IMPLEMENTING VACCINE HESITANCY SCREENING FOR TARGETED EDUCATION

John Terrence Connors

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Approved By:

Eric Hodges

Jennifer D'Auria

Laura Windham

ABSTRACT

John Terrence Connors: Implementing Vaccine Hesitancy Screening for Targeted Education
(Under the direction of Eric Hodges)

PROBLEM STATEMENT: Research evidence suggests that the inability to identify concerns of parents who are vaccine hesitant and subsequently give individualized counseling on the identified concerns negatively impacts vaccination rates. Little research has been performed investigating the effect of utilizing a vaccine hesitancy (VH) screening tool in conjunction with provider counseling on specific vaccination concerns. Standardizing the use of a VH screening tool may allow the provider to more appropriately address parental vaccination concerns, thereby leading to an increased parental intent to vaccinate (ITV).

PURPOSE STATEMENT: The purpose of this study was to determine whether using a VH screening tool in conjunction with increased provider competency in addressing parental vaccination concerns impacted the parental ITV.

METHODS: This study utilized a pre-experimental design (pre-test/post-test) to measure and categorize VH and the ITV. The population for this study included parents of children age 2 months to 6 years that were presenting to the clinic for a well visit. Differences among the categorical VH, the VH score, and demographic data were described. Data analysis was performed using SPSS version 24® and includes descriptive statistics and non-parametric statistics.

RESULTS: The total sample size was 89 with an overall response rate of 15%. Only a minority of parents were identified as vaccine hesitant (20%). Differences between pre-visit and post-visit questionnaires were evaluated and overall showed mean responses for questions that measured specific VH categories had slight increases in the level of VH after the provider-parent discussion. One question (measuring provider trust) showed a significant difference between pre and post-visit questionnaire scores ($p = 0.033$) with post visit scores showing higher levels of VH. There was a significant effect of age, the number of children in the household, and the level of parental education on the distribution of questionnaire responses.

SIGNIFICANCE: The utilization of a VH screening tool used in conjunction with increased provider technical and communication competence in an educated and mildly VH population did not positively affect the level of VH or the parental ITV. It may be that provider education alone is not enough to affect change in a VH parent.

To my wife and children who have shown me continuous love and support throughout my endless journey of learning.

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LIST OF ABBREVIATIONS AND SYMBOLS

AAP	American Academy of Pediatrics
ANOVA	Analysis of variance
CD	College degree
CDC	Centers for Disease Control and Prevention
EB	Evidence based
GD	Graduate degree
HPV	Human papilloma virus
IRB	Institutional review board
ITV	Intent to vaccinate
PACV	Parent attitudes about childhood vaccines
PI	Principle investigator
RA	Representational Approach
SAGE	Strategic advisory group of experts
SD	Standard deviation
SPIRIT	Sharing patients' illness representations to increase trust
STT	Sigma Theta Tau
TPB	Theory of Planned Behavior
TRA	Theory of Reasoned Action
VCS	Vaccine confidence scale
VPD	Vaccine preventable disease
VH	Vaccine hesitancy
WHO	World Health Organization
&	And

%	Percent
N or *n*	Number
>	Greater than
>/=	Greater than or equal to
<	Less than
</=	Less than or equal to

CHAPTER 1: VACCINE HESITANCY PREVALENCE AND INFLUENCES

Introduction

Successful vaccination programs among children have contributed to a drastic decline in the morbidity and mortality associated with vaccine preventable diseases (VPD) (Andre et al., 2008). Regrettably, infectious diseases that were suppressed by vaccines are now re-emerging. This has been ascribed in part to the increasing number of unimmunized children (Omer, Salmon, Orenstein, deHart & Halsey, 2009). The Centers for Disease Control and Prevention (CDC) reported that pertussis infections have now begun to reach levels not seen since the 1950's, increasing 15% between 2013 and 2014 (CDC-pertussis, 2015). Also, in 2011 more cases of measles were reported than at any time since the late 1990's (Lantos, Jackson, & Harrison, 2012).

Connors et al. (2012) conducted an integrative review on factors that may influence parental choice to not have their children vaccinated as currently recommended by the CDC. A number of factors were identified that negatively influenced parental choice. These factors were categorized as: socio-economic, socio-demographic, untruths about vaccination effects, lack of trust in the medical community, and providers' lack of awareness of their impact on parental decisions. A significant factor influencing parental choice was the providers' ability to influence a parent's decision to vaccinate, which was in part based upon provider knowledge about vaccines.

Problem Statement

Research evidence suggests that the inability to identify specific concerns of parents who are vaccine hesitant and subsequently give individualized counseling on the identified concerns negatively impacts vaccination rates (Glanz, Wagner, et al., 2013). Despite the overwhelming amount of literature investigating the issue of VH, little research has been performed investigating the effect of utilizing a VH screening tool in conjunction with provider counseling on specific vaccination concerns (Sadaf , Richards, Glanz, Salmon, & Omer, 2013). Standardizing the use of a VH screening tool for all well visits may allow the provider to more appropriately address parental vaccination concerns, thereby leading to increased parental ITV.

Purpose Statement

The aim of this research project is to better understand provider effectiveness in interacting with parents concerned about childhood vaccination. Specifically, the purpose of this project is to determine whether using a VH screening tool in conjunction with increased provider competency in addressing parental vaccination concerns during face to face provider-parent interactions will impact the parental ITV. An additional goal of this project is to generate evidence-based data applicable to providers treating pediatric patients in support of increasing VH screening and decreasing VH among parents.

Review of the Literature

As recently as 2010, it was reported that over 20% of parents intentionally delay vaccinating their children (Smith, Humiston, Parnell, Vannice, & Salmon, 2010). In a review by Dube et al. (2013), parental VH was defined as a parental attitude towards vaccination that is associated with overall increased undervaccination of children and influenced by "emotional, cultural, social, spiritual, political… [and] cognitive factors" (p. 1764). At an individual level, an

identified vaccine hesitant parent runs the continuum from full vaccine compliance to near complete vaccine refusal. Gust, Darling, Kennedy, and Schwartz (2008) found that up to 28% of parents reported concerns about vaccination, although 9% of these parents reported consenting to vaccination despite their concerns.

Parental concerns about childhood vaccinations have been shown to lead to VH, which places children at risk of not receiving vaccines on the recommended schedule by either being on an alternative vaccination schedule or forgoing specific vaccinations altogether. Dempsey et al (2011) noted that more than 10% of parents utilized an alternative vaccination schedule, and study results showed that parents who intentionally delayed vaccinating their children were significantly less likely to have the recommended CDC vaccination coverage. Smith et al. (2010) conducted a study to investigate the relationship between the intent to deliberately delay childhood vaccination and actual vaccination coverage, finding that children whose vaccinations were delayed were less likely to be up to date. Other studies have confirmed that VH is increasing (Freed, Clark, Butchart, Singer, & Davis, 2011; Glanz, Newcomer, et al., 2013).

Reasons for Delays in Vaccination

A number of research studies have explored the reasons parents may give for why they do not vaccinate or delay vaccinating their child as currently recommended by the CDC. These reasons include: adverse effects to vaccine components (Kelso, 2015), overloading the immune system (Hulsey, & Bland, 2015), neurodevelopmental concerns (Offit, 2008; Price et al., 2010), moral concerns (Furton, 1999; Jirovec, 2013), and efficacy concerns (Wheeler & Buttenheim, 2013). Another parental concern with regards to childhood vaccinations includes unease about multiple injections, especially as the number of recommended childhood vaccines has increased (Luthy, Beckstrand, Asay, & Hewitt, 2013; Wallace et al., 2014;).

Luthy et al. (2013) performed a study utilizing a focus group to better delineate causes of parental apprehension concerning vaccinating their children. Parents offered suggestions for providers to help lessen parents' vaccine-related anxiety. Examples of factors causing anticipated anxiety included: concerns about vaccine components, concerns for the child's immune system, and vaccine links to autism. Unanticipated findings such as, parents needing to restrain their child, or interruptions to the parent's daily routine after vaccination were more varied and dealt with the vaccination process and the after effects.

Wallace et al. (2014) performed an integrative review of the literature to identify and describe parental and provider healthcare attitudes towards multiple injections. The results showed that parental and provider concerns regarding vaccinations increased as the number of recommended injections increased, though little evidence was identified that these concerns impacted vaccination coverage. Smith et al. (2010) noted a statistically significant association between parents that read negative information about vaccines and delayed vaccination of their children. Smith et al. found that the majority of parents who delayed vaccination due to concerns of the child being ill, vaccine safety, and vaccine effectiveness sought additional information from a physician. The percentage of vaccine delaying parents seeking additional information from the physician ranged from 73.9% to 93.9% depending on the parental concern.

In an integrative review of the literature performed by Connors et al. (2012) on barriers and facilitators to childhood vaccination, it was found that varying provider characteristics acted as either a facilitator and a barrier in and amongst different health-care systems. Provider characteristics that acted as a barrier included: being seen by multiple providers, varying vaccine administration practices, insufficient provider knowledge about vaccines, and poor provider communication leading to vaccine concerns not being addressed. Provider characteristics that

acted as a facilitator included: referrals from a single provider, recommending annual seasonal vaccinations, administering vaccines at specific visits, and provider education regarding vaccinations. Provider education was seen as necessary to influence a parents' decision to vaccinate their children. This result is similar to the conclusions in other studies where the provider was viewed as essential in educating parents to ensure vaccination compliance (Gust et al., 2008; Wallace et al., 2014; Wheeler & Buttenheim, 2013).

Provider Influence

It is widely recognized that the interaction between providers and parents when discussing parental vaccination concerns is important in helping to alleviate vaccination concerns. Luthy et al. (2013) found that parents participating in the study offered recommendations to the provider that included answering questions pertaining to childhood vaccination to help decrease parental anxiety. Gust et al. (2008) investigated the main cause as to why vaccine hesitant parents reversed their decision about delaying or refusing a vaccine for their child. The biggest contributing cause to a parent changing his/her mind in the study was listed as the health care provider offering information about vaccines. Kennedy, LaVail, Nowak, Basket, & Landry (2011) acknowledged the weight of the provider's counseling when it comes to enabling parental trust in the safety and value of vaccines. They noted that to be effective, providers need to dedicate a portion of the visit to impart immunization information to parents. Face-to-face discussions between the provider and parent in a respectful format that acknowledges vaccine hesitant parental concerns has been found to aid in parental understanding of the benefits of vaccinations (Domachowske & Suryadevra, 2013). Other expert literature pertaining to communication practices with vaccine hesitant parents also supports the importance of the health care provider-parent interaction. This literature posits that a non-confrontational

discussion and having honest communication with the parent would be the best approach (Healy, 2014; Schwartz, 2013; Tenrreiro, 2005).

A recent systematic review by Kaufman et al. (2013) found limited evidence validating that face-to-face interventions (defined as individual counseling to multi-session interventions) led to increased vaccination rates in unimmunized children. Also, Kaufman et al. reported there was insufficient evidence to recommend any particular face to face intervention other than to incorporate communication about vaccination effectiveness during a clinical encounter. Brunson (2013) concluded that a singular approach/intervention to vaccine hesitant parents is inappropriate and that interventions should be tailored to parents' specific concerns regarding vaccination. Healy and Pickering (2011) recommended the use of customized counseling to address specific parental fears in the setting of a participatory or collaborative discussion, which is the current recommendation by the American Academy of Pediatrics (AAP) (2015). A positive interaction should enable successful individualized communication about parental vaccine concerns after categorizing the level of vaccine hesitancy (Danchin & Nolan, 2014).

Opel et al. (2013), assessing the various formats in how providers communicated with parents about vaccination, found that parents that were identified as vaccine hesitant were noted to have been resistant to the provider initiating a conversation about vaccination as compared to parents that were not vaccine hesitant. Also, parents resisted provider vaccine recommendations if the provider used a participatory (asking parents if they wanted their child to be vaccinated) versus a presumptive format (a child will be receiving the vaccine) in initiating a conversation about vaccines; a finding that is seemingly contrary to current recommendations. These results built upon a prior qualitative study by Opel et al. (2012), in which it was noted that in provider conversations with parents, providers chose to follow either a presumptive conversational format

or a participatory format. The findings from this study showed that participatory conversations with the parent are associated with a higher likelihood of parental resistance to childhood vaccination. However, the studies performed by Opel et al. did not identify specific vaccination concerns prior to the provider-parent communication. Opel and Bahta (2014) also note that a presumptive type conversation format between the provider and parent may be more appropriate initially, turning into a participatory discussion if resistance is encountered.

A qualitative study by Benin, Wisler-Scher, Colson, Shapiro, and Holmboe (2006) found that the theme of trust in the provider was pivotal for the mothers' decision about vaccination of their child. Specifically, mothers stated that trust is gained when a provider spends time with a parent discussing vaccines, is knowledgeable about parents' vaccination concerns, offers satisfactory answers to parent questions, uses a patient centered approach, and is not belittling to parents' concerns. Benin et al. categorized the aforementioned components identified by mothers as increasing trust in the provider as trust in the competence of the provider. The competence of the provider consists of a linkage between technical and interpersonal competence where the provider has the required knowledge and judgment to inform and treat a patient as well as the ability to communicate effectively (Mechanic, 1998; Thom, Hall, & Pawlson, 2004). Lastly, Benin et al. argued that an increase in the trust in competence of the provider can be achieved by having a detailed understanding of vaccine controversies, and being able to communicate effectively vaccine risks and benefits in clear and simple terms.

The CDC (2012) with support from the AAP (2009) recommends a participatory/collaborative discussion format in discussing vaccine concerns with parents in order to achieve better vaccination compliance. Participatory discussions (face-to-face interventions) with hesitant parents have been found to assist in the understanding of the benefits

of vaccinations, which would likely increase childhood vaccination rates in families that are hesitant (Domachowske & Suryadevra, 2013). When taking the other themes of discussion format and the level of customized counseling into consideration, trust can be gained by a provider through being communicative, receptive to concerns, and centering the discussion onto the patient (Murray & McCrone, 2015).

Measuring Vaccine Hesitancy

The rise in vaccine hesitant parents has led to research to categorize VH into distinct areas of parental concern (discussed above) that include: efficacy of vaccines, immune system concerns, neurodevelopmental concerns, moral concerns, and adverse effects to vaccine components. This has led to the development of tools to identify specific vaccination concerns and in some cases measure parental attitudes and opinions towards vaccination. McRee, Brewer, Reiter, Gottlieb, and Smith (2010) attempted to categorize attitudes and beliefs of parents with regards to vaccination, though this study was limited to assessing attitudes and beliefs that pertained to the human papilloma virus (HPV) vaccination. The questionnaire developed in this study consisted of 16 items, which were categorized into several themes that included vaccine safety, barriers, efficacy, and uncertainty. The study findings further showed that identified parental attitudes about HPV vaccination were important to their ITV, i.e. if the parent had concerns about the safety of the HPV vaccine he/she was less likely to intend to vaccinate.

Another attempt at developing a tool for widespread use to measure parental vaccination beliefs was performed by Gilkey et al. (2014). The Vaccination Confidence Scale (VCS) consists of an eight-item questionnaire designed for use with parents of adolescent children, the identified categories of trust, benefits of vaccination, and harms of vaccination are applicable to parents with children in all age ranges. The first true attempt at developing an instrument to specifically

identify vaccine hesitant parents came from Opel et al. (2011). The researchers drew upon prior research as well as data from parent and pediatrician focus groups and identified four content areas of parental VH. The four content areas included: beliefs about vaccine safety and efficacy, immunization behavior, attitudes about vaccine mandates and exemptions, and trust. This instrument known as the Parent Attitudes About Childhood Vaccines (PACV) survey was well received by an expert review panel, though its use in clinical practice has not been well documented.

A study performed under the guidance of the World Health Organization (WHO) by Larson et al. (2015) in a strategic advisory group of experts (SAGE) on VH, reviewed 10 articles with complete survey tools on VH, vaccine confidence, or trust. In this study, the PACV was utilized as a core instrument to better inform key determinants of VH that include contextual influences, individual and group influences, and vaccination specific issues. Content areas previously identified such as trust, beliefs about vaccine safety and efficacy, immunization behavior, and prevalence of VPD in the community were included under the listed key determinants of vaccine hesitancy. Three different types of survey questionnaire tools were developed to help identify parental vaccine hesitancy in three separate formats (open ended, closed ended, and a 10 item Likert scale questionnaire). The authors posit that further studies need to be performed utilizing newly developed VH screening tools to allow not only identification of vaccine hesitant parents, but also to inform the provider about specific vaccine concerns in order to facilitate individualized parental education.

Summary

Although the majority of parents choose to have their child vaccinated, an increasing number of parents have become vaccine hesitant. Over the past two decades there has been a

dramatic increase in the number of parents intentionally not following CDC vaccination guidelines throughout the United States. Studies point to the increasing problem of parents intentionally delaying vaccinating their children (Smith et al., 2010). This can have the unintended consequence of leading to outbreaks of VPD.

Having a trusting parent-provider relationship is essential to achieve vaccination compliance. Vaccine hesitant parents were found to be significantly influenced by a provider to have their children vaccinated (Gust et al. 2008; Smith, Kennedy, Wooten, Gust, & Pickering, 2006). Medical providers are often cited as the most trusted source of information regarding vaccines (Wallace et al, 2014). Though it has been shown that having technical competence and competence in communication increases trust in the provider and leads to an increased ITV, further research needs to be performed to investigate where meaningful interventions can be implemented to identify and decrease parental VH (Benin et al., 2006). This is increasingly important, as in one large study, the particular causes for children not being vaccinated were not documented in 60% of medical records (Glanz, Newcomer, et al., 2013).

CHAPTER 2: CONCEPTUAL AND THEORETICAL FRAMEWORK

The Theory of Planned Behavior

For this project, the Theory of Planned Behavior (TPB) developed by Ajzen (1991) was used to guide the project framework. The TPB is an extension of the Theory of Reasoned Action (TRA) as put forth by Ajzen and Fishbein (1980). This model has been used in several studies that examined the problem of non-vaccination in general, and specifically in vaccine hesitant parents (Agarwal, 2014; Juraskova et al., 2012; Wheeler & Buttenheim, 2013). The TPB allows the clinician to focus in on the components that might affect the provider-parent interaction. In using the TPB, intention to perform a behavior is seen as a strong indicator to perform a behavior. Intention to perform a particular healthcare behavior is directly influenced by several concepts. These concepts allow a deconstruction of the variables affecting the intent to perform a particular healthcare behavior and include: the attitude towards the behavior, the subjective norm, and perceived behavioral control. Ajzen (1991) conceptually defined attitude towards behavior as individual positive or negative beliefs about performing a particular health behavior. The subjective norm is defined as beliefs that important others approve or disapprove of the behavior. Lastly, perceived behavioral control is defined as beliefs about the barriers or facilitators to performing actual behavior in the context of self-efficacy (ease or difficulty to perform behavior) and controllability (performance of the behavior is under an individual's control).

Juraskova et al. (2012) utilized the TPB to investigate the effects of subjective norms, moral norm, perceived behavioral control, and attitude on the intent to receive the HPV vaccination. It was noted that the TPB significantly predicted a majority of the variance in intention to receive the HPV vaccine. As such it was deemed appropriate to use in studies investigating HPV vaccination as well as aiding in the design of interventions with an objective to increase intent to receive the HPV vaccine. Agarwal (2014) utilized the TPB to identify variables (self-efficacy and perceived comparative susceptibility) significantly associated with college students' intentions to receive the influenza vaccine, thereby allowing improved preventative health communication interventions.

Wheeler and Buttenheim (2013) used the TPB to examine aspects associated with a parent's preference to use an alternative vaccination schedule. The concepts of attitude towards the behavior, the subjective norm, and perceived behavioral control were operationalized for use in this study. Attitude towards behavior was labeled as "vaccine concerns," normative beliefs were labeled as "peer vaccine refusal," and perceived behavioral control was labeled as the "ability to implement [the] desired vaccine schedule." The results of the study showed that parents with vaccine concerns were more likely to request an alternative vaccination schedule. The authors posited that there was a need to find efficacious communication policies to alleviate specific parental vaccination concerns.

The Representational Approach to Patient Education

Though the TPB allows an examination of the components that might affect the provider-parent interaction, it does not directly inform the researcher about effective patient education, or how to increase the effectiveness of the provider-parent interaction, where an effective interaction entails improved technical and communication competence that leads to increased

trust in the provider (Thom, Hall, & Pawlson, 2004). The Representational Approach (RA) to patient education as put forth by Ward, Heidrich, and Donovan (2007) was utilized as an additional theoretical framework to guide the educational intervention. The RA to patient education was developed as a person focused intervention theory that draws from psychology and educational theory (Glanz, Burke, & Rimer, 2015). According to Ward et al. (2007), RA consists of using a common sense model to focus on extracting a patient's knowledge, values, and beliefs prior to performing any interventional education activity to increase communication effectiveness. The RA uses a five-step process (seven steps in later iterations of the theory) to perform individualized patient education. The five steps are as follows: representational assessment (patient account), exploring misconceptions, creating conditions for conceptual change (link between mistaken beliefs and acting on them), introducing replacement information, and summarizing (Donovan & Ward, 2001).

This theory is applicable in many patient education activities where conceptual change would be beneficial. It informs the researcher from the level of the individual patient up to a specific patient population on efficacious ways to perform patient education (Donovan & Ward 2001). Several researchers have employed the RA as a framework to guide intervention studies. Ward et al. (2008) looked at performing an RA intervention using the five-step process outlined above in the context of cancer pain. Specifically, the cause, consequences, control of, and identification of cancer pain were explored. The group receiving the RA intervention was compared to a group receiving standardized materials about cancer pain. The study hypotheses were partially supported in that using a RA intervention afforded some change in beliefs, and pain severity. Song et al. (2010) used a RA intervention to help provide individualized end of life care in conjunction with the patient and his/her surrogate. Results from using the RA

intervention known as SPIRIT (Sharing Patients' Illness Representations to Increase Trust) showed that it was successful in improving agreement between patients and their surrogates regarding care goals.

Key concepts identified in the TPB were used to guide the intervention planned in this project as well as measuring VH. These concepts include the attitude towards the behavior of vaccinating as well as identified subjective norms that affect vaccination. The operational definition of these concepts can be classified as health care beliefs about vaccination (vaccine efficacy, vaccine safety, and prevalence of VPD in the community) and the importance to the parent of the provider recommendation for vaccinating (provider trust), respectively. The RA to patient education was utilized to guide the provider-parent interaction and directly inform the researcher on increasing the effectiveness of the provider-parent interaction by affording increased provider competency (technical and communication). This is accomplished by using the VH screening questionnaire to identify the parental concerns (representational assessment), then having the provider explore vaccination misconceptions with the parent, followed by the provider creating conditions for conceptual change with a subsequent introduction of replacement information.

CHAPTER 3: METHODOLOGY

Project Design

This descriptive project utilized a pre-experimental design (pre-test/post-test) to measure and categorize parental VH and the ITV utilizing a VH screening tool. This project was approved by the UNC Office of Human Research Ethics institutional review board (IRB).

Sample

The target population for this project included parents of children age 2 months to 6 years of age that were presenting to the clinic for a well baby or well child visit. Parents of children outside of these age ranges were excluded to help ensure that an established relationship already existed between the parent and the pediatric provider and to control for increasing autonomy in children (older than 6 years) that may affect parental VH. A convenience sample was used with a goal sample size of 100; an interim analysis involving the first 20 subjects was performed to determine if adjustments to the protocol were needed.

Inclusion criteria:

- Parent or guardian must present with the child
- Parent or guardian must be 18 years of age or older
- Children must be age 2 months to 6 years of age
- The child must be presenting to the clinic for a well baby or well child examination

Exclusion criteria:

- Children being seen at the practice for the first time
- Children with a diagnosis of a significant developmental delay
- Any child not meeting criteria to receive vaccinations as recommended by the CDC (i.e. auto-immune issue)

Recruitment

This project was performed at Chapel Hill Children's Clinic in Chapel Hill, North Carolina, a six-provider private practice with a patient empanelment of 7,000 children ranging from newborn to 18 years of age. The specified time frame of 6 months and the number of subjects needed to complete this project took into account the voluntary nature of completing the questionnaire. After reviewing the literature where a survey instrument was used to study parental vaccination concerns in an outpatient setting, it was noted that the time frame of six months was adequate to garner 100 participants with the estimation that only half of all patients approached would complete the questionnaire (Glanz, Wagner, et al., 2013; Daley et al., 2007). Prospective participants were mailed a project information packet that included instructions on participating in the project (Appendix A) as well as the initial pre-visit questionnaire (Appendix B). Eligible parents of children empanelled to the project site were informed that completion of the pre-visit questionnaire indicated that they elected to be a participant in the project.

This project required funding for a financial incentive to encourage parent participation in the project. Participants were offered a 10 dollar electronic gift card to participate. A grant of 1,000 dollars was utilized from the Sigma Theta Tau (STT) Honor Society of Nursing. Other required resources included participation of office staff at the project site. The office staff was utilized to perform minimal additional duties that included collecting the pre-visit questionnaire

to give to the provider and ensuring that the parent received the reminder notice to complete the post visit questionnaire via Qualtrics©. Office staff was also required to transcribe the participant's project number from the initial pre-visit questionnaire onto the post-visit questionnaire reminder card for the parent to use when logging into Qualtrics©.

Procedures

Providers at the Chapel Hill Children's Clinic were briefed on the project methodology and evidence based talking points pertaining to VH (Appendix C) by the principle investigator in a one hour lecture. Providers were given a quick-reference handout (Appendix D) on evidence based talking points related to vaccine hesitant parent concerns that were identified and categorized from the literature. Providers were also be briefed on the RA to patient education as well as the recommended discussion format (verify parent concerns, explore experience(s) that led to misconception(s), inform the parent of the problems associated with their current belief(s) and the possible consequences, introduce replacement information, and summarize the discussion). The principle investigator (PI) was available by e-mail and phone for any questions that arose during the project. The PI checked-in onsite every 7 days to assess participant recruitment and discuss any immediate concerns pertaining to the project. Providers were also afforded the opportunity to give feedback at the end of the study on the benefits of the briefing, the reference materials given, and their confidence in addressing VH concerns (Appendix E).

All potential participants were identified by a nurse employed at the practice site when a well child or well baby appointment was booked. Potential participants were mailed a packet containing the project protocol (Appendix A) and the pre-visit questionnaire (Appendix B). The project protocol outlined the reasons for the project, the potential benefits of participating, the voluntary nature of the project, and the confidentiality of the project participants. Potential

participants were offered a 10 dollar electronic gift card to participate. Subjects completing the pre-visit questionnaire and bringing it to their child's well appointment were considered enrolled in the project.

The pre-visit VH questionnaire (Appendix B) collected the parents' demographic data, linked participants with a unique project identifying number, categorized the type of vaccine hesitancy (if present), and measured parental ITV. The pre-visit questionnaire also allowed the parent to write in any vaccination concerns that were not listed in the questionnaire. The completed pre-visit questionnaire was made available to the provider at the well visit. The provider was encouraged to engage in a discussion with the parent about any identified vaccination concerns. Completed hard-copy pre-visit questionnaires were placed in a locked drawer for the principle investigator to retrieve after the well examination was completed. The parent received a reminder notice (in the form of a handout) upon checking in to the clinic to complete the post-visit questionnaire online through Qualtrics ©.

The post-visit questionnaire (Appendix F) measured the parental perception of the competence of the provider thereby affording an indirect measure of the level of trust in the provider. Additionally, internal validity was ensured by measuring the parental perception of provider technical and communication competence, assessing the parental perception of provider compliance in addressing vaccination concerns, and determining if the discussion was performed in a participatory format. Vaccine hesitancy was again categorized and measured, as well as ITV. Lastly, the parent was instructed to write in any additional vaccination concerns that were not addressed in the visit with the provider.

Each participant was assigned a project number as an identifier on the pre-visit questionnaire. No names, social security numbers, or date of birth were collected. Demographic

information; specifically gender, age, race, level of education, and number of children in household were recorded. The parent was only able to be identified through their respective identifier when presenting at the clinic with the initial pre-visit questionnaire. Lastly, upon completion of the online post-visit questionnaire, the parent was voluntarily asked to give their email address so that they would be able to receive a digital gift card. Participant email addresses were not linked to any individual questionnaire responses nor to any participant project number identifiers.

Participant responses (excluding emails) were transcribed from the hard copy pre-visit questionnaire and the online post-visit questionnaire into a password protected electronic spreadsheet for analysis. Upon participant completion of both the pre-visit and post-visit questionnaires, further differences in reported levels of parental intention to vaccinate were investigated after group categorization by gender, age, race, level of education, and number of children in household. Differences among the categories of VH and demographic data were described. A VH score for each questionnaire was generated by adding participant responses from individual surveys.

Tools/Instruments

Provider education: Evidence based talking points pertaining to VH. Providers at Chapel Hill Children's Clinic received information about evidence-based talking points pertaining to identified vaccine hesitant parent concerns (Appendices C and D). Information on the current CDC recommendations to improve communication competence with regards to vaccine hesitant parents was available for review (Appendix C). Lastly, providers were given a quick reference handout on the most common parental beliefs and concerns that lead to VH as identified in the literature**.** (Appendix D)

Strategic Advisory Group of Experts (SAGE) VH survey tool. The SAGE VH survey tool (10-item Likert scale questionnaire) was developed under the guidance of the World Health Organization (WHO) by Larson et al. (2015). Content areas previously identified such as trust, beliefs about vaccine safety and efficacy, and immunization behavior were included under the listed key determinants of vaccine hesitancy. For this project an additional question was added to the SAGE VH survey tool questionnaire to measure the parental ITV (11-item total Likert scale questionnaire). Other minimal modifications in wording were performed to the SAGE VH survey tool to make it acceptable for use in the United States; I.e. question number three in the original questionnaire was changed from "all childhood vaccines offered by the government programme in my community are beneficial," (p. 4172) was changed to "all childhood vaccines currently recommended are beneficial". Additional modifications included the addition of demographic data (see Appendix B).

Post-visit questionnaire. The modified SAGE VH survey tool was again utilized to measure any changes in the content and level of VH. Additional concepts measured utilizing a Likert Scale pertained to the parental perception of technical and communication competence of the provider to elucidate the level of parent trust in the provider. The effectiveness of the provider-parent interaction as measured by the outcome (intent to vaccinate) was measured. In total the post-visit questionnaire consisted of 15 questions (see Appendix F). One question in the post-visit questionnaire addressed the level of customized counseling, another question addressed the parents rating of the level of participation afforded them, and two questions addressed the level of trust the parent has in the provider.

Provider project evaluation. Participating providers were afforded an opportunity to answer an open-ended questionnaire (Appendix E) on the benefits of being briefed about

common reasons for parental VH, the helpfulness of the reference materials (Appendices C and D), and if their confidence in addressing VH concerns increased by being a participant in this project. Providers were also asked if this project provided a more efficient approach in addressing individual parental concerns about vaccination during a well visit. Lastly, providers were given an opportunity to give any recommendations or concerns about the project for the principle investigator to review.

Data Analysis

Data analysis was performed using SPSS version 24 ® and included descriptive statistics and non-parametric statistics (Wilcoxin signed ranks , analysis of variance [ANOVA] on ranks, Spearman's rank correlation, and binary logistic regression). Non-parametric statistics were utilized due to the non-normal distribution of the sample and the small sample size. The Wilcoxin signed ranks test was utilized to examine if any significant differences existed between pre-visit questionnaire and post-visit questionnaire participant responses that measured parental trust in the provider, vaccine efficacy beliefs, vaccine safety concerns, beliefs about prevalence of VPD in the community, vaccination beliefs, and the ITV. An ANOVA on ranks was performed to examine parent questionnaire responses across parental age, the number of children in the household, and the parental level of education. Spearman's rank correlation was utilized to examine the relationship between dichotomized pre-visit and post-visit overall VH scores and the pre-visit and post-visit parental ITV. Lastly, a parsimonious binomial logistic regression analysis was conducted to predict the post-visit ITV. Variables utilized in the regression model included the number of children in the household and questions that asked parents about beliefs on vaccine efficacy, parental trust in the provider, and parental beliefs about the prevalence of VPD in the community. Upon completion of the project, all participant data was destroyed.

CHAPTER 4: RESULTS

Sample Characteristics

Six hundred nineteen study information packets were sent out to parents that met study inclusion and exclusion criteria. The response rate for the pre-visit questionnaires (n = 143) was 23%. Out of the parents that completed the pre-visit questionnaire, 92 completed the post-visit questionnaire. The overall completion rate for both pre and post-visit questionnaires was 15%. A total sample size of 89 was utilized due to incompleteness of questionnaire responses, ineligibility (child over the age of 6 years), and one case that was excluded due to the difference in the VH score between the pre and post visit questionnaire being >5 standard deviations above the mean score difference.

The average age of the parent present with the child was 35.55 years (range 25-45years). The mean age of the child being seen was 25.03 months (range 2mo to 72mo). The median number of the children in the household was two. The overwhelming majority of respondents were female (92.2%), white non-Hispanic (88.9%), and had completed post-secondary education (college degree-35.6%, graduate degree-61.1%). The pre-test VH mean score was 15.98 (SD = 4.24) while the post-test mean score was 16.49 (SD = 4.5). The pre-visit ITV scores showed that 77.5% of the sample "strongly agreed" to vaccinate as recommended, 18% "agreed", and 4.5% of the sample either "neither agreed or disagreed" or "strongly disagreed". The post-visit ITV scores showed that 68.5% of the sample "strongly agreed" to vaccinate as recommended, 28.1% "agreed", and 3.3% either "disagreed" or "strongly disagreed". Additional characteristics of the sample can be seen below in Table 1.

Table 1: Characteristics of Study Population (*N* = 89)

Parent age in yrs, mean (*SD*)		35.55 (4.97)
	20-29, *n* (%)	14 (15.7)
	30-39, *n* (%)	58 (65.2)
	40+, *n* (%)	17 (19.1)
Number of Children in household, median (range)[a]		2 (1-4)
	1 child, *n* (%)	23 (25.8)
	2 children, *n* (%)	46 (51.7)
	3+ children, *n* (%)	19 (21.3)
Education level		
	High School, *n* (%)	2 (2.2)
	Some College, *n* (%)	1 (1.1)
	College Degree, *n* (%)	31 (34.8)
	Graduate Degree, *n* (%)	55 (61.8)
Age of child in mo, mean (*SD*) and [Range][a]		27.03 (21.08) and [2-72]
Pre-visit intent to vaccinate mean score (*SD*)		4.66 (0.8)
Post-visit intent to vaccinate mean score (*SD*)		4.61 (0.7)
Pre-visit VH median score (*SD*)		15 (4.2)
Post-visit VH median score (*SD*)		15 (4.5)
Pre-visit VH score >/= 20, *n* (%)		17 (18.9)
Post-visit VH score >/= 20, *n* (%)		22 (24.4)

[a] One participant declined to give information pertaining to the number of children in the household and the age of the child being seen.

Comparison Between Pre and Post-Test Responses

Differences between pre-visit and post-visit questionnaire responses were evaluated (Table 2) and showed that the mean responses for questions that measured specific VH categories (trust, efficacy beliefs, safety concerns, beliefs about prevalence of VPD in the community, and vaccination beliefs) overall had slight increases (though not statistically significant) in the level of VH after the provider-parent discussion. A slight decrease in VH (though not statistically significant) was noted in question number 9, which asked about parental concerns regarding the effects of vaccines. The post-visit mean ITV showed a slight decrease

from the pre-visit mean ITV, and the post-visit overall mean VH score showed a slight increase from the pre-visit mean score; though neither change was statistically significant. The Wilcoxin-signed ranks test was performed on repeated measures between the pre-visit and post-visit questionnaires. Question 8 (measuring trust in the provider) showed a significant difference between pre and post-visit questionnaire scores ($p = 0.033$) with post visit scores showing higher levels of VH. However, this significant finding was associated with participants shifting their response to question 8 from "strongly agree" to "agree". There was no significant difference between other pre and post-visit questionnaire responses, the overall VH score, or the ITV.

Participant responses showed significant compression for many questions, i.e. only "strongly agree" or "agree". Exceptions to this were noted for questions 5 and 9, where participant responses were spread out on the Likert scale. These questions measured parental beliefs in vaccine safety "new vaccines carry more risks than old vaccines" and "I am concerned about serious effects of vaccines," respectively.

Table 2: Comparison of Pre-Test and Post-Test Responses (*N* = 89)

Questions from pre-visit and post-visit questionnaire	**Questionnaire responses**	
	Pre-visit response, *n* (%)	Post-visit response, *n* (%)
Q1. Childhood vaccines are important for my child's health.	$z = -1.134$ SA-76 (88.8) A-10 (11.2) $p = 0.257$	SA-77 (86.5) A-11 (12.4) SD-1 (1.1)
Q2. Childhood vaccines are effective.	$z = -1.213$ SA-73 (82) A-15 (16.9) NA or D-1 (1.1) $p = 0.225$	SA-69 (77.5) A-18 (20.2) NA or D-2 (2.3)

Q3. Having my child vaccinated is important for the health of others in my community.	SA-77 (86.5) A-11 (12.4) NA or D-1 (1.1)	$z = 0.000$ $p = 1.000$	SA-76 (86.5) A-13 (14.6)
Q4. All childhood vaccines currently recommended are beneficial.	SA-58 (65.2) A-23 (25.8) NA or D-8 (9.0)	$z = -1.043$ $p = 0.297$	SA-51 (57.3) A- 32 (36) NA or D-6 (6.7)
Q5. New vaccines carry more risks than older vaccines.	SD-20(22.5) D-30 (33.7) NA or D-34 (38.2) A/SA-5 (6.6)	$z = -0.294$ $p = 0.769$	SD-18 (20.2) D-31 (34.2) NA or D-37 (41.6) A/SA- 3 (3.3)
Q6. The information I receive about vaccines from my provider is reliable and trustworthy.	SA-57 (64) A-31(34.8) NA or D-1 (1.1)	$z = -0.808$ $p = 0.419$	SA-53 (59.6) A-35 (39.3) NA or D-1 (1.1)
Q7. Getting vaccines is a good way to protect my child from disease.	SA-75 (84.3) A-14 (15.7)	$z = -1.265$ $p = 0.206$	SA-71 (79.8) A-18 (20.2)
Q8. Generally I do what my doctor/provider recommends about vaccines for my child/children.	SA-67 (75.3) A-22 (24.7)	$z = -2.138$ $p = 0.033$	SA-59 (66.3) A-30 (33.7)
Q9. I am concerned about serious effects of vaccines.	SD-15 (16.9) D-43 (48.3) NA or D-15 (16.9) A-14 (15.7) SA-2 (2.2)	$z = 0.724$ $p = 0.469$	SD-22 (24.7) D-34 (38.2) NA or D-16 (18.0) A-14 (15.7) SA-3 (3.4)
Q10. My child/children does/do not need vaccines for diseases that are not common anymore.	SD-60 (67.4) D-19 (22.3) NA or D-8 (9.0) A-1 (1.1)	$z = -1.013$ $p = 0.311$	SD-54 (60.7) D-25 (28.1) NA or D-9 (10.1) SA-1 (1.1)

Q11. I intend to have my child vaccinated as recommended by my provider.	z = -1.178	
	SA-69 (77.5) A-16 (18.0) NA or D-1 (1.1) SD-3 (3.4)	SA-61 (68.5) A-25 (28.1) D-2 (2.2) SD-1 (1.1)
	p = 0.239	

Note. *Z* value pertaining to Wilcoxin signed ranks test statistic. SA = strongly agree; A = agree; NA or D = neither agree nor disagree; D = disagree; SD = strongly disagree.

The relationship between dichotomized pre-visit and post-visit overall VH score (< 20 or >/= 20) and the pre-visit and post-visit parental ITV was investigated using Spearman's rank correlation coefficient (after the ITV was subtracted from the overall VH score). The VH score was dichotomized due to an overall compression of the resulting participant scores. The range of VH scores after removing the ITV was noted to be only 10 to 28 with a potential range of 10 to 50. Both the pre-visit and post visit questionnaires had a median VH score of 15. Hence, for this study parents were considered to be VH if their VH score was greater than 1 SD above the median score. There was a medium negative correlation between the VH score and the ITV in the pre-visit and post-visit questionnaire. In the pre-visit questionnaire, r (89) = -.34, $p < 0.001$. In the post-visit questionnaire, r (89) = -.5, $p < 0.001$.

Analysis of Variance (ANOVA) for Demographic Variables

A one-way ANOVA on ranks was conducted to examine parent questionnaire responses across the independent variables of parental age, the number of children in the household, and the level of parental education. An explanation of significant differences in the distribution of questionnaire responses with regards to these independent variables is limited to questions where significant findings occurred in both the pre-visit and post-visit questionnaires for a particular question, however all significant findings are presented in Tables 3 to 5. There was a significant effect of age (age category) on the distribution of questionnaire responses regarding questions

dealing with vaccination beliefs (question 1), efficacy beliefs (question 7), and trust in the provider (question 8). There was also a significant effect of the number of children present in the household on the distribution of responses regarding questions dealing with trust in the provider (question 6) and efficacy/safety beliefs (questions 2 and 4). Lastly, there was a significant effect of parental education level on the distribution of questionnaire responses where parents with a graduate degree were more likely to "strongly agree" regarding questions dealing with vaccination beliefs (question 1), efficacy beliefs (question 2), and efficacy/safety beliefs (question 4). Post hoc testing (Bonferroni correction) was performed where significance was seen in both the pre-visit and post-visit questionnaires to confirm where the differences occurred between groups. To reduce the chance of a type 1 error, the alpha level of 0.05 was divided by the number of groups being compared (3); significant differences were identified between groups if the p value was < 0.017. Hence, some significant ANOVA findings were not confirmed when comparing groups.

Post hoc testing showed that parents in the 20-29 age group were significantly less likely to strongly agree that "childhood vaccines are important for my child's health" as compared to the 30-39 age group ($p < 0.001$) and the 40+ age group ($p = 0.002$) in the pre-visit questionnaire only. Parents in the 20-29 age group were significantly less likely to strongly agree that "getting vaccines is a good way to protect my child/children from disease" as compared to the 30-39 ($p < 0.001$) age group in the pre-visit questionnaire only. Parents in the 20-29 age group in both the pre-visit and post-visit questionnaires were significantly less likely to strongly agree that "generally I do what my doctor or health care provider recommends about vaccines for my child/children" as compared to the 30-39 age group (pre, $p < 0.001$; post, $p = 0.012$). Additionally, an overall trend was noted in that parental responses to individual questions

evinced less VH (lower scores) in the 30 to 39 age group as compared to the 20 to 29 and the 40+ age group. Parents in the 40+ age group were also noted to exhibit less VH than parents in the 20 to 29 age group.

Table 3: ANOVA Age Category[a]

Questions from pre-visit and post-visit questionnaire	**Age Category in yrs (*N* = 89) (20-29, 30-39, 40+) *n* (%)**	
	Pre-visit	Post-visit
Q1. Childhood vaccines are important for my child's health.	$X^2(2) = 16.475$, $p < 0.001$ 20-29 = 8 (57.1) SA 30-39 = 55 (94.8) SA 40+ = 16 (94.1) SA	$X^2(2) = 6.940$, $p = 0.031$ 20-29 = 9 (64.3) SA 30-39 = 52 (89.7) SA 40+ = 16 (94.1) SA
Q2. Childhood vaccines are effective.	$X^2(2) = 12.376$, $p = 0.002$ 20-29 = 7 (50.0) SA 30-39 = 52 (89.7) SA 40+ = 14 (82.4) SA	
Q3. Having my child vaccinated is important for the health of others in my community.	$X^2(2) = 8.561$, $p = 0.014$ 20-29 = 9 (64.3) SA 30-39 = 54 (93.1) SA 40+ = 14 (82.4) SA	
Q6. The information I receive about vaccines from my provider is reliable and trustworthy.	$X^2(2) = 8.921$, $p = 0.012$ 20-29 = 5 (35.7) SA 30-39 = 43 (74.1) SA 40+ = 9 (52.9) SA	
Q7. Getting vaccines is a good way to protect my child from disease.	$X^2(2) = 15.687$, $p < 0.001$ 20-29 = 7 (50.0) SA 30-39 = 54 (93.1) SA 40+ = 14 (82.4) SA	$X^2(2) = 5.979$, $p = 0.05$ 20-29 = 8 (57.1) SA 30-39 = 50 (86.2) SA 40+ = 13 (76.5) SA
Q8. Generally I do what my doctor/provider recommends about vaccines for my child/children.	$X^2(2) = 14.268$, p = 0.001 20-29 = 5 (35.7) SA 30-39 = 49 (84.5) SA 40+ = 13 (76.5) SA	$X^2(2) = 8.562$, $p = 0.014$ 20-29 = 5 (35.7) SA 30-39 = 44 (75.9) SA 40+ = 10 (58.8) SA
Q10. My child/children does/do not need vaccines for diseases that are not common anymore.	$X^2(2) = 10.504$, $p = 0.005$ 20-29 = 6 (42.9) SD 30-39 = 45 (78.9) SD 40+ = 9 (52.9) SD	
Q11. I intend to have my child vaccinated as recommended by my provider.	$X^2(2) = 9.677$, $p = 0.008$ 20-29 = 7 (50.0) SA 30-39 = 51 (87.9) SA 40+ = 11 (64.7) SA	

Note. SA = strongly agree; SD = strongly disagree.

[a] Only significant results ($p < 0.05$) are listed (Kruskal-Wallis ANOVA).

Parents with three children were significantly less likely to strongly agree that "childhood vaccines are effective" as compared to parents with two children ($p = 0.004$) in the post-visit questionnaire only. Lastly, parents with three children in both the pre-visit and post-visit questionnaires were significantly less likely to strongly agree that "all childhood vaccines currently recommended are beneficial" as compared to parents with two children (pre, $p = 0.002$; post, $p = 0.004$). No statistically significant differences were noted between parents with one child and those with two and three or more children.

Table 4: ANOVA Number of Children[a]

Questions from pre-visit and post-visit questionnaire	**Number of children ($N = 88$)[b] (1, 2, 3 or more) *n* (%)**	
	Pre-visit	Pre-visit
Q1. Childhood vaccines are important for my child's health.	$X^2(2) = 7.994$, $p = 0.018$ 1 Child = 18 (78.3) SA 2 Children = 45 (97.8) SA 3+Children = 15 (78.9) SA	
Q2. Childhood vaccines are effective.	$X^2(2) = 7.250$, $p = 0.027$ 1 Child = 18 (78.3) SA 2 Children = 42 (91.3) SA 3+Children = 12 (63.2) SA	$X^2(2) = 10.471$, $p = 0.005$ 1 Child = 17 (73.9) SA 2 Children = 41 (89.1) SA 3+Children = 10 (52.6) SA
Q4. All childhood vaccines currently recommended are beneficial.	$X^2(2) = 10.519$, $p = 0.005$ 1 Child = 15 (65.2) SA 2 Children = 35 (76.1) SA 3+Children = 7 (36.8) SA	$X^2(2) = 10.723$, $p = 0.005$ 1 Child = 13 (56.5) SA 2 Children = 32 (69.6) SA 3+Children = 5 (26.3) SA
Q6. The information I receive about vaccines from my provider is reliable and trustworthy.	$X^2(2) = 6.819$, $p = 0.033$ 1 Child = 12 (52.2) SA 2 Children = 35 (76.1) SA 3+Children = 9 (47.4) SA	$X^2(2) = 10.675$, $p = 0.005$ 1 Child = 10 (43.5) SA 2 Children = 35 (76.1) SA 3+Children = 7 (36.8) SA
Q7. Getting vaccines is a good way to protect my child from disease.	$X^2(2) = 9.72$, $p = 0.008$ 1 Child = 17 (73.9) SA 2 Children = 44 (95.7) SA 3+Children = 13 (68.4) SA	
Q8. Generally I do what my doctor/provider recommends about vaccines for my child/children.		$X^2(2) = 9.054$, $p = 0.011$ 1 Child = 11 (47.8) SA 2 Children = 37 (80.4) SA 3+Children = 10 (52.6) SA
Q9. I am concerned about serious effects of vaccines.	$X^2(2) = 6.796$, $p = 0.033$ 1 Child = 12 (52.2) SD or D 2 Children = 36 (78.3) SD or D	

	3+Children = 9 (47.4) SD or D	
Q10. My child/children does/do not need vaccines for diseases that are not common anymore.	$X^2(2) = 11.976$, $p = 0.003$ 1 Child = 18 (81.8) SD or D 2 Children = 45 (97.8) SD or D 3+Children = 15 (78.9) SD or D	
Q11. I intend to have my child vaccinated as recommended by my provider.		$X^2(2) = 7.538$, $p = 0.023$ 1 Child = 16 (69.6) SA 2 Children = 36 (78.3) SA 3+Children = 8 (42.1) SA

Note. SA = strongly agree; SD = strongly disagree; D = disagree.
[a] Only significant results ($p < 0.05$) are listed (Kruskal-Wallis ANOVA).
[b] One participant declined to give information on the number of children in the household.

Post-hoc testing was not performed when examining the education level of parents and the distribution of questionnaire responses as there were fewer than three groups to compare (college degree versus graduate degree). Parents with a college degree (CD) in both pre-visit and post-visit questionnaires were significantly less likely to strongly agree that "childhood vaccines are important for my child's health" as compared to parents having a graduate degree (GD) (pre, $p = 0.006$; post, $p = 0.003$). Parents with a CD were also significantly less likely to strongly agree that "childhood vaccines are effective" as compared to parents having a GD (pre, $p = 0.015$; post, $p = 0.009$). Lastly, parents with a CD in both the pre-visit and post-visit questionnaires were significantly less likely to strongly agree that "all childhood vaccines currently recommended are beneficial" as compared to parents having a GD (pre, $p= 0.039$; post, $p = 0.029$).

Table 5: ANOVA Education Level[a]

Questions from pre-visit and post-visit questionnaire	**Education ($N = 86$)[b] (college degree-CD, graduate degree-GD) *n* (%)**	
	Pre-visit	Pre-visit
Q1. Childhood vaccines are important for my child's health.	$X^2(2) = 7.505$, $p = 0.006$ CD = 24 (77.4) SA GD = 53 (96.4) SA	$X^2(2) = 9.193$, $p = 0.002$ CD = 22 (71.0) SA GD = 52(94.5) SA

Q2. Childhood vaccines are effective.	$X^2(2) = 5.874$, $p = 0.015$ CD = 22 (71.0) SA GD = 50 (90.9) SA	$X^2(2) = 6.875$, $p = 0.009$ CD = 19 (61.3) SA GD = 47 (85.5) SA
Q4. All childhood vaccines currently recommended are beneficial.	$X^2(2) = 4.261$, $p = 0.039$ CD = 17 (54.8) SA GD = 41 (74.5) SA	$X^2(2) = 4.779$, $p = 0.029$ CD = 14 (45.2) SA GD = 36 (65.5) SA
Q7. Getting vaccines is a good way to protect my child from disease.	$X^2(2) = 4.267$, $p = 0.039$ CD = 23 (74.2) SA GD = 50 (90.9) SA	
Q9. I am concerned about serious effects of vaccines.	$X^2(2) = 6.134$, $p = 0.013$ CD =16 (51.7) SD or D GD =40 (72.1) SD or D	
Q10. My child/children does/do not need vaccines for diseases that are not common anymore.	$X^2(2) = 4.813$, $p = 0.028$ CD = 22 (71.0) SD or D GD = 54 (100) SD or D	

Note. SA = strongly agree; SD = strongly disagree; D = disagree.
[a] Only significant results ($p < 0.05$) are listed (Kruskal-Wallis ANOVA).
[b] Three individuals did not have at least a college degree.

Regression Analysis

A parsimonious binomial logistic regression analysis was conducted to predict the post-visit ITV for 86 parents. Intent to vaccinate in the post-visit questionnaire was ascertained by the question "I intend to have my child vaccinated as recommended by my provider". Three post-visit questions (question 7, 8, and 10) and the number of children in the household best met the assumptions put forth in this type of model. The post-visit questions utilized in this model included those that asked about beliefs on vaccine efficacy (question 7), parental trust in the provider (question 8), and beliefs about prevalence of VPD in the community (question 10). A test of the full model against a constant only model was statistically significant, indicating that the predictors as a set reliably distinguished between those with a higher ITV than those with a lower ITV, where X^2 (10, 86) = 63.72, $p < .001$.

Nagelkerke's R^2 of 0.72 indicated a strong relationship between prediction and grouping. Prediction success overall was 93.2% (82.1% for other than strongly agree and 98.3% for

strongly agree. The Wald criterion demonstrated that vaccine efficacy beliefs (question 7, p = 0.038), parental trust in the provider (question 8, p = 0.008), and belief about the prevalence of VPD in the community (question 10, p = 0.024) made a significant contribution to prediction. The number of children in the household was not a significant predictor. Exp(B) values indicate that when beliefs in vaccine efficacy (question 7) and the parental trust in the provider (question 8) is raised by one unit the odds ratio is 12.37 and 22.94 times as large, respectively. Additionally, the Exp (B) value indicates that when a belief about the prevalence of VPD in the community (question 10) is raised by one unit the odds ratio is 0.10 times as large.

Internal Validity and Participant Open-Ended Responses

From the parent's perspective, providers were noted to have been relatively compliant with regards to utilizing a participatory discussion format (77.8% either "strongly agreed" or "agreed" and 22.2% "neither agreed nor disagreed"), were respectful of parent concerns regarding vaccination (84.5% either "strongly agreed" or "agreed"), and answered questions pertaining to vaccinations (85.5% either "strongly agreed" or "agreed"). An overwhelming majority of parents believed that their child's provider had his/her best interests at heart (96.7% either "strongly agreed" or "agreed").

Parents left a total of 32 responses to the open-ended question of "do you have any specific vaccination concerns you would like to discuss with your child's provider today?" Responses were categorized as to the overall content (i.e. pro vaccine response, comments on the questionnaire structure, etc.) versus specific comments on vaccine safety, efficacy, immune system concerns, the vaccination schedule, or concerns relegated to a specific vaccine. Twelve responses were pro-vaccine and included many strong statements such as, "I hope you don't let anti-vaxers in your clinic! Don't need measles in the waiting room!" to "Hope! [I'm] just

grateful for vaccines." There were six questions specific to the measles vaccine, three questions pertaining to the influenza and HPV vaccines, and one question pertaining to the varicella vaccine. Five responses specifically asked about the vaccination schedule or stated the intent of the parent to spread out their child's immunizations and utilize an alternative schedule. Three parents commented on the wording/structure of the pre and post-visit questionnaires. Two parents commented on their concerns about their child's immune system with regards to vaccinations. Two parents questioned the efficacy of the influenza vaccination, and another parent questioned the safety of "new" vaccines.

Provider project evaluation responses overall showed that provider knowledge about VH (identifying and categorizing the level and type) increased and that provider confidence in addressing parental concerns about vaccines increased. Additionally, providers overall reported that the framework of the study and use of the RA to patient education allowed increased efficiency in identifying and counseling parents exhibiting more than mild VH. Lastly, providers noted a positive benefit in being briefed about common reasons for parental VH, though the helpfulness of the quick reference patient handout was noted to be negligible (Appendix D).

CHAPTER 5: DISCUSSION

To the best of my knowledge, this was the first study to analyze whether utilizing a VH screening tool in conjunction with increased provider competency in addressing parental vaccination concerns during face to face provider-parent interactions impacted the level of VH and/or the parental ITV in the context of a single visit. Additionally, the VH screening tool used in this study that was developed by Larson et al. (2015) afforded the researchers a novel way in which to give a composite VH score by adding scaled categories.

Impact of Provider Counseling

Post-visit questionnaire responses in general showed a slightly increased but insignificant level of VH and a non-significant decreased ITV when compared to pre-visit questionnaire responses. The sole exception to this finding was question number 9 that stated "I am concerned about serious effects of vaccines," which showed a slight decrease in the mean level of VH for this particular question. This possibly indicates a mild positive benefit of provider counseling with regards to beliefs about vaccination safety, though this finding was not significant. Question number 8 showed a significant increase in the level of VH as it pertains to parental trust in the provider when compared to the pre-visit response. However, it was noted that a significant number of parents only changed their response from "strongly agree" to "agree" for this question.

The finding in this study that devoting time for provider education about vaccines to alleviate parental vaccination concerns did not significantly affect the level of VH or the ITV contradicts what was expected to occur. This expectation was based upon previously identified

literature findings that showed parents requested providers answer questions pertaining to vaccinations to help decrease parental anxiety and parents stating that the biggest contributing cause to a change in the ITV was the health care provider offering information about vaccines (Luthy et al., 2013; Gust et al., 2008).

Additional Factors Possibly Affecting Participant Responses

These results though unexpected, may be attributable to another factor leading to VH that was not identified in the questionnaire nor addressed during the provider-parent discussion. One possibility was that parents may have let the emotional reaction of their child being vaccinated immediately after the well visit affect their responses in the post-visit questionnaire. This is supported by Luthy, Beckstrand, and Peterson (2009) who found that a greater percentage of parents were concerned about their child's pain/anxiety (34.9%) and short-term adverse effects (29.1%) than they were with the overall safety of vaccines (24.4%). An additional study by Gowda and Dempsey (2013) found that the immediate effects of vaccines are a factor that contributes to the overall VH exhibited by parents. It is possible that the differences between the pre-test and post-test responses can be explained by the parents own anxiety and the immediate after effects of an immunization injection (pain, fussiness, swelling, etc.). Subsequent studies utilizing a vaccine hesitancy screening tool may benefit by including a category that assesses parent concerns on the immediate effects of vaccines.

Another factor to be considered is that a deliberate attempt to engage the parent in a participatory conversation regarding their vaccination concerns can potentially lead to increased resistance to vaccination and a decreased ITV. Evidence of this was noted by Opel et al. (2013) who found that a participatory versus a presumptive conversation format was associated with greater resistance to vaccination. Another study by Brewer et al. (2016) found that following a

presumptive format when informing the parent of the need for vaccinations was associated with a higher vaccination rate, though this study was limited to the HPV vaccination. Brewer et al. posited that using a presumptive type conversation format helped to "normalize" the receipt of the vaccination, which in-turn makes parents more likely to vaccinate their child/children. However, the increase in initial receipt of the HPV vaccination in this study did not carry over into completion of the vaccination series. Hence, additional longitudinal studies are needed to ascertain the full benefit of utilizing a presumptive type format when discussing vaccinations with parents. Additionally, it may be of benefit to perform a clinical study that utilizes a presumptive vs. participatory type conversation while utilizing a VH screening tool that identifies and categorizes the level and type of VH.

Response Rate

The response rate for the pre-visit questionnaire was anticipated to be approximately 50%, as prior studies that utilized a mailed survey instrument to study parental vaccination concerns in an outpatient setting had response rates ranging from 52 to 57 percent (Glanz, Wagner, et al., 2013; Daley et al., 2007). A meta-analysis performed by Shih and Fan (2009) that examined the differences in response rates between mailed and e-mailed surveys (pertaining to a wide range of subjects) showed a 53% response rate for mailed questionnaires and a decreased response rate for e-mailed questionnaires (33%). However, for this study a response rate of 23% for the initial pre-visit questionnaire was achieved with only 15% of those invited to participate completing both the pre-visit (mailed) and post-visit (online) questionnaire. It is not entirely clear as to why the response rate was so low, but it was noted that a large percentage of parents that elected to participate did not express any evidence of VH or were found to be only mildly vaccine hesitant.

One possible reason for the low response rate and the large majority of only mildly VH parents electing to participate in this study may be due to self-selection; parents with significant levels of VH and a decreased ITV might have abstained from participating due to fears of being dismissed from Chapel Hill Children's Clinic, the practice site utilized for this study. A study by Buttenheim, Cherng, and Asch (2013) lends credence to parents having fears about dismissal as the authors found that provider tolerance of vaccine hesitant parents is decreasing. An additional study by Kempe et al. (2011) found that up to 25% of pediatricians would consider dismissing families from their practice if they refused any primary series vaccinations. Recruiting materials used in this study informed parents that participation in this study would not affect the level or quality of care provided, but the materials did not explicitly address the concern of potential dismissal. One way to possibly alleviate parental concerns about dismissal from the practice if using a VH questionnaire routinely for screening would be for the clinical site to explicitly inform parents that their decision to participate as well as their questionnaire responses would not place them at risk of disenrollment.

Additional evidence of self-selection was seen in the demographic characteristics of the study population (Table 1). Nearly 89% of participants self-identified as White not Hispanic in a city where only 69.5% of the population is White (U.S. Census Bureau, 2015). Also, 96.6% of parents completing both questionnaires reported having either a college or graduate degree in a city where only 74% of the population has a bachelor's degree or higher (U.S. Census Bureau, 2015). As such, this study allowed an examination of VH in a highly educated population (bachelors versus graduate level education).

Another possible reason the response rate for this study was low includes an excessive burden being placed on parents (bringing the pre-visit questionnaire to the appointment and

remembering to complete the online post visit-questionnaire). It may have been more beneficial to have encouraged parents to complete both questionnaires while in the clinic prior to and immediately after the appointment or to have included e-mailed reminder notices to complete the online post-visit questionnaire versus using reminder cards given to the parent after the clinic visit.

Response Scores Compression

The finding denoted above that primarily non-vaccine hesitant and mildly vaccine hesitant parents seemingly self selected to participate in this study is based upon the finding that the median VH score of both the pre and post-visit questionnaires (potential range of 11 to 55) was 15. Also, the mean score of the parental ITV in question 11 was noted to be high in both the pre-visit and post-visit questionnaire and generally indicated either "agreeing" (pre-visit, 18%; post-visit, 28.1%) or "strongly agreeing" (pre-visit, 77.5%; post-visit, 68.5%) with the statement "I intend to have my child vaccinated as recommended by my provider." This compression of participant response scores was extended to the questions asked in both the pre-visit and post visit questionnaires (see Table 2). Participant responses had to be combined in many cases (i.e. "strongly disagree" with "disagree") in order to perform statistical analyses. Exceptions to this compression of responses were noted for questions 5 and 9, which indicate wider ranging parental beliefs about the safety of vaccines, especially new vaccines.

As previously stated, VH runs the continuum from full vaccine compliance to near complete vaccine refusal. As such, for the purposes of this study parents were considered VH if their VH score was one *SD* above the median score or >/= to 20. Additionally, this study confirms the findings from the literature that even if a parent is exhibiting VH, the parent can still have a strong ITV (Dube et al., 2013). Future studies utilizing the VH questionnaire used in

this study may wish to expand the Likert scale to allow a greater breadth of responses from parents, i.e. “somewhat agree, mostly agree, entirely agree”. This may increase the scale sensitivity in identifying differences between pre-and post-test responses. Though this study does show that the VH score generated utilizing the modified 5-point Likert-scale questionnaire developed by Larson et al. (2015) correlates well with the parental ITV and may afford providers and other health care professionals an efficacious and efficient tool to categorize parental vaccination concerns and assess the level of VH as well as the ITV.

Significance of Age

The results from this study show that the distribution of responses for younger parents to questions assessing specific VH categories (agreement with positive statements on vaccination beliefs, vaccination efficacy, and trust in the provider) showed that the 20-29 yr age group was associated with being less likely to “strongly agree” as compared to the 30 to 39 age group overall and in one question the 40+ age group. A study by Reiter, Gottlieb, and Smith (2010) found that parents exhibiting concerns with regards to the previously mentioned VH categories were noted to have a decreased ITV. Studies by Opel et al. (2011) and Smith et al. (2004) support the concern that children of younger parents are more likely to be under-immunized. Additional research on interventions to alleviate parental VH might consider targeting parents aged 20-29 and focus on the VH categories of parental vaccination beliefs, beliefs about vaccination efficacy, and building parental trust in the provider, while controlling for additional characteristics of younger parents that are associated with under-immunization (such as lower SES, single parent, etc).

Significance of Number of Children

The finding that the distribution of responses pertaining to parents with 3+ children were significantly less likely to "strongly agree" as compared to parents with 2 children on statements assessing beliefs about vaccine safety and efficacy is somewhat supported by the literature. Studies by Opel et al. (2011) and Smith et al. (2004) found that under-vaccinated children tended to be in households with greater than 1 child and 4 children, respectively. In this study, the percentage of parents with 1 and 3+ children reporting strongly agree to the above categories was decreased as compared to parents with 2 children. However, this finding was only significant when comparing parents that had 3+ children with those that had 2 children.

Significance of the Level of Education

As noted earlier, this study afforded a look into the characteristics of a highly educated population with regards to the level of VH. To my knowledge, this is the first study to delineate and examine the distribution of VH levels between parents having undergraduate versus graduate level education. Interestingly, the distribution of parent responses showed that parents with only a bachelor's degree tended to be less likely to strongly agree with statements supporting positive vaccination beliefs and positive beliefs about vaccination efficacy and safety as compared to individuals with a graduate degree. Other studies in general show that post-secondary education is generally associated with decreased under-vaccination/non-vaccination (Opel et al., 2011; Smith et al., 2004).

Future VH Questionnaires

The parsimonious logistic regression model showed that parent responses to statements pertaining to provider trust, belief in vaccine efficacy, and parental beliefs about the prevalence of VPD in the community significantly explained 72% of the variability in the parental ITV.

Parental trust in the provider has been shown to be essential to ensure vaccination compliance in numerous studies and represents a category of VH (Larson et al., 2015; Opel et al., 2011; Gust et al., 2008; Benin, Wisler-Scher, Colson, Shapiro, & Holmboe, 2006; Smith, Kennedy, Wooten, Gust, & Pickering, 2006). Additionally, parental belief in vaccine efficacy has been shown to be a valid component of VH and a predictor of ITV or actual vaccination status (Wheeler & Buttenheim, 2013; Opel et al., 2011). Lastly, parental perception of the prevalence of VPD in the community or the perceived risk of acquiring a VPD was noted to have been an implied component of VH and the ITV (Wolf, Rowhani-Rahbar, & Opel, 2015; Opel et al., 2011; Kennedy, & Gust, 2008).

Development of future tools should potentially place greater weight on questions that assess parental trust in the provider, parental beliefs pertaining to vaccine efficacy, and parental perception of the prevalence of VPD in the community. A more thorough assessment of these items would potentially allow health professionals to develop interventions that increase trust in the provider and to better inform public health campaigns and mass communications that seek to enlighten parents about the prevalence of VPD in the community as well as alleviate parental concerns about vaccine efficacy.

Provider Technical and Communication Competency

Parental responses measuring internal validity of this study show that the overall study framework allowed providers to identify and categorize parental vaccination concerns and address these concerns utilizing a participatory type format during a well-child visit; I.e. providers were noted to have demonstrated technical and communication competency from the parent perspective. Achieving technical and communication competency were key components to attain in this study as prior identified studies found that mothers identified provider

competency in addressing vaccination concerns was pivotal in affecting their decision to vaccinate, where competency consisted of a linkage of both competence in communication and knowledge about specific concerns of parents (Benin et al., 2006; Thom, Hall & Pawlson, 2004; Mechanic, 1998).

Providers acknowledged that the study framework provided an efficient mechanism to identify, categorize, and discuss parental vaccination concerns in parents that exhibited more than mild VH. Parent responses to the open-ended question of "do you have any specific vaccination concerns you would like to discuss with your child's provider today" were generally positive and pro-vaccine. However, parents did bring up many specific concerns such as questions about the vaccination schedule, and concerns regarding the MMR, influenza, HPV, and the varicella vaccine.

Limitations

Limitations of this study include the sample being restricted to a largely homogenous (White not Hispanic) and highly educated population. This study was also restricted to a single clinic and utilized a small sample. Additionally, there may have been a higher risk of non-response bias for individuals with moderate or higher levels of VH that may have led to an under-sampling of vaccine hesitant parents. Hence, findings from this review may not be fully generalizeable. Furthermore, the sample consisted of parents that were either not vaccine hesitant or exhibited mild levels of VH. As such, the data garnered was relatively compressed on a 5-point Likert scale, which limited the researcher's ability to perform statistical analyses or draw conclusions.

Conclusion

This study found that the utilization of a VH screening tool in conjunction with a participatory conversation format and increased provider technical and communication competence did not positively affect the level of VH or the parental ITV. This was a surprising finding given that a vast majority of parents were seemingly satisfied with their discussion with the provider about vaccines and reported that providers adhered to the study framework, utilized a participatory format, and exhibited communication and technical competency as it related to discussing parental vaccination concerns.

Even without a significant change in the level of VH or the ITV the study findings support the clinical use of a VH screening stool to identify and categorize the level and type of VH as it was predictive of the parental ITV. Additional research on VH screening tools that place greater weight on questions that assess parental trust in the provider, parental beliefs pertaining to vaccine efficacy, parental perception of the prevalence of VPD in the community, and parental anxiety about the immediate after effects of an immunization may improve understanding about VH and allow the development of more efficacious interventions. It may also behoove researchers to develop a survey that is able to delineate specific concerns parents harbor about the safety of vaccines as well as identify if a true concern exists with regards to parents believing old vaccines carry less risk than new vaccines, as questions that assessed these items showed the greatest breadth of responses in this study. Furthermore, the study findings indicate that VH is concentrated in a younger population. Additional research on interventions to alleviate parental VH that target parents aged 20-29,while controlling for additional characteristics of younger parents that are associated with under-immunization should be considered.

It may be that provider education alone in the context of a participatory discussion is not enough to affect change in a highly educated mildly VH population, even when utilizing a framework to ensure provider technical and communication competence. Also, the utilization of a more participatory discussion versus a more presumptive approach when discussing parental vaccination concerns may affect the parental level of VH and ITV. Utilizing a presumptive type conversation format may help "normalize" the receipt of vaccinations. Additional longitudinal studies comparing these two discussion formats (presumptive vs. participatory) should be conducted. As increasing VH and non-vaccination represents a growing public health concern, it may be advisable to develop strategies at the policy level and utilize the public health system for a broad pro-vaccination campaign, while taking into account identified VH categories.

APPENDIX A: PROJECT INFORMATION AND INSTRUCTIONS

University of North Carolina at Chapel Hill
Study Information/Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 3 April 2016
IRB Study # 16-0029
Title of Study: Improving Communication About Vaccines
Principal Investigator: John Connors
Principal Investigator Department: School of Nursing
Principal Investigator Phone number: 919-308-9340
Principal Investigator Email Address: johntc@email.unc.edu
Faculty Advisor: Eric Hodges
Faculty Advisor Contact Information: (919) 966-0534

Funding Source and/or Sponsor: Funding provided in part by Sigma Theta Tau International Honor Society of Nursing, Gamma Iota Chapter.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may refuse to join, or you may withdraw from the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to improve communication between healthcare providers and parents about childhood vaccinations.

How many people will take part in this study?
A total of approximately 100 people at 1 institution will take part in this study.

How long will your part in this study last?
The time involved for you to complete the two questionnaires utilized in this study is approximately 10 to 15 minutes. One questionnaire has been included with this form and the other questionnaire can be completed online after your child's visit. You will be given instructions on completing the online post-visit questionnaire at your child's well appointment.

What will happen if you choose to take part in the study?

If you choose to participate you will need to bring the completed pre-visit questionnaire (attached to this form) with you to your child's scheduled well visit appointment. Your child's provider will review your responses with you and discuss your vaccination concerns. After your appointment you will be given a card containing information to complete an online post-visit questionnaire. Your responses in the pre-visit and post-visit questionnaires will be reviewed to ascertain if any changes occurred with regards to your vaccination concerns and your intent to vaccinate. You may choose not to answer a question contained in the questionnaires for any reason. However, in order to be considered a participant in the study, both the pre-visit and post-visit questionnaires need to be submitted.

What are the possible benefits from being in this study?

It is possible that there may be no benefit to you from your participation in this project. However, information gathered from this project might help healthcare providers come up with methods that better identify parental vaccine concerns and allow a discussion with a medical provider on those concerns.

What are the possible risks or discomforts involved from being in this study?

This project does not include any type of medical treatment; there is no foreseeable significant risk involved. However, there may be uncommon risks such as embarrassment, emotional distress, or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?

You will not be contacted about any new findings or information gleaned from the study.

How will information about you be protected?

You will be assigned a project number that will be used to identify your answers to a pre-visit and post-visit questionnaire. No names, social security numbers, date of birth, or place of residence will be collected. You will be asked to give your e-mail address in a post-visit online questionnaire for the sole purpose of sending you a Target e-gift card. However, providing your email is completely voluntary. Your email will not be associated with any of your questionnaire responses. Data collected will be secured on a password protected desktop. All data collected during the project will be destroyed upon completion of the project.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?

You will receive a 10.00 dollar Target e-gift card for participating in this project after you complete both the pre-visit questionnaire that you will bring with you to your child's well appointment (included in this project packet) and the online post-visit questionnaire (after your child's medical appointment). You will need to provide an email address in the online post-visit questionnaire if you wish to receive an electronic Target e-gift card. Instructions on completing the post-visit questionnaire will be provided to you at your child's well appointment.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

Who is sponsoring this study?

This research is being performed in the context of fulfilling the academic requirements of a doctoral program. The research is in part funded by Sigma Theta Tau, The National Honor Society of Nursing. This means that the research team is receiving money from a funding source to help defray study costs. The researchers do not have a direct financial interest with the funding source, or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Volunteering to be Part of this Research Project

Your participation in this project is entirely voluntary. Regardless of your choice to participate, you will be receiving the best treatment available and your decision will not lead to any penalties or loss of benefits. Completing the attached pre-visit questionnaire and bringing it with you to your child's medical appointment will be seen as consent to participate in this project. If you have any questions about this project **the principle investigator is available to discuss them with you by phone at 919-308-9340.**

APPENDIX B: INITIAL PRE-VISIT PATIENT QUESTIONNAIRE

IRB Reference/Protocol:_____

Participant Project Number (for participant identification):_____

Title of Project: Improving Communication about Vaccines

- This is a completely **voluntary questionnaire;** you do not have to participate if you do not want to. If you choose to participate **you may show how well we identify and address your vaccination concerns** by completing this pre-visit questionnaire now and then an online post visit questionnaire after you and your child are seen by the provider.

- You **must bring this questionnaire with you** to your child's well appointment for review by his/her provider.

Please Fill in the Boxes as Directed					
Age of Parent (in years):			Age of Child Being Seen Today (in years and months):		
Parent Sex (male or Female):			Number of Minor Children in the Household (less than 18yrs):		
Parent Race (Check the Appropriate Box)		Asian	Parent Education (Check the Appropriate Box)		High School
		Black not Hispanic			Some College
		White not Hispanic			College Degree
		Hispanic			Graduate School
		Other			

How much do you agree with each of the following statements on vaccinations? Please indicate your response with a check mark in the appropriate box below.					
	1 Strongly Disagree	2 Disagree	3 Neither Agree nor Disagree	4 Agree	5 Strongly Agree
Q1. Childhood vaccines are important for my child's health.					
Q2. Childhood vaccines are effective.					
Q3. Having my child vaccinated is important for the health of others in my community.					
Q4. All childhood vaccines currently recommended are beneficial.					

Q5. New vaccines carry more risks than older vaccines.					
Q6. The information I receive about vaccines from my provider is reliable and trustworthy.					
Q7. Getting vaccines is a good way to protect my child/children from disease.					
Q8. Generally I do what my doctor or health care provider recommends about vaccines for my child/children from disease.					
Q9. I am concerned about serious effects of vaccines.					
Q10. My child/children does or do not need vaccines for diseases that are not common anymore.					
Q11. I intend to have my child vaccinated as recommended by my provider.					
Do you have any specific vaccination concerns you would like to discuss with your child's provider today? Please write in your response using the space below.					

APPENDIX C: PROVIDER REFERENCE--EVIDENCE BASED TALKING POINTS PERTAINING TO VH

1. **Vaccine Hesitant Parent Profile**
   a) Definition of vaccine hesitancy (VH) by Dube et al. (2013): "A parental attitude towards vaccination that is associated with overall increased under-vaccination of children and influenced by emotional, cultural, social, spiritual, political… [and] cognitive factors" (p. 1764). At an individual level, an identified vaccine hesitant parent runs the continuum from full vaccine compliance to near complete vaccine refusal.
   b) Parents that intentionally delay childhood vaccines were found to more likely be Caucasian, college educated, and to live in a household above the federal poverty level (Smith et al., 2010; Wei et al., 2009).
   c) Parental concerns leading to VH can typically be divided into several categories that include: Provider trust, vaccine safety, vaccine efficacy, moral concerns, and the prevalence of vaccine preventable disease in the community.

2. **Alternative Vaccination Schedules**
   a) Studies show that at least 10% of parents follow an alternative vaccination schedule (Dempsey et al., 2011; Wheeler & Buttenheim, 2013).
      i) In studies specifically addressing parental use of alternative vaccination schedules, a lack of trust in the provider and in vaccines is a common theme. The underlying reasons for this lack of trust mirror those leading to VH.
   b) Delaying vaccination makes it less likely for an immunization series to be completed (Smith, Humiston, Parnell, Vannice, & Salmon, 2013).
   c) Children following a delayed schedule are more susceptible to VPD (Dempsey et al., 2011; Smith, Humiston, Parnel, Vannice, & Salmon, 2010).
   d) Dr. Robert Sears' alternative vaccination schedule (a more commonly used alternative schedule) increase the time that children are susceptible to VPD and depending on the schedule variation, may outright omit vaccinating against certain VPD (Offit & Moser, 2009).
      i) The reasoning behind Dr. Sears alternative schedule as put forth in his book titled "The Vaccine Book: Making the Right Decision for your Child" is based on incomplete, even false information as it is presented and at times offers faulty logic (Offit & Moser,2009).
         (1) Dr. Sears makes claims that the safety testing of vaccines is incomplete as compared to the testing of new medications, though vaccines are tested in tens of thousands of individuals over long periods of time; much longer than individual medications prior to receiving licensure (Offit & Moser,2009).
         (2) Dr. Sears reviews the vaccine adverse event reporting system (VAERS) reports and ascribes these reports as being representative of actual side effects from vaccines. He neglects to state that these reports may represent coincidental and not causal associations with particular vaccinations (Offit & Moser,2009).

3. Promoting Provider Trust

a) Trust is based on "the provider demonstration of interpersonal and technical competence, moral comportment and vigilance to support positive patient outcomes" (Murray & McCrone, 2014).

b) The most significant factor that influences trust is the interpersonal skills of the provider.
   i) Patient centered communication was found to be a predictor of trust (Murray & McCrone, 2014).

c) Medical providers are often cited as the most trusted source of information regarding vaccines (Wallace et al, 2014).

4. Vaccine Safety Concerns

a) Adverse effects to vaccine components (adjuvants and excipients)
   i) Aluminum Salts are present in vaccines as an adjuvant in minimal amounts and are in concentrations significantly below the amount of aluminum that is taken in through the actions of breast feeding, imbibing formula that is milk or soy based (Badger, Kubusek, & Hayney, 2009; Baylor, Egan, & Richman, 2002).
      (1) Aluminum salts have been present in vaccines for nearly 80 years (Gupta, Rost, Relyveld, & Siber, 1995; Offit & Jew, 2003).
      (2) Mild local reactions at the injection site have been reported to occur, which are consistent with delayed hypersensitivity reactions (Chung, 2014; Leventhanl, Berger, Brauer, & Cohen, 2012; Offit & Jew, 2003).
   ii) Thimerosal, a preservative that contains ethyl mercury is no longer used in the manufacture of vaccines (other than a minute amount in influenza vaccine multi-dose vials). There has been no identified a link between its use in vaccines (the MMR vaccine in particular) and an increased risk of developmental delays and autism spectrum disorder (Taylor, Swerdfeger, & Eslick, 2014; Parker, Schwartz, Todd, & Pickering, 2004; Price et al., 2010).
   iii) Formaldehyde is sometimes used to inactivate the pathogen during the vaccine manufacturing process. Minute amounts may be present (0.1mg or less) that are well below what is considered safe. An infant has approximately 1.1mg of formaldehyde circulating as a naturally occurring metabolic byproduct (Offit & Jew, 2003).
   iv) Gelatin is used as a stabilizer in numerous vaccines. It has been associated with rare incidences of urticaria and anaphylaxis (Leventhal, Berger, Brauer, & Cohen, 2012; Wood, 2013). Individuals should abstain from taking gelatin containing vaccines if they have a severe allergy (anaphylaxis) to gelatin (CDC-Pink Book, 2015).
      (1) Gelatin as a cause of immediate type hypersensitivity reactions in vaccines occurs at 1 case per 2 million people (Offit & Jew, 2003).

(2) Another study showed that up to 28% of subjects (0.05 per 100,000 doses) with an immediate type reaction after MMR inoculation had IgE to gelatin present (Patja, Kiljunen, Davidkin, Paunio, & Peltola, 2001).

v) Though rare, an allergy to latex has been implicated in causing hypersensitivity reactions in vaccines. A review of the literature by Chung (2014) revealed only one case of anaphylaxis after inoculation that was attributed to a severe latex allergy.
   (1) Providers should abstain from administration of vaccines from vials or syringes containing latex in patients with a known severe latex allergy (anaphylaxis). Patients with a history of contact dermatitis only, after exposure to latex may be vaccinated in the usual manner (CDC-Pink Book, 2015; Wood, 2013)

vi) Antibiotics are used during the manufacturing process of vaccines and include: neomycin, polymyxin B, chlortetracycline, amphotericin B, and streptomycin. Neomycin is the only antibiotic that is typically present in measureable quantities. Antibiotics most likely to cause an allergic reaction (penicillins, cephalosporins, sulfonamides) are not used in the manufacturing process (FDA, 2014; Offit & Jew, 2003).
   (1) Evidence shows that having a reaction to residual antibiotics in vaccines is exceedingly rare and that the reaction typically occurs in a patient that has a neomycin allergy (Leventhal, Berger, Brauer, & Cohen, 2012; Offit & Jew, 2003). A history of contact dermatitis (delayed hypersensitivity reaction) to neomycin is not a contraindication to receiving a vaccine that potentially contains neomycin (CDC-Pink Book, 2015).
   (2) Patients who experience anaphylaxis to specific antibiotics should avoid vaccines grown in a medium that contained that specific antibiotic (CDC-Pink Book, 2015; Chung, 2013).

vii) Egg protein
   (1) Egg protein is a residual component and is minimally present in influenza vaccines (up to1ug) (Kelso, 2015). Currently the CDC recommendations for administering influenza vaccine to children with a history of an egg allergy depend on the severity of the allergy. Individuals that have only experienced hives may receive the inactivated vaccine with some additional safety precautions. Those individuals with a history of life-threatening allergy to eggs may receive inactivated influenza vaccine if administered by a physician experienced in managing anaphylaxis (CDC-Seasonal Influenza, 2015).
      (a) Numerous studies have been performed investigating individuals with egg-allergies that received the influenza vaccination. No statistically significant differences between adverse reactions occurred when compared to the non-egg allergic (Chung, 2013; Des Roches, Paradis, & Gagnon, 2012).

(2) Measles and Mumps virus are grown in chick embryos; though vaccines containing Measles and Mumps have been shown to be safe to be given to children with egg allergies (CDC-The Pink Book, 2015).
(a) Studies have shown that the MMR vaccine can be given in children with an egg allergy (Andersen & Jorgensen, 2014; Fox & Lack, 2003; Patja, A., Kiljunen, S., Davidkin, I., Paunio, M., & Peltola, H., 2001).

b) Many parents express concerns about "overloading" their child's immune system with multiple vaccination injections or with the use of combination vaccines (Luthy, Beckstrand, Asay, & Hewett, 2013; Wallace et al., 2014).
i) No evidence of immunosuppression has been noted with the administration of multiple vaccinations at visits or with the use of combination vaccines (Offit, Davis, & Gust, 2008).
ii) Infants have a wide range of immune system responses to include Functional T-cell and B-cell responses (Chatterjee & O'Keefe, 2010).
iii) Researchers posit that the immune system could likely respond up to 100 billion different antigens (Offit et al., 2002).
iv) The parental fear of vaccine associated trauma has also been linked to parent resistance to multiple vaccination injections (Hulsey & Bland, 2015).

c) Seizures, nervous system disorders, and neurodevelopmental concerns.
i) DTP and DTAP vaccine.
(1) The risk of seizures from DTP (no longer used in the U.S.) was reported as 6-9 per 100,000 (Barlow et al., 2001)
(2) One study of DTaP did not reveal any increased incidence of seizures after inoculation (Huang et al., 2010). The CDC-Possible Side Effects (2015) reports that the absolute risk of a seizure is approximately 1 per 14,000.
(3) Initial onset of symptoms of Encephalitis within 3 days of DTP inoculation was reported as 0.78 per million. DTaP was reported as 0.095 per million (Geier & Geier, 2004).
ii) The MMR vaccine.
(1) The MMR vaccine has continued to be seen as a causative factor for autism spectrum disorder by parents (either the MMR vaccine itself or the preservative thimerosal), though no evidence exists to support this assertion despite multiple meta-analyses (with sample sizes >1 million) and case control studies (See section 4, subsection ii above).
(2) Incidences of encephalitis/encephalopathy that has been potentially attributed to the Measles strain in the MMR vaccine has been estimated as 1 in 3 million (FDA, 2010). The CDC-MMWR (2013) states that 3 published reports show measles body inclusion encephalitis after vaccination, though this occurred in persons with concomitant immune system disorders.

(a) The incidence of encephalitis for individuals contracting wild-type measles is 1 in 1,000 (CDC-Measles Complications, 2015)

(3) There is a noted small risk for febrile seizures that is associated with the MMR and MMRV vaccine up to 14 days after innoculation. Relative risk was noted to be 2 times greater in individuals receiving the MMRV vaccine than those not receiving the vaccine (Ma, Xiong, Jiang, & Chen, 2015). The absolute risk of febrile seizures to individuals receiving the quadrivalent MMRV vaccine was approx 9 per 10,000 doses as compared to 4 per 10,000 doses with MMR and Varicella. An additional seizure was noted to occur for every 3,000 to 4,000 individuals whom received the MMR vaccine as compared to those that did not receive the vaccine (FDA, 2010).

iii) The Influenza vaccine.

(1) The influenza vaccine given during from 1976 to 1977 was associated with an increased risk of Guillain-Barre´ syndrome (GBS) at 0.04 per 100,000 to 1 per 100,000 (Fiore, Bridges, & Cox, 2009; Haber, Sejvar, Mikaeloff, & DeStefano, 2009). Currently the risk of GBS has been approximated at 0 to 0.025 per 100,000 from a study in Korea (Choe, Cho, Kim, Bae, & Lee, 2011).

(2) Febrile seizures occurring after being inoculated with the influenza vaccine was recently shown to be 3.3 cases per 1000 individuals whom received the vaccine (Principi & Esposito, 2013).

5. Vaccine Efficacy

a) Decreasing parental belief in vaccine efficacy has been associated with concerns about the necessity of vaccines and an increased intention to use an alternative immunization schedule (Wheeler & Buttenheim, 2013). A study by Healy, Montesinos, and Middleman (2013) reported that 16% of parents reported that vaccines prevented illness only some of the time or that it was dependent on the type of disease and vaccine.

b) The fact that vaccines are not 100% effective in preventing disease has likely decreased parent confidence in the necessity of vaccines (Cooper, Larson, & Katz, 2008).

i) An example of limitations in vaccine effectiveness contributing to parents minimalizing their importance can be seen with the reported limitations of the seasonal flu vaccine (Imperato, 2005).

c) Discussing vaccine efficacy (does the vaccine work) with parents may not be as beneficial as discussing vaccine effectiveness in helping prevent the disease without undue risk (LaVail & Kennedy, 2012). Use of graphic narratives or simply providing more information typically does not work or is counterproductive (Nyhan, Reifler, Richey, & Freed, 2014).

6. Moral Concerns

a) Parental moral concerns pertaining to vaccines derived from diploid cell lines that originated from aborted fetuses can lead to parents not fully vaccinating their children (Chatterjee & O'Keefe, 2010).
   i) Typically this concern is fueled by religious objections to abortion. The Catholic Church has issued several position papers examining the issue of utilizing vaccines where the vaccine strains are grown from cell lines originating from aborted fetuses.
      (1) Pruss (2006) notes that currently there are no alternatives to vaccines produced in this manner and that there is no option other than to utilize the vaccine to protect children and the community for numerous vaccine preventable diseases.
      (2) Furton (1999) states that it would be an untenable standard if individuals were to require all benefits received in the present to be completely free from past immorality.

b) Several vaccines utilize products initially derived from animals such as pork gelatin that may pose concerns to members of the Jewish or Muslim faith.
   i) Both Jewish and Muslim leaders agree that the receipt of vaccines containing pork derived gelatin is allowable (Grabenstein, 2013; Institute for Vaccine Safety, 2003).

7. Prevalence of Vaccine Preventable Disease in the Community

a) Smith et al. (2010) found that parents who delayed or abstained vaccinating their child were significantly more likely to believe that their child was not at risk of the disease.

b) Increasing exemption rates to vaccines can lead to geographic clustering of VPD susceptible populations and increase the risk of losing the benefit of herd immunity (Fefferman & Naumova, 2015).
   i) The nonmedical-exemption rate in counties in Washington State was reported to range from 1.2 to 26.9% (Omer, Salmon, Orenstein, DeHart, & Halsey, 2009).
   ii) Orange County, NC has the 8th lowest vaccination rate in the state (out of 100 counties).
      (1) In 2013 an outbreak of measles occurred in Orange and Stokes Counties, NC with a total of 23 cases identified and approximately 1,000 persons that were exposed (CDC, 2013).
      (2) It was noted that one school in Orange County (Emerson Waldorf) only had 62.2% of students fully vaccinated for the 2015 school year (Orange County Department of Health, 2015).

8. Communication with vaccine hesitant parents

a) Provider education is seen as necessary to influence a parents' decision to vaccinate his/her child and has been listed as a key influence in effectively overcoming concerns that lead to VH (Gust, Darling, Kennedy, & Schwartz, 2008; Kennedy, LaVail, Nowak, Basket, & Landry, 2011; Wallace et al., 2014)

b) Kaufman et al. (2013) reported there is insufficient evidence to recommend any particular face to face intervention other than to incorporate communication about vaccination effectiveness during a clinical encounter. Brunson (2013) concluded that a singular approach/intervention to vaccine hesitant parents is inappropriate and that interventions should be tailored to parents' specific concerns regarding vaccination.
    i) Individually tailored education on MMR vaccine-hesitant parents was shown to have increased the proportion of parents that had a greater intent to vaccinate as compared to the group receiving untailored education (Gowda, Schaffer, Kopec, Markel, & Dempsey, 2013).
c) The CDC (2012) with support from the American Academy of Pediatrics (AAP) (2009) recommends a participatory/collaborative discussion format in discussing vaccine concerns with parents in order to achieve better vaccination compliance.
    i) Participatory discussions (face-to-face interventions) with hesitant parents have been found to assist in the understanding of the benefits of vaccinations, which would likely increase childhood vaccination rates in families that are hesitant (Domachowske & Suryadevra, 2013).
    ii) When taking the other themes of discussion format and the level of customized counseling into consideration, trust can be gained by a provider through being communicative, receptive to concerns, and centering the discussion onto the patient (Murray & McCrone, 2015).

APPENDIX D: PROVIDER QUICK REFERENCE HANDOUT

- Both Jewish and Muslim leaders agree that the receipt of vaccines containing pork derived gelatin is allowable [28,29].

Vaccines may overload infant/child immune systems

- No evidence of immunosuppression noted [30]. Infants have a wide range of immune system responses to include Functional T-cell and B-cell responses [25].
- The immune system could likely respond up to 100 billion different antigens [31].

Belief that certain ingredients are harmful

- Aluminum Salts are present in vaccines as an adjuvant in minimal amounts. This is below the amount of aluminum taken in by breast feeding and imbibing milk or soy based formula [32,33].
  - Aluminum salts have been present in vaccines for nearly 80 years [34,35].
  - Mild local reactions at the injection site have been reported to occur [35,36,37].
- Thimerosal, a preservative that contains ethyl mercury is no longer used in the manufacture of vaccines (other than a small amount in influenza vaccine multi-dose vials). There has been no identified link between its use in vaccines (the MMR vaccine in particular) and an increased risk of developmental delays or autism spectrum disorder [11,12,13].
- Formaldehyde is sometimes used to inactivate the pathogen during the vaccine manufacturing process. Minute amounts may be present (0.1mg or less) that are well below what is considered safe.
  - An infant has approximately 1.1mg of formaldehyde circulating as a naturally occurring metabolic byproduct [35].
- Gelatin is used as a stabilizer in numerous vaccines. It has been associated with rare incidences of urticaria and anaphylaxis [37,38]. Individuals should abstain from taking gelatin containing vaccines if they have a severe allergy (anaphylaxis) to gelatin [39].
  - Gelatin as a cause of immediate type hypersensitivity reactions in vaccines occurs in 1 case per 2 million people [35].
- Though rare, an allergy to latex has been implicated in causing hypersensitivity reactions. A review of the literature revealed only one case of anaphylaxis after inoculation was due to a severe latex allergy [36].
  - Providers should abstain from administrating vaccines from vials or syringes containing latex in patients with a known severe latex allergy (anaphylaxis). Patients with a history of contact dermatitis only (after latex exposure) may be vaccinated in the usual manner [38,39].
- Antibiotics used in the manufacturing process of vaccines include: neomycin, polymyxin B, chlortetracycline, amphotericin B, and streptomycin.
- Neomycin is the only antibiotic that is typically present in measureable quantities [35,40].
  - A reaction to residual antibiotics in vaccines is rare and the reaction typically occurs in a patient that has a neomycin allergy [35,37].
    - A history of contact dermatitis to neomycin is not a contraindication to receiving a vaccine that potentially contains neomycin [39].
    - Patients who experience anaphylaxis to specific antibiotics should avoid vaccines grown in a medium that contained that specific antibiotic [36,39].
- Egg protein is a residual component and is minimally present in influenza vaccines (up to1ug) [41]. Currently the CDC recommendations for administering influenza vaccine to children with a history of an egg allergy depend on the severity of the allergy [42].

John Connors
DNP Student

School of Nursing
The University of North Carolina
at Chapel Hill
Chapel Hill, NC 27599-7460

Evidence-Based Talking Points Pertaining to Reported Reasons for Vaccine Hesitancy

Answers to Common Concerns about Vaccines

UNC SCHOOL OF NURSING

Evidence Based Talking Points Pertaining to Reported Reasons for Vaccine Hesitancy

Beliefs

Belief that preventable diseases no longer exist or vaccines are not efficacious

- Increasing exemption rates to vaccines can lead to geographic clustering of vaccine preventable disease (VPD) susceptible populations [1].
- The nonmedical-exemption rate in counties in Washington State in 2007 was reported to range from 1.2 to 26.9% [2].
  - Total number of cases of pertussis reported in Washington state for 2015 was 1,303 with over 300 cases reported in a single county [3]
- Orange County, NC has the 8th lowest vaccination rate in the state (out of 100 counties) [4].
  - 2013, an outbreak of measles occurred in Orange and Stokes Counties [5].
  - 2015, one school in Orange County (Emerson Waldorf) only had 62.2% of students fully vaccinated [6].
  - Several cases of whooping cough were identified in Hillsborough, NC in 2015 [7].
- The fact that vaccines are not 100% effective in preventing VPD has likely decreased parent confidence in the necessity of vaccines [8, 9].
- Discussing vaccine effectiveness in preventing disease without undue risk may be more beneficial than discussing vaccine effectiveness alone[10].

Belief that using an alternative vaccination schedule is better for the child

- Up to 10% of parents follow an alternative vaccination schedule primarily due to a lack of trust in the provider and the vaccine(s)[44, 45, 47].
- Delaying vaccination makes it less likely for an immunization series to be completed[46]. Children following a delayed schedule are more susceptible to VPD[44, 46].
- Alternative vaccination schedules put forth by Dr Robert Sears increase the time that children are susceptible to VPD or outright omit vaccinating against certain VPD[47].
  - Claims that safety testing of vaccines is incomplete as compared to the testing of new medications and that vaccine adverse event report system (VAERS) reports are fully representative of actual side effects from vaccines are misleading[47].

Doubts

Doubt about the safety profile of vaccines

- The MMR vaccine seen as a causative factor for autism spectrum disorder (either the MMR vaccine itself or the preservative thimerosal). No evidence supports this assertion despite multiple meta-analyses (with sample sizes >1 million) and case control studies [11,12,13].
- Encephalitis/encephalopathy potentially attributed to the measles strain in the MMR vaccine has been estimated as 1 in 3 million [48].
  - Only three published case-reports show measles body inclusion encephalitis after vaccination [48].
  - Alternatively, the incidence of encephalitis for individuals contracting wild-type measles is 1 in 1,000 [15].
- MMR and MMRV vaccines are associated with a small risk of febrile seizures up to 14 days after inoculation [16].
  - The absolute risk of febrile seizures to individuals receiving the quadrivalent MMRV vaccine was approx 9 per 10,000 doses as compared to 4 per 10,000 doses with MMR and varicella [14].
- Influenza vaccine given from 1976 to 1977 was associated with an increased risk of Guillain-Barre' syndrome (GBS) at 0.04 per 100,000 to 1 per 100,000 [17,18]. Currently the risk of GBS has been approximated at 0 to 0.025 per 100,000 from a study in Korea [19].
- Febrile seizures occurring after inoculation with influenza vaccine recently shown to be 3.3 cases per 1000 individuals who received vaccine [20].
- One study of DTaP did not reveal increased incidence of seizures after inoculation [22]. Absolute risk of a seizure is reported to be approximately 1 per 14,000 by the CDC [23].
- Initial onset of symptoms of encephalitis within three days DTaP inoculation was reported as 0.095 per million [24].

Concerns

Moral concerns about vaccines

- Parental moral concerns pertaining to vaccines derived from diploid cell lines originating from aborted fetuses [25].
  - Currently, there are no alternatives to these vaccines[26].
  - The Catholic Church states one is morally free to use vaccines regardless of the historical association with abortion [27].
- Several vaccines utilize products initially derived from animals such as pork gelatin.

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APPENDIX E: PROVIDER PROJECT EVALUATION

By being a participating provider in this project:

1. Has your overall knowledge about vaccine hesitancy (identifying and categorizing the level and type) increased? Please explain.

2. Has your knowledge about common reasons for parental vaccine hesitancy increased? If so, how?

3. Do you feel more confident in addressing parental concerns about vaccines? Please explain.

4. Do you feel that you were able to use the information presented to you (prior to the project commencing) in your clinical practice? If so, how?

5. Were the reference materials given to you by the principle investigator helpful in alleviating parental concerns about vaccination? If no, why not?

6. Do you believe that your clinical practice has been more efficient in addressing individual parental concerns about vaccination? Please explain.

7. Do you have any recommendations or comments about this project that you would like share with the principle investigator?

APPENDIX F: QUALTRICS POST-VISIT QUESTIONNAIRE

Please enter your participant study identification number. It is listed on the note-card given to you at your child's recent well visit.

Have you completed this online questionnaire previously?

- ❍ Yes (1)
- ❍ No (2)

Please answer all of the following questions.

Childhood vaccines are important for my child's health.

- ❍ Strongly Disagree (5)
- ❍ Disagree (4)
- ❍ Neither Agree nor Disagree (3)
- ❍ Agree (2)
- ❍ Strongly Agree (1)

Childhood vaccines are effective.

- ❍ Strongly Disagree (5)
- ❍ Disagree (4)
- ❍ Neither Agree nor Disagree (3)
- ❍ Agree (2)
- ❍ Strongly Agree (1)

Having my child vaccinated is important for the health of others in my community.

- ❍ Strongly Disagree (5)
- ❍ Disagree (4)
- ❍ Neither Agree nor Disagree (3)
- ❍ Agree (2)
- ❍ Strongly Agree (1)

All childhood vaccines currently recommended are beneficial.

- ❍ Strongly Disagree (5)
- ❍ Disagree (4)
- ❍ Neither Agree nor Disagree (3)
- ❍ Agree (2)
- ❍ Strongly Agree (1)

New vaccines carry more risks than older vaccines.

- ❍ Strongly Disagree (1)
- ❍ Disagree (2)
- ❍ Neither Agree nor Disagree (3)
- ❍ Agree (4)
- ❍ Strongly Agree (5)

The information I receive about vaccines from my provider is reliable and trustworthy.

- ❍ Strongly Disagree (5)
- ❍ Disagree (4)
- ❍ Neither Agree nor Disagree (3)
- ❍ Agree (2)
- ❍ Strongly Agree (1)

Getting vaccines is a good way to protect my child/children from disease.

- ❍ Strongly Disagree (5)
- ❍ Disagree (4)
- ❍ Neither Agree nor Disagree (3)
- ❍ Agree (2)
- ❍ Strongly Agree (1)

Generally I do what my doctor or health care provider recommends about vaccines for my child/children from disease.

- ❍ Strongly Disagree (5)
- ❍ Disagree (4)
- ❍ Neither Agree nor Disagree (3)
- ❍ Agree (2)
- ❍ Strongly Agree (1)

I am concerned about serious effects of vaccines.

- ❍ Strongly Disagree (1)
- ❍ Disagree (2)
- ❍ Neither Agree nor Disagree (3)
- ❍ Agree (4)
- ❍ Strongly Agree (5)

My child/children does or do not need vaccines for diseases that are not common anymore.

- ❍ Strongly Disagree (1)
- ❍ Disagree (2)
- ❍ Neither Agree nor Disagree (3)
- ❍ Agree (4)
- ❍ Strongly Agree (5)

I intend to have my child vaccinated as recommended by my provider.

- ❍ Strongly Disagree (5)
- ❍ Disagree (4)
- ❍ Neither Agree nor Disagree (3)
- ❍ Agree (2)
- ❍ Strongly Agree (1)

My provider answered my questions pertaining to my child's vaccinations

- ❍ Strongly Disagree
- ❍ Disagree
- ❍ Neither Agree nor Disagree
- ❍ Agree
- ❍ Strongly Agree

My provider was respectful of my concerns regarding vaccination.

- ❍ Strongly Disagree
- ❍ Disagree
- ❍ Neither Agree nor Disagree
- ❍ Agree
- ❍ Strongly Agree

My child's provider has his/her best interests at heart.

- ❍ Strongly Disagree
- ❍ Disagree
- ❍ Neither Agree nor Disagree
- ❍ Agree
- ❍ Strongly Agree

I was able to participate in the discussion with my child's provider about my vaccination concerns.

- ❍ Strongly Disagree
- ❍ Disagree
- ❍ Neither Agree nor Disagree
- ❍ Agree
- ❍ Strongly Agree

Do you have any specific concerns about your child's vaccinations that were not addressed in your visit with your child's healthcare provider? Please write in your response (if any) using the space below (there is a limit of 400 characters).

Do you wish to receive a $10.00 Target e-gift card? Please note that if you choose yes you will be asked for your email address.

- ❍ Yes (1)
- ❍ No (2)

Please enter a valid email address below.

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