Spring 5-9-2018

Identifying vaccine-hesitant caregivers of children age 0-5 years using the Parent Attitudes about Childhood Vaccines (PACV) Survey

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Abstract

Title: Identifying vaccine-hesitant caregivers of children age 0-5 years using the Parent Attitudes about Childhood Vaccines (PACV) Survey

Purpose: Vaccine hesitancy is the refusal, delay, or modification of the recommended vaccine schedule. This project aimed to identify and explore caregiver vaccine hesitancy of parents with children age 0-5 years.

Methods: The Parent Attitudes about Childhood Vaccines (PACV) survey was used to identify vaccine-hesitant caregivers of children age 0-5 years. Once identified a brief educational session was conducted one-one with the investigator, this session included verbal as well as written educational intervention. The survey was repeated via telephone within 4-6 weeks.

Results: Seventy-five caregivers participated in the study, 11 of which were identified as vaccine-hesitant. Among respondents, 58% were white/Caucasian, and 27% were black/African American. Upon completion of a brief educational session using vaccine teaching tools, four caregivers remained vaccine-hesitant. The rate of vaccine hesitancy within the study population was approximately 15%, with little variation between levels of hesitancy when comparing mothers and fathers. There was a statistically significant correlation between vaccine hesitancy and race.

Conclusions: Open dialogue coupled with educational handouts from the Centers for Disease Control and Prevention (CDC) can be effective in reducing the level of hesitancy as measured by the PACV survey.

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Background and Significance

As a part of standard practice, pediatric advanced practice nurses routinely have conversations about vaccination. In pediatric primary care offices, caregivers bring their children in for well-child exams routinely. With these visits, however, pediatric providers across the country are alarmed with the frequency they encounter an alarming trend. Although the child is fully vaccinated, the caregivers inform the provider that they no longer want to expose their child to vaccines. This scenario is an example of the phenomenon called vaccine hesitancy (Leask, Willaby, & Kaufman, 2014). Defined by Larson and colleagues (2015) vaccine hesitancy is the refusal, delay, or modification of the recommended vaccine schedule. The prevalence of vaccine hesitancy can affect global vaccination rates and increase the incidence of communicable diseases (Barrows, Coddington, Richards & Aaltonen, 2015; P.J. Smith, Humiston, Parnell, Vannice, & Salmon, 2010; Centers for Disease Control and Prevention[CDC], 2016).

Vaccine hesitancy is encountered most often in pediatric primary care as the primary series for vaccination is completed between the ages of 0-5 years (CDC, 2016). Caregiver vaccine hesitancy presents in multiple forms, with the most common being delaying vaccination through modification of the vaccine schedule (Williams, 2014). Pediatric healthcare providers have a responsibility to provide quality, evidence-based care. Part of this care includes therapeutic communication with caregivers. Therapeutic communication should include listening to caregivers and having a mutually respectful dialogue (Witteman, 2015). When caregivers learn about vaccination risks and benefits from their trusted providers, there should also be an opportunity for shared decision making as recommended (Witteman, 2015).

Caregivers value the opinion of their child's provider and when allowed to have their own opinions heard the caregiver would feel empowered and increase trust in the provider (D. J. Opel, Heritage, et al., 2013). The opportunity to promote vaccination could decrease hesitancy if providers remain neutral and empathetic toward caregiver concerns (D. J. Opel, Heritage, et al., 2013). Studies have shown compassionate, open communication with providers is necessary to combat vaccine hesitancy (Kennedy, LaVail, Nowak, Basket, & Landry, 2011; Leask et al., 2014).

Problem Statement

Vaccination has been a mainstay of pediatric primary preventative care for years. Vaccination has led to the decreased prevalence of vaccine-preventable diseases such as measles, pertussis, varicella, and influenza (Siddiqui, Salmon, & Omer, 2013). Recent controversy has emerged surrounding vaccination including an unfounded causal link to autism (Kennedy et al., 2011). Other controversial topics of concern regarding vaccination in children are the number of immunizations administered per visit within the first year of life, as well as the safety of vaccine components (Kennedy et al., 2011).

While anecdotal evidence suggests that more caregivers are declining vaccines for their children, the exact occurrence of this phenomenon is unknown. In addition, there is a lack of evidence to explain caregiver rationales behind caregiver vaccine hesitancy of parents of children age 0-5 years and effective educational interventions that can be implemented to decrease vaccine hesitancy in primary practice.

PICOT Question

Will a brief educational intervention decrease vaccine hesitancy among caregivers of children aged 0-5 years, who are identified as vaccine-hesitant, as measured by the Parent Attitudes about Childhood Vaccines (PACV) survey?

Synthesis of Evidence

Search Strategy

A literature review was conducted using the keywords: vaccine hesitancy, vaccine refusal, parent, caregiver, and childhood vaccine hesitancy. The databases utilized were: Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, MEDLINE PLUS, Translating Research into Practice (TRIP) and Cochrane Library. A total of 88 studies met the initial search criteria. Studies that did not address vaccination within the pediatric population, nor addressed an intervention to combat vaccine hesitancy were excluded. A total of thirteen articles were used after further review and in-depth study. A second search was conducted recently and yielded, 65 articles, however many were duplicates from the initial search, and only five additional studies met criteria. Studies were also excluded if they referred to a specific, individual vaccine or the age of the patients was greater than five years. A total of 18 studies were appraised. Of the 18 articles, there was one prospective study, two systematic reviews of the literature, two randomized control trials, one meta-analysis with the remaining consisting of basic reviews of the literature.

Appraisal of the evidence was conducted using Grading of Recommendations Assessment and Evaluation (GRADE); a strategic approach to analyzing research literature for the quality of methods and strength of recommendations (Guyatt et al., 2008). According to the GRADE system if further research will not change the estimated effect of an intervention the

study is high quality (Guyatt et al., 2008). Studies of moderate quality indicate further studies are likely to have an effect and there is confidence in the intervention (Guyatt et al., 2008). Whereas, low and very low-quality research findings indicate that the confidence level is low and a definite change in the estimate of effect would occur with future research (Guyatt et al., 2008).

In a systematic review of the literature, Dube, Gagnon, and MacDonald (2015) explored what data currently exists regarding addressing vaccine hesitancy. Of the thirteen articles reviewed, only two articles had clear strategies to address vaccine hesitancy (Dube et al., 2015). Dube and colleagues concluded that there was not substantial evidence to recommend an intervention (2015). However, they did feel that mixed-method intervention, combining written, verbal or media instruction as an intervention, would be best for future studies (Dube et al., 2015).

In their systematic review, Jarrett, Wilson, O'Leary, and Eckersberger (2015) found few studies have been assessed for effects on vaccine uptake or change in attitude towards vaccination after the proposed intervention. The interventions discussed in their review included raising awareness and imparting knowledge regarding vaccination while addressing inadequate information obtained from social media or peers (Jarrett et al., 2015). The most effective intervention utilized education and was associated with a 25% increase in vaccine uptake and decreased hesitancy resulting in a change in attitude (Jarrett et al., 2015). The least effective interventions were passive interventions (such as posters) and quality improvement initiatives at the clinical site. Such interventions were only associated with a 10% increased uptake in vaccination (Jarrett et al., 2015).

Sadaf, Glanz, Salmon, and Omer (2013) meta-analysis found that there are no high-quality studies addressing vaccine hesitancy or evidence on strategies to reduce parental vaccine

hesitancy. Of the studies included in their review, there were seventeen studies which evaluated the impact of an educational intervention on parent's decision to vaccinate, of which five studies had statistically significant results (Sadaf et al., 2013). The educational interventions included an educational pamphlet, one PowerPoint video, and a multi-component study where the interventions consisted of providing balanced information to parents, a group meeting and coaching intervention (Sadaf et al., 2013). Sadaf et al. (2013) did, however, recommend that more randomized control trials be implemented and include assessment of the intervention's impact on vaccine uptake as well as parental attitude toward vaccination.

An educational literature review by M. J. Smith and Marshall (2010) provided background information on parental fears of autism as it relates to vaccination, including a timeline. M. J. Smith and Marshall (2010) briefly discuss the requirements needed for vaccines to become licensed for use as well as provide informative statistics concerning the increase in communicable disease which result from vaccine hesitancy. An example found in their article on Table 1., rates of measles increased significantly worldwide after the now redacted article published by Dr. Wakefield suggesting a link between the Measles, Mumps, and Rubella (MMR) vaccine and autism (M. J. Smith & Marshall, 2010). M. J. Smith and Marshall (2010) recommended high-quality studies be done using interventions focused on communicating with parents and providing evidence-based written information. Lastly, they emphasized the need for a trusting provider-parent relationship to facilitate vaccine discussions (M. J. Smith & Marshall, 2010).

The 2010 Health Styles Survey, utilized by Kennedy and colleagues (2011), found many parents have concerns or questions regarding vaccines. The sample consisted of 376 participant families who had children aged six years or younger (Kennedy et al., 2011). Only 23% of the

sample reported having no concerns regarding vaccination for their children (Kennedy et al., 2011). Parents were found to seek out vaccine information, 60% of respondents reported that they often look for information regarding vaccines (Kennedy et al., 2011). Parents sometimes used the internet to explore vaccine concerns and misperceptions, and social media sites were visited most (Kennedy et al., 2011). However, most parents (85%) listen to healthcare providers, while 46% of respondents cited other people, such as friends, family, and other parents, to help gather information that will shape their vaccine decisions (Kennedy et al., 2011).

P.J. Smith and colleagues (2010) studied the association between parents intentionally delaying the administration of recommended vaccinations and coverage for the affected children. The study revealed that approximately 22% of parents intentionally delayed vaccination. Of the 22% of parents, the reasons for delayed vaccination included, safety and efficacy concerns, as well as the child being ill at the time the vaccine was offered (P. J. Smith, Humiston, Parnell, Vannice, & Salmon, 2010). Parents most likely to delay vaccination of children age 0-6 years were non-Hispanic white, completed some college, and had an income level above the federal poverty level (P. J. Smith et al., 2010). When parents delayed administration of the recommended vaccines between the ages of 0-19 months, the children were less likely to be completely vaccinated (P. J. Smith et al., 2010).

Emerging work exploring legislation and the enforcement of childhood vaccines was identified. Parasidis & Opel (2017) discussed court cases where vaccine refusal was argued as medical neglect. They are exploring whether this could become an option to combat parental vaccine hesitancy (Parasidis & Opel, 2017). This study is currently ongoing. Many states have legislation upholding parental right to exempt their child from receiving vaccinations for either religious or personal beliefs (Parasidis & Opel, 2017). However, the American Academy of

Pediatrics (AAP) is not in support of applying medical neglect laws for vaccine refusal (Parasidis & Opel, 2017).

The Parent Attitudes about Childhood Vaccines (PACV) survey was used in a recent study by Zangger Eby (2017). In the study, voice-over PowerPoint was used as a teaching tool for parents identified as vaccine-hesitant after taking the survey (Zangger Eby, 2017). The PACV survey was found to be able to identify parents with vaccination concerns correctly. The survey was also used to identify that after the intervention, trust in the provider remained (Zangger Eby, 2017). However, Zangger Eby concluded that parents continued to have concerns about vaccine safety despite trusting their child's provider as a source of vaccine information (2017). This study does help further validate the PACV survey as a tool for use in the identification of vaccine-hesitant parents.

The overall GRADE criteria for all the articles reviewed is moderate. It was found that the need for more literature and research regarding interventions to combat vaccine hesitancy remains (Atwell & Salmon, 2014; Kennedy et al., 2011; Leask et al., 2012). There was a strong recommendation to continue working to develop interventions to assist providers in communications regarding vaccination (Bloom, Marcuse, & Mnookin, 2014). Evidence-based interventions will need to be tested. Williams et al. (2013) had one small-scale study as an initial effort which will need to be replicated on a larger, more robust sample. Understanding what parental factors contribute to vaccine hesitancy is required. Exploration of this has also been addressed on a small scale in the literature (Larson et al., 2015).

Conceptual framework and theory

Nursing theory and framework

The nursing theory used to guide this DNP project is Orem's Theory of Self-Care Deficit. Orem's Self-Care Deficit Theory has four components, two of which are for the patient and the remaining two are for the nurse (Taylor & Renpenning, 2011). Patient variables include self-care/dependent-care agency, therapeutic self-care/dependent-care demand (Taylor & Renpenning, 2011). The nursing component is the nursing agency, and there is an interaction between the nurse and the patient variables (Taylor & Renpenning, 2011). Orem's Self-Care Deficit Theory defines agency as the ability to do something that will move toward a goal (Taylor & Renpenning, 2011). Taylor and Renpenning (2011) give a summation of the Self-care deficit theory stating, "….is a theory about variables of concern when the service of nursing is required as nurses and patients interact, and about the variations in relationships among those variables" (p. 9). Exploring caregiver beliefs regarding vaccination will require interaction between caregivers and the Advanced Practice Registered Nurse (APRN). The role the student investigator takes concerning the project focuses on the supportive-educative aspect of Orem's theory (McCaffrey, 2012). Educating caregivers will allow them to have an active role in the care of their children. Empowering caregivers by involving them in the decision-making process is how providers can support and guide their decision to vaccinate. Smith and Marshall (2010) found that communication style, as well as content, should be considered when having the vaccine conversation with parents. Providers should be willing to balance the information they give to caregivers while addressing their vaccine concerns (Glanz, Kraus, & Daley, 2015). Effective communications, guided by Orem's theory, will enhance caregiver-provider relationships (Glanz et al., 2015).

Children are under the care of their parents, often unable to make decisions for themselves regarding their care. The Self-Care Deficit theory can be utilized when the patient is

not the decision maker (Taylor & Renpenning, 2011). The dependent-care system is considered equivalent to the individual unit because the care is provided to the dependent (Taylor & Renpenning, 2011). In the multi-person dependent-care system the goal of maintaining the best interest of the dependent is critical (Taylor & Renpenning, 2011).

Methodology

A quasi-experimental design with pretest-posttest was used to collect information about vaccine hesitancy among caregivers who utilized a single pediatric primary care facility in the southeast United States.

Setting

The project was implemented in a private pediatric practice. Primary demographics for this area include a population size of approximately 30,000 people, 29.8% of whom are age 18 years or older and have graduated high school (U.S. Department of Commerce, 2017). Households in the surrounding community have approximately three people residing in them (U.S. Department of Commerce, 2017). The primary care clinic serves the pediatric patient population between the ages of 0-18 years. On average the practice can see anywhere from 28-32 patients depending upon whether they schedule well-child or sick appointments. The facility has 16 exam rooms, 12 of which are utilized for patient care. The exam rooms are equipped with exam tables and chairs for caregivers and the provider. Five primary care providers are working at this location, three pediatricians, and two advanced practice nurses. Each provider has one medical assistant assigned to work with them daily. There are two receptionists, one billing/coding specialist, one referral coordinator and one practice administrator. The practice

has two locations; the study was conducted at only one location. The practice accepts patients with private insurance, Medicaid, and some of their subsidiary policies.

Recruitment

Providers and clinic staff directed caregivers interested in participating in the study to the student investigator. Caregivers then received an invitation to participate from the student investigator. Recruitment posters were also strategically placed in the office. Inquiries were directed to the student investigator.

Subjects

Participants were deemed eligible if they met the following inclusion criteria: caregivers must have a child between the ages 0-5 years, and the child must be a patient of the practice. Eligible participants completed informed consent. If requested, the student investigator read the consent form aloud with the caregivers.

Measure and Intervention Implementation

Participants were administered the Parent Attitudes about Childhood Vaccines (PACV) survey (D. J. Opel, Taylor, et al., 2013). Caregivers completed the PACV survey with paper and pencil/pen. Participant selection was at random. The survey and consent forms were stored separately in a locked cabinet off-site. Surveys were given a code with the letters “VH” followed by a number, and a random number generator was used to select the numbers. Data was stored on a password-protected laptop.

The PACV survey was developed to measure parental attitudes and beliefs about vaccination (D. J. Opel, Taylor, et al., 2013). The PACV survey was validated through a prospective cohort study conducted by Opel, Taylor, et al. and found to be reliable with an α

0.74-0.84 per question domain (2013). The PACV survey contains 22-items; 17 items with three response formats: dichotomous (yes/no), 5-pt Likert and 11-pt scale, and the remaining 5 were demographic questions (Douglas J. Opel et al., 2011). Scores could range from 0-30. A total score of 15 or more was indicative of vaccine hesitancy, and those participants were subsequently identified as vaccine-hesitant.

Vaccine-hesitant participants received a brief face-to-face educational intervention which included a handout from the Centers for Disease Control and Prevention (CDC) on vaccines, see Appendix D, and engaged in open dialogue with the student investigator. The teaching sheets guided the discussion of vaccine safety and the common adverse reactions to routine vaccinations. Handouts of the materials discussed were given, as well as websites that caregivers could review on their own. Time was allotted for questions. Vaccinations were not administered as part of this study. All vaccine-hesitant participants were the administered the PACV survey twice. The follow-up survey was conducted via telephone. Caregivers were compensated for their time with a $10 gift card to Chic fil a restaurant, after completion of the initial survey.

The educational intervention addressed any knowledge deficit identified. Utilization of the supportive-educative aspects of Orem's theory of Self-Care deficit was realized during this time (McCaffrey, 2012). The aim is that caregivers will have a decrease in their level of hesitancy after the dialogue with the student investigator.

Results

Statistical analysis of the data was performed using the Statistical Package for Social Science (SPSS), version 25. Information was first placed into a Microsoft Excel spreadsheet and then uploaded into SPSS. The individuals involved in the analysis of the data include the

principal investigators Dr. Lisa Cranwell-Bruce and Dr. Sandra Leonard, as well as expert statistical consultation from Dr. Kimberly Hires.

Cronbach's alpha was performed and scored 0.78 indicating the PACV survey performed well and had good internal reliability and consistency. The PACV survey has been previously validated by eliminating three survey questions which did not correlate with a change in vaccine hesitancy (Douglas J. Opel et al., 2011). The questions were then broken down into three domains with Cronbach's alpha scores as follows dichotomous (yes/no) 0.74, 5-point Likert 0.84 and an 11-point scale 0.74 (Douglas J. Opel et al., 2011). Descriptive statistics including mean, median, mode, and standard deviation (SD) were analyzed. Pre/Post-test responses among the vaccine-hesitant caregivers were also examined.

Among all survey respondents, 89% were mothers, with an average of approximately two first-time mothers. Fifty-eight percent of respondents were white/Caucasian, 27% were black/African American. The mean initial survey score among mothers was 7.13 (SD=6.61), while the mean initial score among fathers was 4.63 (SD=2.77). The telephone follow-up was conducted, and the respondents were all mothers with mean follow-up score 14.36 (SD=5.43). Overall, when asked if they were vaccine-hesitant 69% of mothers responded no, while 28% responded yes. Among fathers, 75% responded not vaccine-hesitant, while 25% were vaccine-hesitant.

The participants had some variation in their demographics. However, 70.7% of caregivers were above the age of thirty. 81% were married, and 67.1% live in a household with two or more children. The average household income level was between $50-75,000, see Figure 1. Educational level ranged from high school graduate to advanced degree, and on average respondents had at minimum a 2-year college degree.

Among the 75 caregiver respondents only 15% (N=11), were identified as vaccine-hesitant after completion of the PACV survey with scores 15 or higher. All 11 vaccine-hesitant respondents participated in the teaching intervention and completed the follow-up survey. After the teaching intervention, four caregiver respondents remained vaccine-hesitant. Among the vaccine-hesitant caregivers, the age of the child that correlated with the highest initial score of hesitancy was 13 months.

Among all caregivers, the Mean initial total score for the PACV survey was 6.87 (SD= 6.34). The maximum possible initial total score was 25, and the minimum possible score was 0. Among vaccine-hesitant caregivers, the Mean initial score was 18.6 (SD= 3.20) while Mean follow-up PACV survey score was 14.36 (SD= 5.43). The highest overall survey score among the vaccine-hesitant at follow-up was 26, with a minimum score of 7.

Race and ethnicity were also analyzed. Most of the respondents (85%) were white/Caucasian and black/African American. The remaining 15% of respondents reported their ethnicity to be either Hispanic, Asian, and mixed race. There was a statistically significant correlation, between the total initial scores and race/ethnicity. Pearson's correlation coefficient was 0.29 with a p-value 0.05.

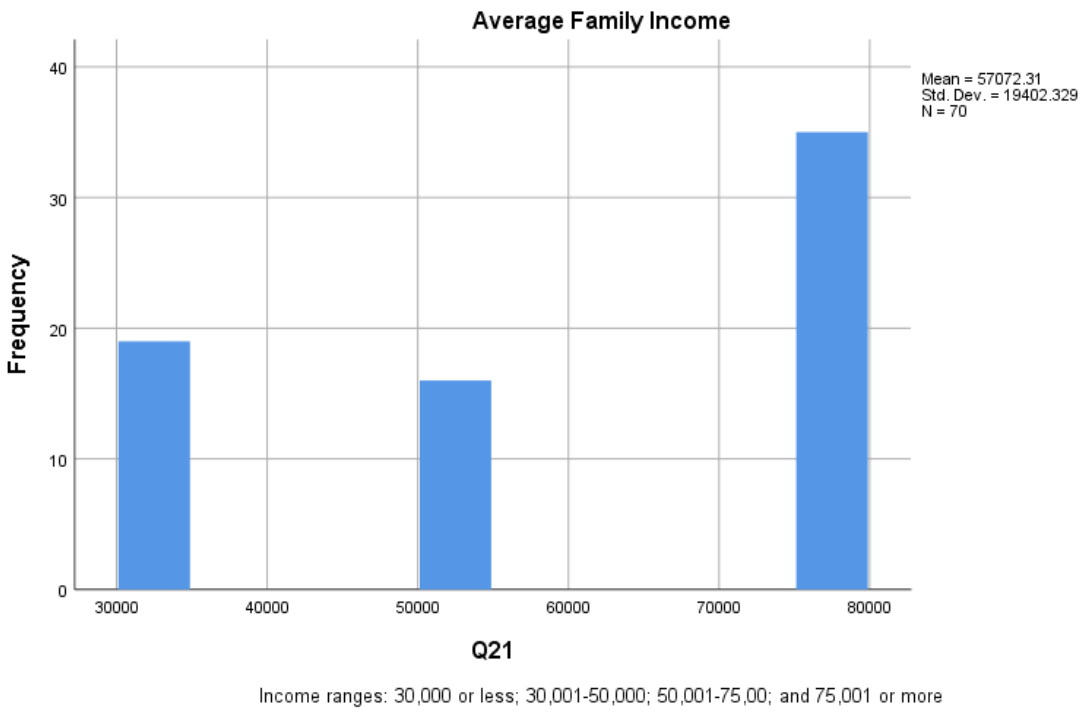

Figure 1. Family income

The clinical question was answered with this study. The teaching intervention was successful in reducing vaccine hesitancy in 7 of 11 caregiver respondents. It was feasible to assess caregiver vaccine hesitancy in a primary care clinic.

Discussion

Education can play a role in reducing caregiver vaccine hesitancy. There is a need for further exploration to find effective methods to combat vaccine hesitancy, and a mixed method approach could be used (Dubé, Gagnon, & MacDonald, 2015). Findings also demonstrate that within this population the rate of vaccine hesitancy is 15%. Although there is not a high level of caregiver vaccine hesitancy, open dialogue and teaching can be effective methods of educational

intervention. Utilization of Orem's Self-Care Deficit Theory allows practitioners the ability to simultaneously examine the needs of caregivers based on the conversation and answers to the survey questions. Also, the open dialogue was empowering for the families as they could express their true feelings regarding vaccination. One mother was adamant not to get her child vaccinated for fear of autism or seizures. Another mother was very hesitant to vaccinate based on her personal experiences, she received the Human Papilloma Virus (HPV) vaccine and was then diagnosed with endometriosis. Also, her sibling passed away after receiving vaccinations.

This study supports the findings of Jarrett and colleagues (2015) who used education as an intervention which led to a 25% increase in vaccine uptake. Further, this study supports the findings of Sadaf and colleagues (2013) as well as Dube and colleagues (2015) who suggest better understanding can be obtained by implementing a randomized control trial, looking specifically at the impact of specific interventions on caregiver vaccine uptake.

Practice implications

This project demonstrated using the PACV survey tool to aid in the identification of vaccine-hesitant caregivers can help providers target who should receive vaccine education. Utilizing readily available teaching tools, such as the CDC handouts, to guide teaching will educate caregivers and give them reference material as they contemplate the decision to vaccinate. Further, this project demonstrated that rates of vaccine hesitancy may not be as high as postulated. Further investigation in different demographic regions could be next steps for future work in this population. Also, adapting the method of teaching to the individual caregiver will improve their retention of information and could better engage them.

Vaccine hesitancy is emerging as an obstacle to APRN's providing evidence-based care. APRN's want to practice at a high level, administering vaccines according to the recommended schedule is a part of this care. When encountering vaccine-hesitant caregivers providers must remain calm, have an open discussion about vaccine concerns. Utilizing current, easy to read evidence-based teaching tools will assist providers in their efforts to educate caregivers about the necessity of timely vaccination as well as the risks if their choice is to remain vaccine-hesitant. Not all vaccine-hesitant caregivers will change their minds, and though from a healthcare provider's perspective this is negative, the caregiver's willingness to discuss their concern's openly may one day result in a change in their child's immunization status.

Limitations

Ideally, the sample would be diverse, and though there was demographic variation, this is only within this specific clinic population. The results can only be compared with patients seen at a similar clinic sharing the same characteristics within their patient population.

The student investigator was not blinded to the study participants, which could lead to bias. Further, many of the participants have familiarity with the student investigator, and although the consent made it clear that their participation would not impact their standing within the clinic, participants may have unknowingly been influenced to answer a certain way for fear of how the provider would view them. Selection bias, although attempts were made to reduce its effect, is a limitation.

Finally, a follow-up survey was given only to vaccine-hesitant caregivers. In future studies, the investigator could perform the teaching intervention and administer the follow-up survey to all study participants. Administering a follow-up survey to all participants would

increase the validity of the results and assess for any changes that could occur by chance. Conducting the follow-up survey via telephone may have impacted the follow-up responses if caregivers felt more comfortable in their homes.

Summary

In conclusion, vaccine hesitancy is a phenomenon that requires the attention of DNP prepared APRN's. In addition to identifying vaccine-hesitant caregivers, finding the best intervention to address vaccine hesitancy and improve immunization uptake rates were the aims of this study. The rate of vaccine hesitancy in the population studied was lower than anticipated. Having a brief teaching session with open communication was effective in decreasing caregiver vaccine hesitancy in the population of study. The potential for increased communicable disease and decreased herd immunity make vaccine hesitancy a priority to be addressed, particularly in the subspecialty of pediatrics.

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Appendix A: Evidence Table

Evidence Matrix Table

Dube, E., Gagnon, D., & MacDonald, N. (2015). Strategies intended to address vaccine hesitancy: Review of published review. *Vaccine,* 33,4191-4203.doi:10.1016/j.vaccine.2015.04.041	**Grade Level of Evidence:** No strong evidence, Low quality Rating level: 2

Hypothesis/Questions	Design	Sample	Measurement	Results/Implications
Review of published reviews on strategies to address vaccine hesitancy and increase vaccine acceptance, discuss promising approaches to address vaccine hesitancy and its determinants.	Search strategy utilizing using a combination of key words for four concepts: interventions, beliefs, attitudes, and knowledge; vaccination; and review. Accepted abstracts were reviews or meta-analysis of interventions addressing vaccine hesitancy or interventions to improve acceptance	Literature published in books, journals, or website from January 1, 2008-November 30, 2014	**None**	No strong evidence to recommend any specific intervention to address hesitancy. Could not generalize study results due to location conducted. Few studies used vaccine uptake or on-time vaccination as outcome. Mixed methodology for interventions may work best, however the results of future studies will need to be evaluated for rigor.

Edwards, K. M., Hackell, J.M. (2016). Countering Vaccine Hesitancy. *Pediatrics*, 138 (3), e1-e14. doi: 10.1542/peds.2016-2146.	**Grade Level of Evidence:** No strong evidence, Low quality Rating level: 2

Hypothesis/Questions	**Design**	**Sample**	**Measurement**	**Results/Implications**
Provide information addressing parental concerns about vaccination	Historical review of vaccine hesitancy reported, also review of the literature regarding vaccine information sharing methods for providers	n/a	**None**	Pediatricians should respect parents with vaccine hesitancy, provide direct, evidence-based information. Having an open discussion is critical while referencing the vaccine schedule. Providers should also provide information handouts or web references to support parent's decision-making process.

Gowda, C., Schaffer, S., Kopec, K., Markel, A., & Dempsey, A. (2013). A pilot study on the effects of individually tailored education for MMR vaccine-hesitant parents on MMR vaccination intention. *Human Vaccines & Immunotherapeutics*. 9(2), 437-445.

Grade level of evidence: Strong recommendation
Rating level: 4

Hypothesis/Questions	Design	Sample	Measurement	Results/Implications
Is individually tailored education more effective than untailored education at improving vaccination intention among MMR vaccine-hesitant parents?	Randomized control trial, intervention pilot study	n=77 parents of children < 6 mo. of age who were screened as hesitant to vaccinate Control group received an untailored educational web page intervention, while the other group received tailored education	The 11-point scale used to measure intention to immunize before and after the intervention	58% of parents in the intervention group had increased intention to vaccinate, with 46% in the control. Parents in the intervention group also had a greater magnitude of change in intention to vaccinate, however not statistically significant. Tailoring of the message may be effective in improving compliance among vaccine-hesitant parents. Limitations: Small sample size. Need a diverse sample

Jarret, C., Wilson, R., O'Leary, M., Eckersberger, E., & Larson, H. (2015). Strategies for addressing vaccine hesitancy: A systematic review. *Vaccine*, 33(34), 4180-4190.

Grade level of evidence: Moderate level, strong recommendation
Rating level: 3

Hypothesis/Questions	Design	Sample	Measurement	Results/Implications
To identify, describe and assess the effectiveness of interventions to address vaccine hesitancy on a diverse, global scale	Broad systematic review of the literature examining the dimensions of public trust, confidence, and hesitancy concerning vaccines were searched	166 Peer-reviewed articles and 15 grey literature articles were searched.	Review Manager analysis application utilized Descriptive analysis was used in addition to PICO standards set by the SAGE working group. GRADE criteria were used	Few strategies found that have been evaluated for impact on vaccine uptake, change in knowledge awareness or attitudes. Most studies were conducted in America and focused on influenza, HPV, or childhood vaccines. Most interventions were multi-component, focusing on raising knowledge and awareness. *Recommendations*: intervention strategies should be carefully tailored to the target population, the parents' reason for hesitancy. Interventions should include specific content to address these issues.

Larson, H.J., Jarrett, C., Shutz, W. S., Chaudhuri, M., Zhou, Y., Dube, E., Shuster, M., MacDonald, N.E., Wilson, R. (2015). Measuring vaccine hesitancy: the development of a survey tool. *Vaccine,* 33 (34), 4165-4175.

Grade level of evidence:
Recommendation; Moderate level of evidence
Rating level: 3

Hypothesis/Questions	Design	Sample	Measurement	Results/Implications
What are the determinants of vaccine hesitancy and what is the best tool to address hesitancy?	A systematic review of peer-reviewed and grey literature Two process indicator questions were used to guide the reviewers toward responses indicating hesitancy Developed a matrix to map the determinants of vaccine hesitancy. Survey tool developed based on matrix	108 articles reviewed	Matrix revealed three categories that factor into the decision to vaccinate: 1. Contextual 2. Individual and group 3. Vaccine-specific	Indicators of vaccine hesitancy not fully addressed in the literature. More qualitative studies are needed to address gaps that surveys cannot cover. Need a more in-depth knowledge of vaccine hesitancy and the parents who are choosing to delay vaccination *Limitations*: Vaccine hesitancy is new, limited availability of survey questions; no validation, the survey questions do not address all determinants of hesitancy. Also, survey questions found were designed to address higher income population

Leask, J., Kinnersley, P., Jackson, G., Cheater, F., Bedford, H., Rowles, G. (2012). Communicating with parents about vaccination: a framework for health professionals. *BMC Pediatrics*, 12, 154.

Grade Level of Evidence
Recommendation-moderate evidence
Rating level: 3

Hypothesis/Questions	Design	Sample	Measurement	Results/Implications
Utilized the developed framework will help providers combat vaccine hesitancy.	Framework developed based upon: 1. Literature review was performed. 2. Classification of parental positions on vaccination. 3. Positions were matched with strategies 4. Assessment of the face validity with healthcare professionals	3 studies were utilized screening the results of databases searched	Framework utilized to determine which category the parent fits in.	The framework is a guide, sets a base for open dialogue that leads the parent towards vaccine acceptance. Limitations: the framework will need to be fully evaluated Recommendation: randomized control trial at cluster or individual level needs to be completed

Opel, D.J., Taylor, J. A., Zhou, C., Catz, S., Myaing, M., Mangione-Smith, R. (2013). The relationship between parent attitudes about childhood vaccines, survey scores and future child immunization status: A validation study. *JAMA Pediatrics* 167(11), 1065-1071.

Grade Level of Evidence
Strong recommendation
Rating level: 4

Hypothesis/Questions	Design	Sample	Measurement	Results/Implications
To determine the predictive value and test-retest reliability of the Parent Attitudes About Childhood Vaccines (PACV) survey. Hypothesis: Higher parental scores would be associated with higher degree of under immunization at 19 mo. of age. Further the PACV levels would remain stable over time.	Prospective cohort study	English speaking parents of children age two mo., born between 7/10/2010-12/10/2010, all within and integrated care system in Seattle, WA, of whom completed a baseline survey and follow-up survey after 8 wks.	Pearson x2 tests Children's immunization status measured in the number of days under immunized from birth to 19 mo.	PACV has high reliability and can predict childhood immunization status Consistent results at 8 weeks make the tool useful in clinical and research interventions to improve parental acceptance of vaccines Limitations: potential for response bias because the PACV survey was not administered simultaneously to the cohort. Potential for sampling variance Not generalizable outside of Seattle Homogenous study population The 3-tier PACV categorization was performed Post Hoc

Roberts, J. R., Thompson, D., Rogacki, B., Hale, J.J., Jacobson, R. M., Opel, D.J., Darden, P. M. (2015). *Vaccine hesitancy among parents of adolescents and its association with vaccine uptake.* 33(14), 1748-1755.

Grade Level of Evidence
moderate recommendation
Rating level: 2

Hypothesis/Questions	Design	Sample	Measurement	Results/Implications
To determine if a modified version of the Parent Attitudes About Childhood Vaccines (PACV) predicts adolescent vaccine uptake.	Survey	Convenience, Parents and adolescents aged 11-17 y/o at a diverse group of pediatric practices in South Carolina and Oklahoma. 363 surveys	Fisher's exact tests used to compare vaccination status with each survey item and with an overall general hesitancy scale that the researchers constructed	Responses indicated hesitancy among parents of adolescents, however no correlation between this and vaccine status for Tdap. Parents did not feel they could openly discuss vaccines if due for the HPV vaccine PACV failed to predict adolescent vaccination status The 2 survey items which are consistent with hesitancy tend to support the notion that safety, trust and hesitancy are the cause. *Limitation*s: PACV as is does not address adolescent parental concerns

Sadaf, A., Richards, J.L., Glanz, J., Salmon, D.A., Omer, S.B. (2013). A systematic review of interventions for reducing parental vaccine refusal and vaccine hesitancy. *Vaccine,* 31(40), 4293-4304.

Grade Level of Evidence
Strong Recommendation, Rating level: 4

Hypothesis/Questions	Design	Sample	Measurement	Results/Implications
What literature exists regarding interventions to reduce vaccine hesitancy and refusal to current recommended schedule?	Meta-analysis of intervention studies Inclusion and exclusion criteria clearly defined	30 studies reviewed	Data extraction tool utilized Data then compiled into three categories: 1. Passage of state laws 2. State or School-level intervention of laws 3. Parent-centered information or education GRADE criteria were utilized to rate the evidence	No high-quality evidence on strategies to reduce parental vaccine refusal. Practice implications were not found Research implications include need for good, quality randomized control trials to evaluate interventions to address parental vaccine hesitancy. Should also assess the impact on vaccination rates among refusing parents.

Smith, M. J., Marshall, G.S. (2010). Navigating parental vaccine hesitancy. *Pediatric Annals*, 39 (8), 476-482.

Grade Level of Evidence
Low Recommendation
Rating Level: 2

Hypothesis/Questions	Design	Sample	Measurement	Results/Implications
What are the common themes regarding parent attitudes and vaccine hesitancy	Literature review	National vaccine survey	n/a	Parents need a trusting relationship with provider to have effective dialogue and vaccine promotion. Need for strong, evidence-based recommendation to vaccinate

Williams, S.E., Rothman, R.L., Offit, P.A., Schaffner, W., Sulivan, M., Edwards, K.M. A randomized control trial to increase acceptance of childhood vaccines by vaccine-hesitant parents: a pilot study. *Academic Pediatrics*, 13 (5), 475-480.

Grade Level of Evidence
Moderate quality,
Rating Level: 4

Hypothesis/Questions	Design	Sample	Measurement	Results/Implications
Will providing information to vaccine-hesitant parents at the 2-week office visit improve parental attitudes regarding childhood vaccines in this population?	Randomized control trial - 2 arm cluster Intervention group received usual care plus a video and written information Control group received usual care	Parents aged 18 y & older of full-term infants less than 30 days old. Primary language English and PACV survey suggesting hesitancy	PACV survey at 2 weeks of age and repeated at 12 weeks along with vaccine status assessment.	Parents within the intervention group demonstrated a significant decrease in PACV scores at 2 months comparted to the control group Brief educational intervention for vaccine-hesitant parents was associated with a modest but significant increase in measured parental attitudes towards vaccination. Limitations: PACV survey could influence control group (Hawthrone Effect) Potential for social distractibility bias (surveys given in person)

Appendix B: Study Flyer

Georgia State University Byrdine F. Lewis School of Nursing and Health Sciences

Conversing about vaccines

A research study about caregiver vaccine concerns.

September-December 2017

Wednesdays 9a-5 pm

Please join the researcher for an exciting chance to talk about pediatric vaccines. Parents/caregivers want the best for their children. This research study will help providers talk about vaccination. By volunteering, you agree to spend about 20 minutes completing a survey, followed by a brief teaching session with the DNP candidate. Follow-up phone survey will be done 4-6 weeks later. Your time is valuable, a $10 gift card will be given.

Lawrenceville Pediatrics does not sponsor this project. For more details please contact Stacy Buchanan as listed below.

Stacy B. Buchanan, CPNP, DNP student investigator
980 Lawrenceville Hwy
Lawrenceville, GA 30047
Phone (770) 962-8025
sbuchanan7@student.gsu.edu
Alternate Contact: Lisa Cranwell-Bruce, DNP, Faculty investigator
(404) 413-1189

Appendix C: Consent Form

Georgia State University

Byrdine F. Lewis College of Nursing and Health Professions

Informed Consent-Parental Permission Form

Title: Vaccine Hesitancy Study

Principal Investigator: Lisa Cranwell-Bruce, DNP

Student Principal Investigator: Stacy B. Buchanan, CPNP, DNP-candidate

Co-Investigator: Sandra Leonard, DNP, FNP-C, Center for Disease Control, and Prevention

I. Purpose:

Please accept the chance to volunteer in a research study. The purpose of this study is to identify vaccine-hesitant parents. A teaching session to decrease hesitancy will also be given. You have been invited to join the study because you are the parent of a child between the ages of 0-5 years.

A total of 75 participants will be recruited for this study. The study will require 40 minutes of your time. Over the 4-6-month time span you will spend 30 minutes during the initial session. A survey will be given, and then a brief teaching session. The follow-up telephone survey will take 10 minutes.

Procedures:

If you decide to join, you will complete a survey on childhood vaccines. If you qualify, you will then have a teaching session with the student investigator. If you do not qualify for the teaching session, you will not proceed any further with the study. The teaching session will include time for you to ask questions. Should you feel uneasy with the talk or the survey questions please tell the investigator. You may stop participating at any time. Within 4-6 weeks after teaching has been completed, you will re-take the survey over the phone.

II. Risks:

In this study, you will not have any more risks than you would in a normal day of life.

III. Benefits:

Joining this study may or may not benefit you personally. The personal benefit could be reassurance of the safety of vaccines. Trust in the provider gained through an open talk, and

respect of personal choices are also benefits. Overall, we hope to gain information about why parents chose to decline, delay, or modify the vaccine schedule.

IV. Compensation:

You will receive a gift card for Chic-fil-a in the amount of $10 for participating in this study by completing the initial survey.

V. Voluntary Participation and Withdrawal:

Participation in research is voluntary. You do not have to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. You may skip questions or stop participating at any time. Whatever you decide, you will not lose any benefits as a patient within the practice.

VI. Confidentiality:

We will keep your records private to the extent allowed by law. The primary investigator, student investigator and co-investigator will each have access to the information you provide. The data also will be shared with those who make sure the study is done correctly (GSU Institutional Review Board, the Office for Human Research Protection (OHRP)). We will use the code VH + a randomly generated number rather than your name on study records. The data you provide will be stored on a password protected computer.

The key code to identify participants of the study will be kept separately from the data to protect privacy. The data will be locked and stored in the office of the faculty on the campus of Georgia State University. Your name and other facts that might point to you will not appear when we present this study or publish its results. The findings will be summarized and reported in group form. You nor your child will not be identified personally. The data key will be destroyed 18 months after study completion.

VII. Contact Persons:

Contact Lisa Cranwell-Bruce, DNP at 404-413-1189 or email lcranwellbruce@gsu.edu or myself, Stacy B. Buchanan, CPNP at 770-962-8025 email: sbuchanan7@student.gsu.edu if you have questions, concerns, or complaints about this study. In addition, please call if you think you the study has caused you harm. Call Susan Vogtner in the Georgia State University Office of Research Integrity at 404-413-3513 or svogtner1@gsu.edu if you want to talk to someone who is not part of the study team. You can talk about questions, concerns, offer input, obtain information, or suggestions about the study. You can also call Susan Vogtner if you have questions or concerns about your rights in this study.

XI. Copy of Consent Form to Participant:

We will give you a copy of this consent form to keep.

If you are willing to volunteer for this research, please sign below.

_____ _____

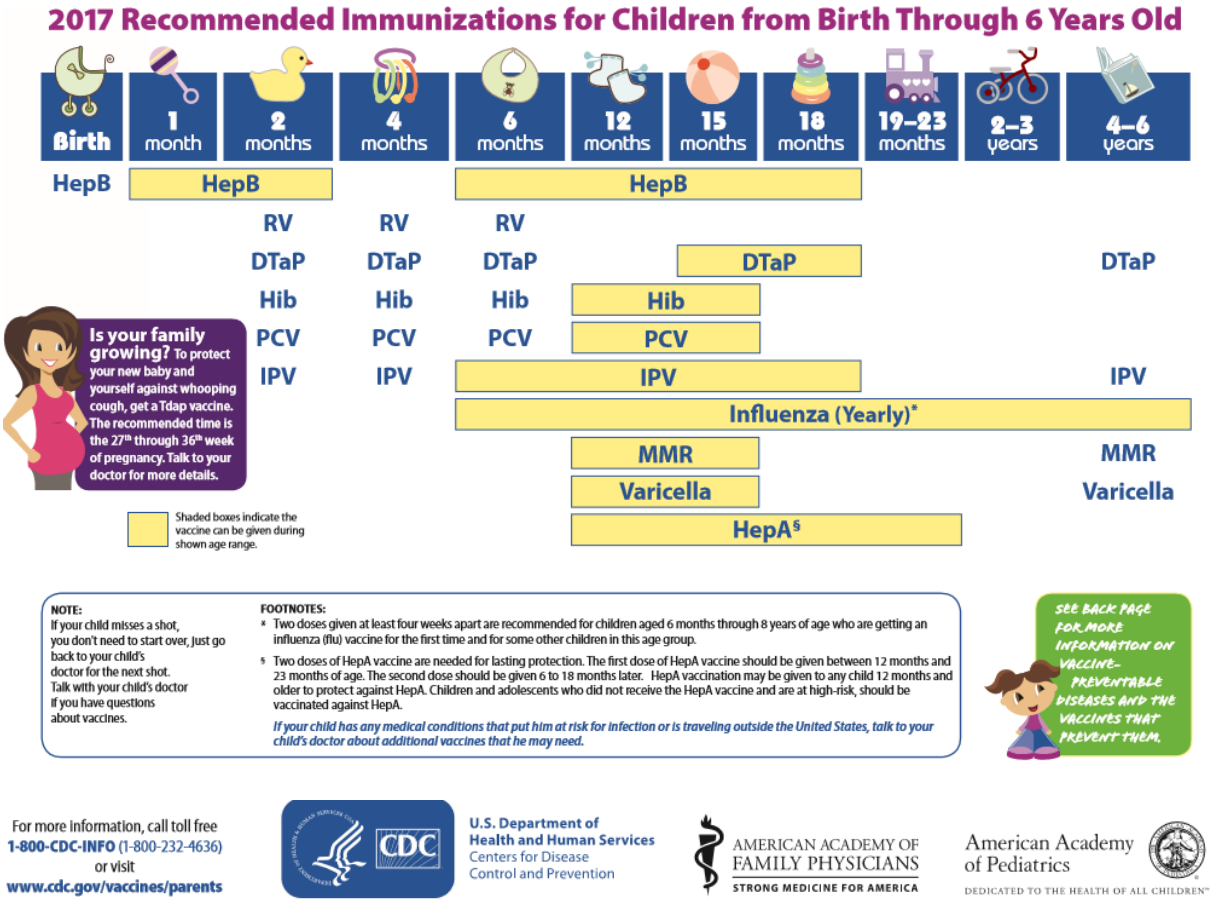
Participant Date

_____ _____

Principal investigator or Researcher Obtaining Consent Date

Appendix D: Teaching Tools

CDC Teaching sheets



Vaccine-Preventable Diseases and the Vaccines that Prevent Them

Disease	Vaccine	Disease spread by	Disease symptoms	Disease complications
Chickenpox	**Varicella vaccine** protects against chickenpox.	Air, direct contact	Rash, tiredness, headache, fever	Infected blisters, bleeding disorders, encephalitis (brain swelling), pneumonia (infection in the lungs)
Diphtheria	**DTaP*** vaccine protects against diphtheria.	Air, direct contact	Sore throat, mild fever, weakness, swollen glands in neck	Swelling of the heart muscle, heart failure, coma, paralysis, death
Hib	**Hib** vaccine protects against *Haemophilus influenzae* type b.	Air, direct contact	May be no symptoms unless bacteria enter the blood	Meningitis (infection of the covering around the brain and spinal cord), intellectual disability, epiglottitis (life-threatening infection that can block the windpipe and lead to serious breathing problems), pneumonia (infection in the lungs), death
Hepatitis A	**HepA** vaccine protects against hepatitis A.	Direct contact, contaminated food or water	May be no symptoms, fever, stomach pain, loss of appetite, fatigue, vomiting, jaundice (yellowing of skin and eyes), dark urine	Liver failure, arthralgia (joint pain), kidney, pancreatic, and blood disorders
Hepatitis B	**HepB** vaccine protects against hepatitis B.	Contact with blood or body fluids	May be no symptoms, fever, headache, weakness, vomiting, jaundice (yellowing of skin and eyes), joint pain	Chronic liver infection, liver failure, liver cancer
Influenza (Flu)	**Flu vaccine** protects against influenza.	Air, direct contact	Fever, muscle pain, sore throat, cough, extreme fatigue	Pneumonia (infection in the lungs)
Measles	**MMR**** vaccine protects against measles.	Air, direct contact	Rash, fever, cough, runny nose, pinkeye	Encephalitis (brain swelling), pneumonia (infection in the lungs), death
Mumps	**MMR****vaccine protects against mumps.	Air, direct contact	Swollen salivary glands (under the jaw), fever, headache, tiredness, muscle pain	Meningitis (infection of the covering around the brain and spinal cord) , encephalitis (brain swelling), inflammation of testicles or ovaries, deafness
Pertussis	**DTaP*** vaccine protects against pertussis (whooping cough).	Air, direct contact	Severe cough, runny nose, apnea (a pause in breathing in infants)	Pneumonia (infection in the lungs), death
Polio	**IPV** vaccine protects against polio.	Air, direct contact, through the mouth	May be no symptoms, sore throat, fever, nausea, headache	Paralysis, death
Pneumococcal	**PCV** vaccine protects against pneumococcus.	Air, direct contact	May be no symptoms, pneumonia (infection in the lungs)	Bacteremia (blood infection), meningitis (infection of the covering around the brain and spinal cord), death
Rotavirus	**RV** vaccine protects against rotavirus.	Through the mouth	Diarrhea, fever, vomiting	Severe diarrhea, dehydration
Rubella	**MMR**** vaccine protects against rubella.	Air, direct contact	Children infected with rubella virus sometimes have a rash, fever, swollen lymph nodes	Very serious in pregnant women—can lead to miscarriage, stillbirth, premature delivery, birth defects
Tetanus	**DTaP*** vaccine protects against tetanus.	Exposure through cuts in skin	Stiffness in neck and abdominal muscles, difficulty swallowing, muscle spasms, fever	Broken bones, breathing difficulty, death

* DTaP combines protection against diphtheria, tetanus, and pertussis.
** MMR combines protection against measles, mumps, and rubella.

Last updated December 2016 • CS272886-E

If You Choose Not to Vaccinate Your Child, **Understand the Risks and Responsibilities.**

| Information for parents |

Revised March 2012

If you choose to delay some vaccines or reject some vaccines entirely, there can be risks. Please follow these steps to protect your child, your family, and others.

With the decision to delay or reject vaccines comes an important responsibility that could save your child's life, or the life of someone else.

Any time that your child is ill and you:

- call 911;
- ride in an ambulance;
- visit a hospital emergency room; or
- visit your child's doctor or any clinic

you must tell the medical staff that your child has not received all the vaccines recommended for his or her age.

Keep a vaccination record easily accessible so that you can report exactly which vaccines your child has received, even when you are under stress.

Telling health care professionals your child's vaccination status is essential for two reasons:

- When your child is being evaluated, the doctor will need to consider the possibility that your child has a vaccine-preventable disease. Many of these diseases are now uncommon, but they still occur.
- The people who help your child can take precautions, such as isolating your child, so that the disease does not spread to others. One group at high risk for contracting disease is infants who are too young to be fully vaccinated. For example, the measles vaccine is not usually recommended for babies younger than 12 months. Very young babies who get measles are likely to be seriously ill, often requiring hospitalization. Other people at high risk for contracting disease are those with weaker immune systems, such as some people with cancer and transplant recipients.

Before an outbreak of a vaccine-preventable disease occurs in your community:

- Talk to your child's doctor or nurse to be sure your child's medical record is up to date regarding vaccination status. Ask for a copy of the updated record.
- Inform your child's school, childcare facility, and other caregivers about your child's vaccination status.
- Be aware that your child can catch diseases from people who don't have any symptoms. For example, Hib meningitis can be spread from people who have the bacteria in their body but are not ill. You can't tell who is contagious.

CDC

AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

American Academy of Pediatrics

When there is vaccine-preventable disease in your community:

- It may not be too late to get protection by getting vaccinated. Ask your child's doctor.
- If there are cases (or, in some circumstances, a single case) of a vaccine-preventable disease in your community, you may be asked to take your child out of school, childcare, or organized activities (for example, playgroups or sports).
- Your school, childcare facility, or other institution will tell you when it is safe for an unvaccinated child to return. Be prepared to keep your child home for several days up to several weeks.
- Learn about the disease and how it is spread. It may not be possible to avoid exposure. For example, measles is so contagious that hours after an infected person has left the room, an unvaccinated person can get measles just by entering that room. -
- Each disease is different, and the time between when your child might have been exposed to a disease and when he or she may get sick will vary. Talk with your child's doctor or the health department to get their guidelines for determining when your child is no longer at risk of coming down with the disease.

Be aware.

- Any vaccine-preventable disease can strike at any time in the U.S. because all of these diseases still circulate either in the U.S. or elsewhere in the world.
- Sometimes vaccine-preventable diseases cause outbreaks, that is, clusters of cases in a given area.
- Some of the vaccine-preventable diseases that still circulate in the U.S. include whooping cough, chickenpox, Hib (a cause of meningitis), and influenza. These diseases, as well as the other vaccine-preventable diseases, can range from mild to severe and life-threatening. In most cases, there is no way to know beforehand if a child will get a mild or serious case.
- For some diseases, one case is enough to cause concern in a community. An example is measles, which is one of the most contagious diseases known. This disease spreads quickly among people who are not immune.

If you know your child is exposed to a vaccine-preventable disease for which he or she has not been vaccinated:

- Learn the early signs and symptoms of the disease.
- Seek immediate medical help if your child or any family members develop early signs or symptoms of the disease. -

  IMPORTANT: Notify the doctor's office, urgent care facility, ambulance personnel, or emergency room staff that your child has not been fully vaccinated before medical staff have contact with your child or your family members. They need to know that your child may have a vaccine-preventable disease so that they can treat your child correctly as quickly as possible. Medical staff also can take simple precautions to prevent diseases from spreading to others if they know ahead of time that their patient may have a contagious disease.

- Follow recommendations to isolate your child from others, including family members, and especially infants and people with weakened immune systems. Most vaccine-preventable diseases can be very dangerous to infants who are too young to be fully vaccinated, or children who are not vaccinated due to certain medical conditions.
- Be aware that for some vaccine-preventable diseases, there are medicines to treat infected people and medicines to keep people they come in contact with from getting the disease.
- Ask your health care professional about other ways to protect your family members and anyone else who may come into contact with your child.
- Your family may be contacted by the state or local health department who track infectious disease outbreaks in the community. -

If you travel with your child:

- Review the CDC travelers' information website (*http://www.cdc.gov/travel*) before traveling to learn about possible disease risks and vaccines that will protect your family. Diseases that vaccines prevent remain common throughout the world, including Europe. -
- Don't spread disease to others. If an unimmunized person develops a vaccine-preventable disease while traveling, to prevent transmission to others, he or she should not travel by a plane, train, or bus until a doctor determines the person is no longer contagious.

For more information on vaccines, ask your child's health care professional, visit **www.cdc.gov/vaccines** or call **800-CDC-INFO** (800-232-4636)