population of participating daycares

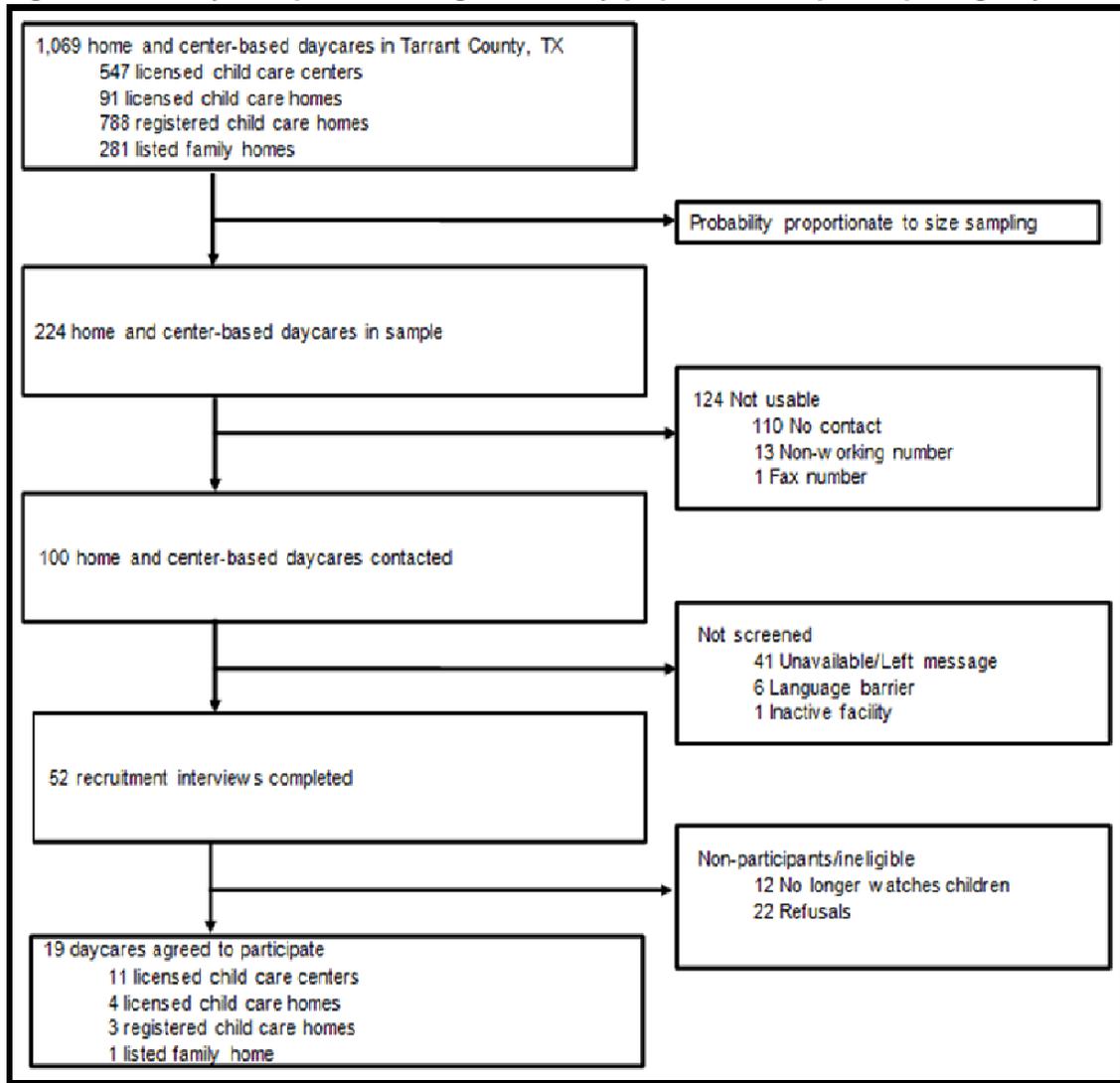


Table 5. Confounders adjusted for in logistic regression models to assess Health Belief Model factors on influenza vaccination.

Factor	Confounders
Parental prevention behaviors	Race/ethnicity; Perceived threat of flu
Perceived risk of vaccine adverse events	Child's previous flu vaccination
Perceived threat of flu	Physician recommendation; Race/ethnicity
Physician recommendation	Child's age; Child's medical indications and contraindications; Race/ethnicity; Insurance coverage

Table 6. Characteristics of sample children aged 6 – 59 months attending daycare in Tarrant County, Texas, accounting for sampling method (weighted) and stratified by daycare type for the 2010 – 2011 influenza season.

<i>Characteristic</i>	<i>Daycare type</i>		
	<i>LC^a</i> <i>N= 758</i>	<i>RH^b</i> <i>N= 96</i>	<i>LCCH^c</i> <i>N= 20</i>
Age in months, median (IQR) ^d	44 (29, 56)	38 (29, 47)	32 (21, 48)
Sex, male, n (%)	429 (56.6)	35 (36.4)	11 (55.0)
Race/ethnicity, n (%)			
Non-Hispanic White	510 (67.2)	44 (45.5)	6 (30.0)
Black	56 (7.4)	9 (9.1)	9 (45.0)
Hispanic	93 (12.3)	44 (45.4)	3 (15.0)
Uninsured child, n (%)	12 (1.6)	0 (0)	1 (5.0)
Family Income, n (%)			
\$0 – \$34,999	131 (17.2)	17 (18.2)	2 (10.0)
\$35,000 – \$49,999	31 (4.1)	9 (9.1)	3 (15.0)
\$50,000 – \$74,999	143 (18.9)	44 (15.7)	4 (20.0)
\$75,000 – \$99,999	106 (13.9)	17 (18.2)	3 (15.0)
> \$100,000	323 (42.6)	0 (0)	5 (25.0)
Education level of mother or guardian, n (%)			
Did not graduate high school	6 (0.8)	0 (0)	1 (5.0)
High school graduate	106 (13.9)	0 (0)	3 (15.0)
Vocational or trade school	31 (4.1)	0 (0)	1 (5.0)
Some college	168 (22.1)	17 (18.1)	4 (20.0)
College graduate or higher	447 (59.0)	78 (81.8)	11 (55.0)
Survey response rate, proportion (%)	130/1,208 (10.8)	13/19 (68.4)	1/3 (33.3)

^aLC= Licensed center;

^bRH= registered home;

^cLCCH= Licensed home;

^dIQR= Interquartile range

Table 7. Characteristics of sample children aged 6 – 59 months attending daycare in Tarrant County, Texas, accounting for sampling method (weighted) and stratified by influenza vaccination status for the 2010 – 2011 influenza season.

Characteristic	Influenza vaccination	
	No doses n=278	Initiation (≥1 dose) n=596
Age in months, median (IQR) ^a	49 (38, 60)	40 (26, 52)
Sex, male, n (%)	169 (60.6)	306 (51.4)
Race/ethnicity, n (%)		
Non-Hispanic White	138 (49.5)	421 (70.7)
Black	36 (13.0)	38 (6.3)
Hispanic	53 (18.9)	87 (14.6)
Other	52 (18.6)	50 (8.3)
Uninsured child ^b , n (%)	6 (2.2)	2 (2.0)
Daycare type		
Registered child care home	0 (0)	96 (16.0)
Licensed center	267 (96.0)	491 (82.4)
Listed home	0 (0)	0 (0)
Licensed child care home	11 (4.0)	9 (1.5)
Respondent's relationship to child		
Mother	251 (90.3)	518 (87.0)
Father	20 (7.1)	58 (9.8)
Other	7 (2.6)	19 (3.1)
Family Income, n (%)		
\$0 – \$34,999	58 (20.8)	92 (15.4)
\$35,000 – \$49,999	7 (2.6)	36 (6.0)
\$50,000 – \$74,999	94 (7.0)	96 (16.2)
\$75,000 – \$99,999	40 (14.5)	86 (14.4)
> \$100,000	59 (21.2)	269 (45.2)
Education level of mother or guardian, n (%)		
Did not graduate high school	1 (0.4)	6 (1.0)
High school graduate	58 (20.8)	51 (8.5)
Vocational or trade school	13 (4.8)	19 (3.1)
Some college	88 (31.6)	101 (17.0)
College graduate or higher	118 (42.4)	419 (70.3)

^aIQR= Interquartile range;

^bUninsured child=a child that was reported by the parent/caregiver to not have health care insurance of any type including private health insurance, prepaid plans such as HMOs, or government plans such as Medicaid.

Table 8. Influenza vaccine belief and behavior factor loadings with estimated Cronbach's alpha for influenza vaccination Health Belief Model constructs.

Survey question	Factors		
	Perceived threat	Perceived risk of vaccine-related adverse events	Parental prevention behaviors
My child has a low chance of getting the flu this year.	0.62	-0.20	0.23
The flu is not that serious.	0.49	-0.12	0.44
If my child gets the flu then he/she will be very ill.	0.23	0.21	0.41
Because my child is healthy, he/she is less likely to get the flu.	0.38	-0.36	0.40
Overall, how likely is your child to get the flu this year?	0.55	0.15	0.08
The flu shot is safe for my child.	0.23	0.08	-0.68
The flu shot can cause the flu.	0.15	0.35	-0.57
The flu shot can cause side effects such as runny nose, nasal congestion or a sore arm, leg, or thigh (where the shot was given).	0.23	0.52	-0.16
The flu shot prevents my child from getting the flu.	0.24	-0.41	-0.20
Overall, how concerned are you that the flu shot will make your child sick?	0.36	0.38	-0.60
Adult respondent: did you get the flu shot last year (August 2009 to May 2010)	0.05	0.46	0.73
Adult respondent: have you gotten the flu shot this year (August 2010 to April 2011)?	-0.10	0.34	0.72
Have you see a doctor or other health professional in the past year about your own health for preventive services (such as an annual check-up, etc.) at a doctor's office, hospital, clinic, or some other place?	-0.09	0.34	0.27
Cronbach's alpha	0.39	0.54	0.67

Table 9. Prevalence odds ratios for the association between perceived threat of flu and influenza vaccination^a.

<i>Health beliefs and behaviors</i>	<i>Influenza vaccination</i>	
	Odds ratio	95% CL ^b
<i>Perceived threat of influenza illness^c</i>		
High	0.8	0.2, 3.1
Moderate	1.9	0.5, 7.0
Low	1.0	REF
<i>Perceived risk of vaccine-related adverse events^d</i>		
High	1.0	REF
Moderate	5.1	0.7, 38.2
Low	7.0	0.9, 51.9
<i>Parental prevention behaviors^e</i>		
High	7.1	1.9, 26.4
Moderate	1.4	0.4, 5.3
Low	1.0	REF
<i>Physician recommendation^f</i>		
Influenza vaccination recommended to parent	16.4	5.5, 48.6

^aVaccination: refers to children who received at least one dose of the influenza vaccine;

^bCL=Confidence limit;

^cAdjusted for physician recommendation and race/ethnicity;

^dAdjusted for child's previous influenza vaccination status;

^eAdjusted for race/ethnicity and perceived threat of flu construct;

^fAdjusted for child's age, child's medical indications and contraindications, race/ethnicity, and insurance coverage.

CHAPTER 4

H1N1 PANDEMIC INFLUENZA AND VACCINATION

Introduction

The rapid events of the 2009 H1N1 influenza pandemic, which began with the diagnosis of the first cases in April 2009, led to the World Health Organization's declaration of a pandemic.[70] The introduction of a novel strain of influenza across the world, which resulted in the 2009 H1N1 influenza pandemic, was well-publicized in the media.[71] The constant media coverage and changing landscape of the influenza pandemic left the public with mixed perceptions about the severity of the illness caused by the 2009 H1N1 pandemic influenza strain and the need for influenza vaccination.[71] In studies conducted to assess parental perceptions during the 2009 H1N1 influenza pandemic, parents were more likely to vaccinate their children than themselves, although these parents questioned vaccine safety throughout the course of the pandemic.[72] Current evidence suggests that decision-making and risk perceptions regarding the 2009 H1N1 influenza pandemic were related.[72] Whether these concerns translated to behaviors that may influence pediatric vaccination beyond the 2009 pandemic influenza season is not well understood.

Recent research has begun to describe the impacts of the 2009 H1N1 influenza pandemic on risk perception and influenza vaccine uptake among pediatric populations. The lack of increased vaccination coverage for specific age

groups among children during the pandemic may reflect insufficient concern regarding the threat of influenza.[3] Theoretical frameworks such as the Health Belief Model (HBM) provide utility for evaluating whether the 2009 H1N1 influenza pandemic influenced influenza vaccine uptake. Therefore, using the HBM and inferential methods, our study aimed to evaluate the effect of the 2009 H1N1 influenza pandemic on parental decisions to vaccinate children for the influenza vaccine during the 2010 – 2011 influenza season in Tarrant County, Texas, one year after the pandemic influenza season. Furthermore, racial/ethnic disparities have been reported in influenza vaccination of children aged 6 months to 17 years [73]. We explored whether race/ethnicity modified the effect of the 2009 H1N1 influenza pandemic risk perception of parents on influenza vaccination of children attending daycare.

Methods

The current study was designed to investigate the influence of the 2009 H1N1 influenza pandemic on vaccine decision making by caregivers of children attending daycare and whether the influence varied by racial/ethnic group. The study population, survey design, and sampling methods are detailed elsewhere. Briefly, the study involved the administration of a one-time self-administered paper survey to parents of children aged 6 months to 59 months attending home- or center-based daycare in Tarrant County, Texas. The self-administered survey included both modified questions from the National 2009 H1N1 Flu Survey

(NHFS)[50] and questions that measure parental perceptions of the 2009 H1N1 influenza pandemic and influenza vaccination of their children. A weighted sampling scheme using probability proportionate to size sampling method was used to sample child care providers (home- and center-based) and ascertain responses from parents of children aged 6 months to 59 months attending child care. Analyses were weighted to account for complex survey design.

Measures

Our outcome of interest was influenza vaccine initiation defined as received at least one dose of the influenza vaccine during the 2010 influenza season, beginning August 2010 through May 2011. Influenza vaccine initiation was ascertained from responses to the question, “Has he/she gotten a flu shot this year (August 2010 to April 2011)?” and coded as a dichotomous variable. Two questions were used to assess awareness of the 2009 H1N1 influenza pandemic: “How much do you know about the 2009 H1N1 flu?” was assessed using Likert scale response categories (very little, some, a lot (quite a bit), and haven’t heard of the 2009 H1N1 flu or swine flu) and “I knew someone who got the swine flu last year.” The exposure, perceived threat of the 2009 H1N1 influenza pandemic, was measured using 7 questions in which the respondent indicated that they agreed or disagreed with the statements used as items in the HBM construct.

Data analysis

Survey-item scales for measurement of constructs

We conducted an exploratory factor analysis of the 7 survey items of the 2009 H1N1 influenza pandemic influenza vaccine belief and behavior items using principal components analysis with direct oblimin rotation. The oblique rotation method was used to address correlation of underlying factors. Kaiser criterion of eigenvalues ≥ 1.0 and Cattells scree test were used to select factors for the final scale. We retained factors with loadings larger than 0.4. Reverse coding was performed for items with negative correlations. Cronbach's coefficient α was used to evaluate the internal reliability of each individual factor. We used a Cronbach's alpha reliability estimate of ≥ 0.70 to suggest reliability of each subscale.[61] Principal components analyses were unweighted. Resulting scale-reliability estimates were generated.

2009 H1N1 influenza Health Belief Model factor assessment

Descriptive characteristics of our study population were evaluated by influenza vaccination status and weighted to address the study sampling scheme. Continuous variables were evaluated to determine whether mean and corresponding standard deviation or median and interquartile range (IQR) were reported. Logistic regression was used to estimate overall odds ratios and race/ethnicity-stratified estimates for total associations and corresponding 95% confidence limits (CL) of the perceived threat of the 2009 H1N1 influenza

pandemic on influenza vaccine uptake. The analyses excluded participants with missing values for variables in the model (i.e., complete subject analyses). All statistical analyses and data management were performed using SAS 9.2 (SAS Institute, Cary, NC) and STATA IC 11 (College Station, TX).

Variables identified for adjustment

We encoded dependency assumptions regarding factors that influence influenza vaccination, their relations to the 2009 H1N1 influenza pandemic, and their inter-relations in a directed acyclic graph (DAG). We subsequently applied the back-door criterion to identify a minimal sufficient set of covariates for our multivariable exposure-outcome model.[69] Our DAG (*Figure 3*) indicated that the crude estimate was sufficient for estimating the total association between the 2009 H1N1 influenza pandemic and influenza vaccine initiation.

Results

There were 1,261 surveys distributed to daycares. Although one hundred sixty-eight surveys were returned for a response rate of 13.3%, response rates varied widely by daycare (median=29%, IQR=6.7%, 50%). Characteristics of sample children stratified by influenza vaccination status are reported in *Table 9* and were weighted to address complex survey sampling methods. Our study population consisted of 150 children with a median age of 43 months (IQR: 28, 56). In general, children who received the influenza vaccination for the current

influenza season (2010-2011) were younger than those who were not vaccinated (median age in months (IQR): no doses=49 (38, 60); initiation=39 (26, 52). A greater proportion of unvaccinated children were male (no dose=61.1%; initiation=52.1%). A large proportion of families with a vaccinated child had a household income greater than \$100,000, while total combined incomes of families with an unvaccinated child were more homogeneously distributed among the other income categories than families of vaccinated children. Furthermore, a greater proportion of families with unvaccinated children reported incomes under \$35,000 than families with vaccinated children. The education level of the adult respondents was higher in vaccinated children compared with adult respondents of unvaccinated children. A larger proportion of adults with unvaccinated children reported high school as the highest completed level of education. Vaccination status of children varied by daycare type. Specifically, the largest proportion of unvaccinated children and vaccinated children attended licensed child care centers, although a larger proportion of vaccinated children attended registered child care homes compared to unvaccinated children.

We identified 3 possible factors to define HBM constructs from the survey questions by examining factor eigenvalues in the exploratory factor analysis. Two factors were selected after evaluating the scree plot and considering the conceptual framework of the HBM constructs of interest, knowledge of the 2009 H1N1 influenza pandemic and perceived threat of the 2009 H1N1 influenza pandemic. Factor loadings with associated survey questions are detailed in *Table*

10. Briefly, knowledge of the 2009 H1N1 influenza pandemic was measured using 2 questions that met satisfactory factor loading values (knowledge of H1N1 influenza =0.62, knew someone who got swine flu=0.72). Perceived threat of the 2009 H1N1 influenza pandemic construct contained 7 questions including items that were intended to measure perceived susceptibility to influenza and perceived severity of influenza illness. All questions met satisfactory factor loading values of 0.40 or greater. Factor loadings for perceived threat of vaccine-related adverse events were satisfactory to create a score for perceived threat of vaccine-related adverse events and parental prevention behaviors. Internal consistency was generally acceptable for 1 of 2 constructs (knowledge of H1N1 influenza: $\alpha=0.67$; perceived threat of H1N1: $\alpha=0.75$).

The prevalence of influenza vaccination was 65.3% (95% CL: 57.5%, 72.6%) in our study population. Measures of association for the relation between parents' perceived threat of the 2009H1N1 influenza pandemic and influenza vaccination among children attending daycare are detailed in *Table 11*. Specifically, parents with a high perceived threat of the 2009 H1N1 influenza pandemic had greater odds of vaccinating their children than parents with moderate perceived threat of influenza illness compared to parents with a low perceived threat of influenza illness (High: OR=3.3, 95% CL: 2.1, 5.1; Moderate: OR=1.2, 95% CL: 0.8, 1.8). Furthermore, parents with moderate perceived threat of the 2009 H1N1 had similar odds of vaccinating their children against influenza as parents with low perceived threat of the 2009 H1N1 influenza pandemic.

Parents of racial/ethnic minority groups with high perceived threat of the 2009 H1N1 influenza pandemic had greater odds of vaccinating their children against influenza than those parents with low perceived threat (Blacks: High=4.3, 95% CL: 1.2, 15.9; Moderate=1.8, 95% CL: 0.6, 5.6; Hispanic: High=4.4., 95% CL: 1.3, 15.7; Moderate=0.5, 95% CL: 0.1, 1.7). In contrast, Non-Hispanic White parents with high perceived threat of the 2009 pandemic influenza group were just as likely to vaccinate their children against influenza as parents with low perceived threat (Non-Hispanic Whites: High=1.5, 95% CL: 0.7, 2.9; Moderate=0.6, 95% CL: 0.3, 1.1)

Discussion

Our results suggest that parents who had a high perceived threat of the 2009 H1N1 influenza pandemic had greater odds of vaccinating their children compared to parents with low perceived threat of the 2009 H1N1 influenza pandemic. Although our findings are generally consistent with previously published studies that have assessed the likelihood (i.e., intent) of pediatric H1N1 influenza immunization [74], we advance this line of research by exploring risk perceptions of parents with actual influenza vaccine uptake and restrict it to a daycare population. Parents with moderate levels of perceived threat, regardless of racial/ethnic group, had similar odds of vaccinating their children against influenza compared to parents with low levels of perceived threat and thus

moderate levels of perceived threat did little to influence parental decisions to vaccinate their children.

While our findings provide preliminary evidence regarding the influence of the 2009 H1N1 influenza pandemic one year post-pandemic, certain limitations of our study should be considered when interpreting our results. Our study population may not necessarily represent the population from which we are interested in drawing inferences; a large proportion of daycares did not participate, particularly listed homes. It may be more appropriate to consider our findings in the context of the health behaviors and beliefs of parents who have placed their children in licensed child care centers. Furthermore, non-participation from a considerable proportion in the probability sampled population most likely resulted in selection bias. Those daycares who did not participate in the survey may include parents with differing levels of education, income, or knowledge regarding the 2009 H1N1 influenza pandemic and result in a different distribution of influenza vaccination of children. A second level of selection bias potentially occurred from non-participation of parents in participating daycares. Parents with greater knowledge of the pandemic may be more likely to participate in a survey than parents with little knowledge of the pandemic and these same parents may be more likely to practice a higher level of preventive behaviors such as influenza vaccination. Although we attempted to reduce the potential for selection bias in the design stage by including home-based child care providers, few home-based daycares, specifically listed homes, participated

in the study. Recruitment strategies to encourage participation from listed homes may address some of these issues.

Although temporality of the exposure-outcome relation is typically a concern in cross-sectional studies [47], the 2009 H1N1 influenza pandemic occurred prior to influenza vaccination during the 2010-2011, our outcome of interest. Therefore, we anticipate that temporality of the exposure and outcome relation to be less of a concern in our study. Nonetheless, both exposure and outcome of interest were measured simultaneously during the peak of the 2010-2011 influenza season. Measurement error and information bias may be a concern in our study and may be more likely to occur with the measurement and classification of our exposure, perceived threat of the 2009 H1N1 influenza pandemic, more so than our outcome variable, influenza vaccination.[68] To address concerns regarding misclassification of influenza vaccination, we ascertained vaccination status during the height of the typical flu season; therefore, we anticipate that most parents would likely recall the administration of a non-mandatory vaccination that most often requires a scheduled visit with a medical provider or health clinic. Additionally, if recall bias were a concern, we would anticipate that this would result in non-differential misclassification of vaccination status and most likely downward bias the estimates.[62]

The primary objective of this research intended to quantify the relation and estimate the magnitude between the 2009 H1N1 influenza pandemic and parental decisions to vaccinate children attending daycare one year following the

pandemic. Our study results suggest that only the highest levels of concern regarding the pandemic influenced parents to vaccinate their children. Within racial and ethnic minority groups, parents with greater concern of the pandemic were more likely to vaccinate their children than parents with lower perceived concern. Whites were not influenced greatly by the 2009 H1N1 pandemic to vaccinate their children. The underlying causes for differential uptake of influenza vaccination by racial/ethnic group are uncertain, although we speculate that this may be in part explained by mixed messages, those which supported vaccination and others that questioned the severity of the pandemic with less emphasis on the need for vaccination, conveyed by the media throughout the pandemic. Further research to elucidate the underlying constructs may provide additional insight regarding the effect of highly publicized events, such as a circulating influenza pandemic strain, on influenza vaccination of children. Future studies that address issues regarding non-participation may improve inference regarding the parental health beliefs and behaviors and influenza vaccination of children attending daycare. Elucidating the underlying mechanisms that influence parental decision making may inform the development of interventions to increase pediatric influenza vaccination, a population that is responsible for the significant spread of the virus to other populations.

Figure 3. Proposed structural representation for the relation between the 2009 H1N1 influenza pandemic and influenza vaccine initiation

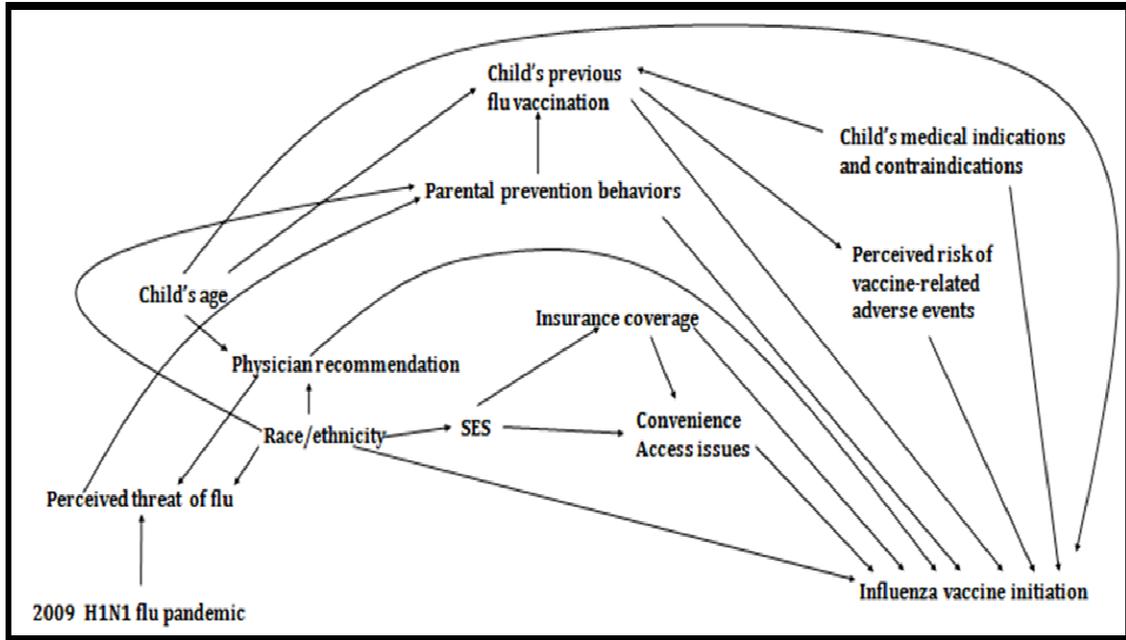


Table 10. Characteristics of sample children aged 6 – 59 months attending daycare in Tarrant County, Texas, accounting for sampling method (weighted) and stratified by influenza vaccination status for the 2010 – 2011 influenza season.

Characteristic	Influenza vaccination	
	No doses n=266	Initiation (≥1 dose) n=587
Age in months, median (IQR) ^a	49 (38, 60)	39 (26, 52)
Sex, male, n (%)	162 (61.1)	306 (52.1)
Race/ethnicity, n (%)		
Non-Hispanic White	138 (51.8)	421 (71.8)
Black	36 (13.6)	38 (6.4)
Hispanic	47 (17.5)	78 (13.3)
Other	46 (17.1)	50 (8.5)
Uninsured child ^b , n (%)	6 (2.3)	7 (1.2)
Daycare type		
Registered child care home	0 (0)	87 (14.8)
Licensed center	255 (95.9)	491 (83.6)
Listed home	0 (0)	0 (0)
Licensed child care home	11 (4.1)	9 (1.5)
Respondent's relationship to child		
Mother	239 (89.9)	510 (86.9)
Father	20 (7.4)	58 (10.0)
Other	7 (2.7)	19 (3.2)
Family Income, n (%)		
\$0 – \$34,999	58 (20.8)	92 (15.7)
\$35,000 – \$49,999	7 (2.6)	36 (6.1)
\$50,000 – \$74,999	94 (7.0)	88 (14.9)
\$75,000 – \$99,999	40 (14.5)	86 (14.6)
> \$100,000	59 (21.2)	269 (45.9)
Education level of mother or guardian, n (%)		
Did not graduate high school	1 (0.4)	6 (1.1)
High school graduate	52 (19.5)	51 (8.6)
Vocational or trade school	13 (5.1)	19 (3.2)
Some college	82 (30.8)	101 (17.2)
College graduate or higher	118 (44.3)	410 (69.9)

^aIQR= Interquartile range

Table 11. Influenza vaccine belief and behavior factor loadings with estimated Cronbach's alpha for influenza vaccination Health Belief Model constructs.

Survey question	Factor loadings	
	Knowledge	Perceived threat of H1N1 influenza illness
How much do you know about the 2009 H1N1 flu?	0.62	-0.06
I knew someone who got the swine flu last year.	0.72	0.32
Many people got sick from the swine flu last year.	0.24	0.53
I was concerned that my child would catch the swine flu last year.	0.26	0.76
I am concerned about my child getting the swine flu.	-0.04	0.76
I wash my hands more this year because of concerns about getting sick from the flu.	-0.35	0.66
I use more hand sanitizer this year than I have in the past because of concerns about getting sick from the flu.	-0.45	0.68
I got my child the flu shot or plan to do so this year because I am concerned that the flu will make a lot of people sick.	0.08	0.56
Cronbach's alpha	0.29	0.75

Table 12. Prevalence odds ratios for the association between perceived threat of the 2009 H1N1 pandemic flu and influenza vaccination^a of children attending daycare in Tarrant County, Texas, 2010-2011 influenza season.

Perceived threat of 2009 H1N1 pandemic influenza	<i>Influenza vaccination by self-reported race/ethnicity</i>			
	<i>Overall</i>	<i>Non-Hispanic White</i>	<i>Black</i>	<i>Hispanic</i>
High	3.3 (2.1, 5.1)	1.5 (0.7, 2.9)	4.3 (1.2, 15.9)	4.4 (1.3, 15.7)
Moderate	1.2 (0.8, 1.8)	0.6 (0.3, 1.1)	1.8 (0.6, 5.6)	0.5 (0.1, 1.7)
Low	1.0 (Reference)	1.0 (Reference)	1.0 (Reference)	1.0 (Reference)

^aVaccination: Parents reported child received at least one dose of influenza vaccine during the 2010-2011 influenza season;

^bUnadjusted estimates based on proposed causal diagram;

^cCL= Confidence limits.

CHAPTER 5

SUMMARY

Influenza vaccination of children is dependent on factors that influence parental decision making. Factors that influence parental decisions to vaccinate their children against influenza involve inherently social and behavioral concepts and underpinnings. Parents and caregivers are thus influenced by internal (endogenous) and external (exogenous) factors that reflect the multi-factorial contributions of health behavior constructs. Given suboptimal levels of influenza vaccination coverage in pediatric populations in the United States, we investigated behavioral factors that may influence influenza vaccination of children attending daycare in Tarrant County, Texas. Furthermore, we aimed to quantify the relation and estimate the magnitude between the 2009 H1N1 influenza pandemic and parental decisions to vaccinate children attending daycare, one year following the pandemic.

Our results suggest that physician recommendation and parents with high levels of preventive behaviors may influence influenza vaccination of children in daycare. Furthermore, only the highest levels of concern regarding the 2009 H1N1 influenza pandemic influenced parents to vaccinate their children. Within racial and ethnic minority groups, parents with greater concern of the pandemic were more likely to vaccinate their children than parents with lower perceived

concern. Whites were not influenced greatly by the 2009 H1N1 pandemic to vaccinate their children. The underlying causes for differential uptake of influenza vaccination by racial/ethnic group are uncertain, although we speculate that this may be in part explained by mixed messages, those which supported vaccination and others that questioned the severity of the pandemic with less emphasis on the need for vaccination, conveyed by the media throughout the pandemic.

Certain limitations of our study should be considered when interpreting our results. Foremost, these findings are preliminary given imprecise estimates. Nonetheless, our findings are consistent with previous research suggesting that physician recommendation is an important factor that influences parental decisions to obtain to the influenza vaccination for their children. Recruitment strategies to increase daycare participation and ultimately parental participation in a survey such as this are necessary.

Our use of standard regression methods is only sufficient to convey the total association (combined direct and indirect association) between HBM constructs and influenza vaccination. Further analyses (e.g. marginal structural models, structural equation modeling) are necessary to elucidate the magnitude of the direct and indirect pathways, which may provide additional evidence for policy-related public health program decisions.

Another concern in this study is the potential for selection bias. Our study population may not necessarily represent the population from which we are interested in drawing inferences; a large proportion of daycares did not

participate, particularly listed homes. Nearly half of all children under five years of age are placed in organized child care, including home and center-based daycares.[67] Forty percent of children under age five are cared for in informal child care (relative care only) arrangements; 29.5 percent with grandparents.[67] It is suggested that parents of children who are in organized daycares differ from parents of children in informal daycare environments with respect to certain characteristics (i.e., income, education, occupation, health insurance coverage, etc.). Furthermore, the differences in population characteristics of parents who do not have their children in daycare may influence influenza vaccine uptake differently between each exposure group depending on the factor-outcome relation under investigation. Thus, selection bias is a potential concern in our study. We attempted to reduce the potential for selection bias by including home-based child care providers in addition to center-based child care providers.

Measurement error and information bias may be a concern in our study and may be more likely to occur with the measurement and classification of our exposure constructs more so than our outcome variable. Our outcome variable, influenza vaccination, is unlikely to be reported incorrectly and less susceptible to recall bias.[68] We ascertained vaccination status during the height of the typical flu season; therefore, we anticipate that most parents would be likely to recall the administration of a non-mandatory vaccination that most often requires a scheduled visit with a medical provider or health clinic. If this was to occur, the misclassification would most likely be non-differential. Non-differential

misclassification typically biases estimates toward the null for a dichotomous outcome, in which case our estimates may underestimate the 'true' magnitude of the association between our exposure and outcome.[62]

A strength of our research is the use of causal diagrams. Causal diagrams provide a uniform framework for evaluating design and analysis strategies for any causal question under any set of causal assumptions (parametric and non-parametric) and enables researchers to evaluate multiple biases (e.g., confounding, selection bias).[62, 69] They are particularly useful for guiding model specification because the simultaneous relations between multiple covariates can be evaluated. The conventional criteria for assessing confounding can be unreliable because they may lead to the specification of a regression model with covariates that increase bias. Adjusting for certain covariates may introduce conditional associations that are not evident when using these criteria.[62, 69]

Influenza-associated pediatric deaths are preventable. Increasing influenza vaccination coverage in pediatric populations, especially those in children attending daycare, will impact the morbidity and mortality associated with influenza outbreaks. The focus and breadth of our study was to better describe and understand the underlying health behaviors and constructs that lead to parental decision making of influenza vaccination for young children, in particular for children in daycare. Although preliminary, our findings suggest the potential relation between physician recommendation and parental preventive

behaviors are influential factors in the relation between health beliefs and behaviors with vaccination decision-making for children attending daycare in Tarrant County, Texas.

Given the still poorly defined nature of the topic, the inconsistent use of health behavior models and marginal incremental increases in influenza vaccination coverage suggests a continued need for research that identifies factors that influence vaccine uptake in children. As more studies incorporate social behavioral models [1], such as the Health Belief Model, in their research to measure health behavior constructs and to identify factors that influence vaccine uptake, efforts should be made to ensure the reliability and validity of the questions and scales used to measure the health behavior and belief constructs. Future research may benefit from continued exploration of social and behavioral factors that influence influenza vaccination of children in pediatric populations with consideration of the measurement of social and health behavior constructs.

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APPENDICES

APPENDIX A

Human Subject Research Training

CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report Printed on

Learner: Tabatha Powell (username: tpowell1977)

Institution: University of North Texas Health Science Center

Contact Phone: 817-599-8881

Information Email: tpowell@hsc.unt.edu

Social-Behavioral:

Stage 2. Refresher Course Passed on 09/25/09 (Ref # 3232314)

Required Modules	Date Completed	
SBR 101 REFRESHER MODULE 1. History and Ethics	09/25/09	4/5 (80%)
SBR 101 REFRESHER MODULE 2. Regulatory Overview	09/25/09	5/5 (100%)
SBR 101 REFRESHER MODULE 3. Fundamental Issues.	09/25/09	4/5 (80%)
SBR 101 REFRESHER MODULE 4. Vulnerable Subjects	09/25/09	4/4 (100%)
SBR 101 REFRESHER MODULE 5. Additional Topics	09/25/09	5/5 (100%)
How to Complete The CITI Refresher Course and Receive the Completion Report	09/25/09	no quiz
University of North Texas Health Science Center	09/25/09	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

APPENDIX B

Institutional Review Board Approvals



UNIVERSITY OF NORTH TEXAS
HEALTH SCIENCE CENTER at Fort Worth

Education, Research,
Patient Care and Service

DATE: 04 January 2011

Institutional Review Board

TO: Kathryn Cardarelli, PhD
with doctoral student Tabatha Offutt-Powell, MPH
Department of Epidemiology
School of Public Health

PROTOCOL: # 2010-160

"Individual Child and Parental Factors that Influence Influenza Vaccination in Children 6 months to 59 months of Age"

IRB BOARD ACTION AND NOTICE OF APPROVAL

The Institutional Review Board (IRB) has reviewed your protocol under Expedited Review Procedures and has granted approval under the provisions of 45 CFR 46.110 (b) (1) Category (7).

Approval is effective January 4, 2011 through January 4, 2012

You are responsible for complying with all UNTHSC IRB and OPHS policies, decisions, conditions and requirements. You are responsible for insuring that the research is implemented as specified in the approved protocol. Unless otherwise authorized by the UNTHSC-IRB, you are responsible for obtaining and documenting informed consents in accordance with applicable Federal Regulations (45 CFR 46 and 21 CFR 50) using ONLY the IRB approved consent forms designated for this protocol.

You must report to the Chair of the IRB any changes affecting the protocol upon which this certification is based. **No changes may be made without prior approval by the IRB** except those necessary to eliminate immediate hazards.

Should your project period extend beyond this expiration date, you must submit a Progress Report for Continuing Review to the IRB. You must allow sufficient time for the request for renewal to be reviewed and approved **before expiration of the current approval**. Be sure to *prepare for a renewal 2 months prior to the protocol expiration date*. If the project is finished before the approval expiration date, you must submit a final Progress Report (Continuing Review) either at the time the project is completed or before the expiration.

The Office for the Protection of Human Subjects (OPHS) will send out a reminder notice for your Progress Report (Continuing Review), however it is the responsibility of the Principal Investigator to prepare such a report in order for continuing review to occur **BEFORE** the expiration date.

Sincerely,

Brian Gladue, PhD
Chair, UNTHSC Institutional Review Board

Texas College of Osteopathic Medicine • Graduate School of Biomedical Sciences • School of Public Health • School of Health Professions
Institutes for Discovery • University of North Texas Physicians Group

3500 Camp Bowie Boulevard, Fort Worth, Texas 76107-2699 • 817-735-0400 • Fax: 735-0175

UNTHSC Institutional Review Board

UNIVERSITY of NORTH TEXAS HEALTH SCIENCE CENTER at Fort Worth
TEXAS COLLEGE OF OSTEOPATHIC MEDICINE
INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS

BOARD ACTION

IRB PROJECT #: 2010-160 DATE SUBMITTED: December 21, 2010

PRINCIPAL INVESTIGATOR: Kathryn Cardarelli, PhD with Tabatha Offutt-Powell, MPH

PROJECT TITLE: Individual Child and Parental Factors that Influence Influenza Vaccination in Children 6 months to 59 months of Age

PROTOCOL #: _____

DEPARTMENT: Epidemiology/ SPH TELEPHONE EXTENSION: _____

In accordance with UNT Health Science Center policy on the protection of human subjects, the following action has been taken on the above referenced project:

Approval, when given, is **only** for the project as submitted. **No changes** may be implemented without first receiving IRB review and approval.

Project has received approval through January 4, 2012.

Informed Consent approved as submitted on January 4, 2011. You **MUST** use this version (attached) rather than previously approved versions. In addition, only consent documents which bear the official UNTHSC IRB approval stamp can be used with subjects.

Study Protocol dated January 4, 2011 approved as submitted.

Protocol Synopsis approved as submitted on January 4, 2011.

_____ Amendment _____ to the protocol approved as submitted.

_____ Based upon the recently completed Continuing Review (IRB Form 4), project has received continued approval through _____.

_____ Project has been reviewed. In order to receive approval, you must incorporate the attached modifications. You must submit one "highlighted" copy and one "clean" copy of the revised protocol synopsis, informed consent and advertisements to the IRB for review. **YOU MAY NOT BEGIN YOUR PROJECT UNTIL NOTIFIED BY THE IRB.**

_____ Consideration of the project has been tabled pending resolution of the issue(s) outlined below.

_____ Project is disapproved for the reason(s) outlined below.

_____ Completion of project is acknowledged and all required paperwork has been received.

Special Findings:

Please see attached.



Chairman, Institutional Review Board

January 4, 2011

Date

UNT Health Science Center
Office for the Protection of Human Subjects
Institutional Review Board
BOARD ACTION

IRB Project #: 2010-160

Date Submitted: March 28, 2011

Principal Investigator: Kathryn Cardarelli, PhD

Project Title: Individual Child and Parental Factors that Influence Influenza Vaccination in Children 6 months to 59 months of Age

Sponsor Protocol #: _____

Department: Epidemiology/ SPH Contact Info: _____

In accordance with UNT Health Science Center policy on the protection of human subjects, the following action has been taken on the above referenced project. Approval, when given is **only** for the project as submitted. **No changes** may be implemented without first receiving IRB review and approval.

The Principal Investigator must notify the IRB immediately if any new potential Conflict of Interest arises or if CITI educational training lapses for any of the Key Personnel involved with the study.

- Project has received approval through: _____
- Informed consent(s) approved as submitted on: April 1, 2011

You **MUST** use the version (s) attached rather than previously approved versions. In addition, only consent documents which bear the official UNTHSC IRB approval stamp can be used with subjects.

*including:

- Study Protocol dated _____ approved as submitted.
- Investigator's Brochure _____ approved as submitted.
- Protocol Synopsis approved as submitted on: April 1, 2011
- Amendment Amendment #1 dated 4/1/11 to the protocol approved as submitted.
- Progress Report/Continuing Review completed, project has received approval through: _____
- Project has been reviewed. In order to receive approval, you must incorporate the attached modifications. You must submit one "tracked changes" version showing the markup and one "clean" copy of the revised protocol synopsis, informed consent, and advertisements to the IRB for review. **YOU MAY NOT BEGIN YOUR PROJECT UNTIL NOTIFIED BY THE IRB.**
- Project is disapproved for the reason(s) outlined (see attached).
- Consideration of the project has been **DEFERRED** pending resolution of the issue(s) outlined (see attached).
- Completion of project is acknowledged and all required paperwork has been received.
- Special Findings/Other (see attached)

Revised: 1) survey mode to self-administered (survey will now be anonymous; no identifiers being collected); 2) incentive amount modified for day cares; 3) increased number of incentives for subjects; 4) implement consent cover letter; 5) reformatted questionnaire to fit new mode; and 6) removed follow-up survey from protocol.


Chairwoman, Institutional Review Board

Date: April 1, 2011
IRB Form 2 (Revised March 2011)

APPENDIX C
Reference Style Approval

October 12, 2011

University of North Texas Health Science Center
School of Public Health
Department of Epidemiology
3500 Camp Bowie Blvd
Fort Worth, TX 76107

RE: Permission to modify reference style for dissertation

The formatting guidelines for the University of North Texas Health Science Center, School of Public Health currently suggest using the 5th edition of the Publication Manual of the American Psychological Association (APA style guide) for referencing. However, other formats may be used if the content is to be submitted for publication. Tabatha N. Offutt-Powell has requested permission to utilize the American Medical Association (AMA) style because the content from his dissertation will be submitted to journals formatted according to the AMA guidelines. We hereby grant Tabatha permission to utilize the AMA reference style for her dissertation to maintain consistency with her manuscripts for submission purposes.



Chair, Department of Epidemiology



Dissertation Committee Chair

APPENDIX D

Survey

7. Was this a shot or spray in the nose?

Flu shot

Flu nasal spray

Don't know

8. Where did your child get his/her flu shot this year?

a) Doctor's office

e) Pharmacy or drug store

b) Health department

f) Elementary/middle/high school

c) Clinic or health center

g) Other place (please specify: _____)

d) Hospital

h) Don't know

9. Is your child allergic to eggs?

No

Yes

Don't know

10. Did your child's doctor or other health professional recommend that he/she get a flu shot this year?

No

Yes

Don't know

Parental perceptions of flu The following questions ask about your perceptions about the flu. Please indicate whether you agree or disagree with the following statements by placing an 'X' in the appropriate box.

Statement	Agree	Disagree
11. My child has a low chance of getting the flu this year.		
12. The flu is not that serious.		
13. If my child gets the flu then he/she will be very ill.		
14. Because my child is healthy, he/she is less likely to get the flu.		

15. Overall, how likely is your child to get the flu this year? Your child getting the flu is

a) Not at all possible

b) Possible but not likely

c) Possible

d) Very likely

e) Will definitely

Vaccine-related adverse events

Please indicate whether you agree or disagree with the following statements by placing an 'X' in the appropriate box.

Statement	Agree	Disagree
16. The flu shot is safe for my child.		
17. The flu shot can cause the flu.		
18. The flu shot can cause side effects such as runny nose, nasal congestion or a sore arm, leg, or thigh (where the shot was given).		
19. The flu shot prevents my child from getting the flu.		

20. Overall, how concerned are you that the flu shot will make your child sick?

- a) Not at all concerned
- b) Somewhat concerned
- c) Concerned
- d) Very concerned

Medical indications and contraindications

The following questions ask about your child's health.

21. Has a doctor ever told you that your child has asthma?

- No Yes Don't know

22. The following is a list of health conditions. Please indicate whether a doctor, nurse, or other health professional has ever said that your child has the condition by placing an 'X' in the appropriate box.

Condition	Yes	No
a. Heart problem, including congenital heart disease		
b. Blood problems such as anemia or sickle cell disease		
c. Cerebral palsy		
d. Muscular dystrophy		
e. Kidney problems		
f. Liver problems		
g. Cancer		
h. Diabetes		
i. Lung problems		
j. Weakened immune system caused by chronic illness or by medicines		
k. Difficulty breathing or respiratory problems (other than asthma)		

Influenza vaccination – Parent/caregiver

The following questions ask about your experience with the flu and flu shot.

23. Did you get the flu shot last year (August 2009 to May 2010)?

No Yes Don't know

24. Have you gotten the flu shot this year (August 2010 to April 2011)?

No Yes Don't know

25. Have you seen a doctor or other health professional in the past year about your own health for preventive services (such as an annual check-up, etc.) at a doctor's office, hospital, clinic, or some other place?

No Yes Don't know

2009 H1N1 Influenza

The following questions ask about the 2009 H1N1 flu (also referred to as swine flu).

26. How much do you know about the 2009 H1N1 flu? Would you say that you know:

- a) Very little
- b) Some
- c) A lot (quite a bit)
- d) Haven't heard of the 2009 H1N1 flu or swine flu.

Please indicate whether you agree or disagree with the following statements by placing an 'X' in the appropriate box.

Statement	Agree	Disagree
27. I knew someone who got the swine flu last year.		
28. Many people got sick from the swine flu last year.		
29. I was concerned that my child would catch the swine flu last year.		
30. I am concerned about my child getting the swine flu.		
31. I wash my hands more this year because of concerns about getting sick from the flu.		
32. I use more hand sanitizer this year than I have in the past because of concerns about getting sick from the flu.		
33. I got my child the flu shot this year because I am concerned that the flu will make a lot of people sick.		

Demographics

Now I would like to ask a few general questions about your household.

34. Do you have health care insurance for your child; this includes private health insurance, prepaid plans such as HMOs, or government plans such as Medicaid?

No Yes Unsure Other _____

35. What is the highest grade or year of school that you have completed?

- a) Less than high school (no diploma)
- b) High school graduate or GED
- c) Completed vocational or trade school
- d) Some college but no degree
- e) College degree or higher

36. What range best describes your family's total combined income before taxes?

- a) \$0 – \$34,999
- b) \$35,000 – \$49,999
- c) \$50,000 – \$74,999
- d) \$75,000 – \$99,999
- e) \$100,000 and over
- f) Prefer not to respond.

37. Is your child Hispanic or Latino? (Including Mexican, Central American, South American, Puerto Rican, Cuban, or other Spanish-Caribbean)

No Yes Don't know

38. Which of the following categories best describes your child's race?

- a) White
- b) Black or African American
- c) American Indian/Alaskan Native
- d) Asian/Pacific Islander/Native Hawaiian
- e) Don't know
- f) Other (please specify: _____)

39. What is your age today? _____ years

That completes the survey. We really appreciate the time that you have spent answering these questions. Your name will be entered into a drawing to receive one of eight \$25.00 gift cards for Walmart. We will be informing the parents who were selected to receive the gift cards in May 2011. Again, if you would like more information about this study, please call me at 903-399-2781 or Dr. Kathryn Cardarelli at 817-735-5192. If you have questions about your rights as a study participant, you may call the Institutional Review Board (IRB) Chairman at 817-735-0409.

APPENDIX E
Recruitment Documents

RECRUITMENT OF DAYCARES

PHONE SCRIPT

Hello. My name is Tabatha Powell, and I am doctoral student at the University of North Texas Health Science Center. I am conducting a research study to understand factors that influence a parent's decision to vaccinate their child against influenza. This research has been approved by the university's Institutional Review Board. Your daycare was randomly selected to participate in this research, but your participation is completely voluntary. We would like to survey the parents of the children in your daycare; therefore, we are asking for permission to leave a paper-based survey/questionnaire at your center. Parents who are interested in taking the survey can complete it and return it to you in a manila envelope in which I provide to you. The surveys are anonymous and should take about 20 minutes for the parents to complete. In addition, parents who take the survey will be entered into a drawing to receive one of 8 \$25 gift cards to Walmart. They detach and return the last sheet of the survey with their name and number and put it in another manila envelope separate from the completed surveys.

The amount of the gift card is determined by child enrollment and percentage of parent participation. Each daycare will receive a minimum of \$25 gift card for having at least one parent survey completed. Center-based daycares with less than 100 children enrolled will receive a \$25 gift card. If more than 50% of their parents participate, then the center will receive a \$50 gift card. Daycares with 101 – 199 children enrolled will receive a \$25 gift card. If more than 50% of their parents participate then the center will receive a \$75.00 gift card. Daycares with more than 200 children enrolled will receive a \$25 gift card. If more than 50% of their parents participate, then the center will receive a \$100 gift card. The daycare will receive the gift card for the appropriate amount upon receipt of the completed surveys. I would also like to provide this information to you in person, so that you have documented information about the research and contact information for the university's Institutional review board (IRB).

Would you be willing to allow us to leave a paper-based survey at your daycare for your parents to complete in order to participate in this research study?

If unsure: schedule a time to meet with the director within the next week.

If yes: schedule a time to meet with the director within the next week to provide the surveys, manila envelopes, letter to daycares describing research, and postcard reminder card.

If no: "Thank you for your time. May I ask your center/daycare's basis for this decision?"

IRB APPROVED

APR 01 2011

University of North Texas
Health Science Center

LETTER TO DAYCARES DESCRIBING RESEARCH



Dear daycare provider,

My name is Tabatha Powell, and I am doctoral student at the University of North Texas Health Science Center. I am conducting a research study to understand factors that influence a parent's decision to vaccinate their child against influenza. This research has been approved by the university's Institutional Review Board. Your daycare was randomly selected to participate in this research, but your participation is completely voluntary. We would like to survey the parents of the children in your daycare; therefore, we are asking for permission to leave a paper-based survey/questionnaire at your center. Parents who are interested in taking the survey can complete it and return it to you in a manila envelope in which I provide to you. The surveys are anonymous and should take about 20 minutes for the parents to complete. In addition, parents who take the survey will be entered into a drawing to receive one of five \$25 gift cards to Walmart. They detach and return the last sheet of the survey with their name and number and put it in another manila envelope separate from the completed surveys.

The amount of the gift card is determined by child enrollment and percentage of parent participation. Each daycare will receive a minimum of \$25 gift card for having at least one parent survey completed. Center-based daycares with less than 100 children enrolled will receive a \$25 gift card. If more than 50% of their parents participate, then the center will receive a \$50 gift card. Daycares with 101 – 199 children enrolled will receive a \$25 gift card. If more than 50% of their parents participate then the center will receive a \$75.00 gift card. Daycares with more than 200 children enrolled will receive a \$25 gift card. If more than 50% of their parents participate, then the center will receive a \$100 gift card. The daycare will receive the gift card for the appropriate amount upon receipt of the completed surveys. I would also like to provide this information to you in person, so that you have documented information about the research and contact information for the university's institutional review board (IRB).

If you have any questions regarding this research project, please feel free to contact:

Principal investigator: Kathryn Cardarelli, PhD, MPH
Email: Kathryn.cardarelli@unthsc.edu
Phone: 817-735-5192

Co-investigator: Tabatha Offutt-Powell, MPH
Email: tpowell@live.unthsc.edu
Phone: 903-399-2761

IRB Chairman: 817-735-0409

IRB APPROVED

APR 01 2011

University of North Texas
Health Science Center

LETTER TO PARENTS



Dear parent/caregiver,

Each year from October through May, we are faced with seasonal flu and its impact on our children and families. My name is Tabatha Powell, and I am doctoral student at the University of North Texas Health Science Center. Our research team includes Dr. Kathryn Cardarelli (Associate Professor in the Department of Epidemiology, Director of the Center for Community Health), Dr. Hampton (Assistant Professor in the Department of Epidemiology), Dr. Singh, PhD (Professor and Chair of the Department of Biostatistics), and Dr. Stonecipher (Regional Zoonosis Veterinarian for the Texas Department of State Health Services).

We are conducting a research study involving a survey of parents with children age 6 months to 59 months (6 years) who are currently attending daycare or are cared for by someone outside of the child's home. You must be 18 years or older to participate in the study. The purpose of this study is to better understand factors that contribute to a parent's decision to get their child a flu shot. This survey will ask about your perceptions regarding seasonal flu illness and the vaccine. The survey is anonymous; you will not have to provide your name. Your daycare has allowed us to provide this survey to you. It should take you about 20 minutes to complete.

Participation in the study is completely voluntary. If you decide to complete the survey, please leave the completed survey at your daycare in the envelope labeled Completed Surveys. The final page of the survey is a Gift Card Drawing sheet. If you would like to be entered in a random drawing to receive one of eight \$25 gift cards to Walmart, please complete this page and return it in the envelope at your daycare labeled Gift Card Drawing.

There is minimal risk associated with participating in this survey. You may receive no direct benefit from participating in this study. The benefits of this survey will allow us to better understand why parents do and don't get their children vaccinated against the flu.

If you have any questions regarding this research project, please feel free to contact:

Principal investigator: Kathryn Cardarelli, PhD, MPH
Email: Kathryn.cardarelli@unthsc.edu
Phone: 817-735-5192

Co-investigator: Tabatha Offutt-Powell, MPH
Email: tpowell@live.unthsc.edu
Phone: 903-399-2761

If you have any questions about your rights as a research subject, please contact the University of North Texas Health Science Center Institutional Review Board at 817-735-0409.

Thank you for your time.

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**CONTACT PARENT FOR GIFT CARD SELECTION
PHONE SCRIPT**

Hello. This is Tabatha Powell. You or someone in your household previously completed a survey regarding your opinions of the flu shot for your child. At that time your name (or that person's name) was entered into a pool of all parents who completed the survey to receive one of eight \$25 gift cards for Walmart. Are you _____?

If "no": ask for that person

If they respond "yes", continue: Your name was randomly selected. You have a choice as to where you would like us to send your \$25 Walmart gift card. Please let me know if you would prefer to pick up your gift card at your child's daycare or you may provide me with your mailing address so that the gift card can be mailed directly to your residence.

If prefer to pick up at daycare: "I will be leaving the gift card with your daycare director within the next week. If you don't receive it, please call me at 903-399-2761."

If prefer to provide mailing address: "What is your mailing address? You should receive the gift card within the next week. If for some reason you haven't, please call me at 903-399-2761."

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MAILING LETTER TO GIFT CARD RECIPIENT PARENTS



Dear parent,

You were recently notified by phone that you were randomly chosen to receive one of eight \$25 gift cards for your participation in a survey regarding your opinions on the flu shot for your child. At the time that we notified you by phone regarding the gift card, you indicated that you preferred to have your gift mailed to this address. Please find within this envelope your gift card. If you have any questions, please feel free to contact me at tpowell@live.unthsc.edu or 903-399-2761.

Sincerely,

Tabatha Offutt-Powell
Study personnel
Department of Epidemiology
School of Public Health
University of North Texas Health Science Center

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