THE EFFECTIVENESS OF AN EDUCATIONAL INTERVENTION IN INCREASING PARENTAL KNOWLEDGE AND WILLINGNESS TO VACCINATE

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School of Nursing
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Abstract

of

THE EFFECTIVENESS OF AN EDUCATIONAL INTERVENTION IN INCREASING PARENTAL KNOWLEDGE AND WILLINGNESS TO VACCINATE

by

Marisa Leigh Deptala

Purpose- Vaccine preventable diseases have been making a comeback in the United States in the past decade. Research suggests that the outbreaks of Pertussis and Measles that the U.S. has been experiencing are due to small pockets of unvaccinated individuals. Misinformation from the media and celebrities who are part of the Anti-Vaccine movement is leading to undervaccination. This proposed study’s aim is to introduce an educational program on childhood vaccines so as to provide parents with accurate information on vaccine preventable diseases and the benefits of being immunized.

Design/Methodology- The proposed study will be a quasi-experimental quantitative study that targets parents with children at private preschools throughout San Diego County with average up to date (UTD) vaccination percentages of less than 70 percent. The non-randomized sample will receive an educational intervention, which will be analyzed statistically with a pre-test/post-test design so as to determine if there is a difference in knowledge and willingness to vaccinate before and after the applied intervention.

Value/Significance- While there have been many studies on interventions to increase the vaccination rate of specific vaccines, none were found targeting the entire childhood vaccination
schedule. Completing the childhood vaccination schedule has been found to not only cut healthcare costs, but also save lives.

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Index

Chapter

1. INTRODUCTION ................................................................. 9
   Background and Significance ............................................. 10-11
   The Problem ....................................................................... 10
   Purpose of the Research ................................................. 12
   Implications for Nursing Practice/Policy/Research .............. 11
   Research Question .......................................................... 12
   Research Variables ......................................................... 12

2. LITERATURE REVIEW ........................................................... 13
   Introduction ....................................................................... 13
   Major Variables Defined ................................................. 13-18
   Theoretical Framework or Conceptual Model ................. 18

3. METHODOLOGY ................................................................. 20
   Introduction ....................................................................... 20
   Research Question .......................................................... 20
   Hypothesis ........................................................................ 20
   Identification of Setting .................................................. 21
   Research Design .............................................................. 21
   Population and Sample .................................................... 22
   Measurement Methods ..................................................... 24
   Data Collection Process ................................................... 24-25
   Coding and/or scoring ....................................................... 25
   Data Analysis ..................................................................... 25
   Bias .................................................................................. 26-27
   Ethical Considerations ...................................................... 27
4. GRANT ELEMENTS.................................................................................................................28
   Potential Grants and Selected Grants.................................................................................28-30
   Budget and Justification.................................................................................................31-33

5. REFERENCES
   Appendix A: Theoretical Framework...............................................................................37
   Appendix B: Research Design.............................................................................................38
   Appendix C: G*Power Calculation of Sample Size.........................................................39
   Appendix D: Knowledge Questionnaire............................................................................40
   Appendix E: Willingness to Vaccinate Questionnaire......................................................41
   Appendix F: IRB Application..............................................................................................42
Chapter 1

The Effectiveness of an Educational Intervention on Parental Knowledge and Willingness to Vaccinate

In 2014, a year that had not even yet reached completion, the United States had seen approximately 600 cases of measles. According to the Center for Disease Control and Prevention [CDC], this was three times more than the previous year, and six times more than the year before that. This fact is truly shocking as only 14 years earlier, in 2000, measles was declared eliminated in this country due to the highly effective vaccine program that had been implemented. The vast majority of those affected were children and adults who had not been vaccinated with the Measles, Mumps and Rubella vaccine commonly known as the MMR (CDC, 2014).

As healthcare professionals, it is often difficult to understand why members of the community would choose to put themselves and their loved ones at risk for an infectious disease. However, it is necessary to remember that clients are influenced not only by modern medicine, but also by the rest of the world that they live in. The Washington Post published an article in 2014 on rising rates of diseases such as measles and pertussis. In this article, the author states that celebrities such as Jenny McCarthy and other anti-vaccine advocates have had a greater affect than could have been expected. Celebrity status and access to the media has allowed these familiar faces to spread the unsubstantiated rumor that vaccines cause autism. This fear mongering may be largely responsible for the drop in childhood vaccination rates, especially in communities that are well-educated and affluent (“How the anti-vaccine movement is endangering lives”, 2014).
With adversaries such as celebrities, with unlimited resources and extensive power over the masses, healthcare professionals are the underdogs in the fight to influence their communities. Yet this is exactly what must be done to keep children in the United States safe from preventable diseases. A cost-effective, time efficient, and reliable way of educating parents on childhood vaccinations is one method by which this may be accomplished. However, parents must not only be given the knowledge of the horrible diseases that immunizations can prevent, but also the truth behind the inaccurate falsities that have been widely distributed due to popular culture.

The following paragraphs will discuss the background of the comeback of infectious diseases once eliminated from the United States and their tie to decreased vaccination rates in children. In addition, it will discuss the literature available on childhood vaccine education, and the methodology proposed to perform an educational intervention for parents of young children who are behind in the vaccine schedule.

The Problem: Vaccine Opposition

Opposition to vaccines has existed for as long as vaccinations have existed themselves. However, the most recent anti-vaccine movement began in 1998 when Dr. Andrew Wakefield had his research on the MMR vaccine was published in The Lancet. Wakefield claimed that his research showed evidence of a link between autism, bowel disease and the MMR vaccine. However, this research was performed unethically and Wakefield received monetary support to substantiate the claims for a legal litigation. The Lancet formally retracted the paper in 2010, but the damage had already been done (“History of Anti-Vaccination Movements”, 2014).

Despite many scientists being unable to replicate Dr. Wakefield’s results and substantiate his claim of a link between vaccines and autism, the anti-vaccine movement continued and grew.
Celebrities such as Jim Carrey and Jenny McCarthy publicly denounced immunization and blamed their son’s autism on the ingredients used to preserve vaccines. The rally “Green Our Vaccines” was created, and Carrey and McCarthy’s celebrity status allowed for the anti-vaccine messages to be spread throughout the United States (Gorski, 2008). Despite the medical community doing their best to dispel the myths that are propagated by people with no scientific or medical background, the movement continues on. It is for this reason that interventions to increase knowledge of vaccines and ultimately vaccination coverage itself continues to be an important endeavor.

**Significance to Nursing**

According to an article published by the American Nurses Association (ANA) in 2011, at least 66 percent of nurse practitioners (NPs) practice in primary-care settings. These settings include family medicine and pediatrics. NPs account for more than 600 million patient visits each year. Because of their backgrounds and affinity for primary-care settings, NPs are excellent practitioners to rally for improved immunization coverage. As NPs continue to increase in number and role in the primary care setting, many issues that were once left to doctors will be passed on to advanced practice nurses (ANA, 2011).

Healthy People 2020 states that immunizations and vaccines are the most cost-effective preventative service that healthcare workers have access to. According to evidence-based practice outcomes, “for each birth cohort that is immunized with the standard schedule, 33,000 lives are saved, 14 million cases of disease are prevented, healthcare costs are reduced by $9.9 billion, and $33.4 billion in indirect costs are saved” (Gromek, 2013). With statistics like these, health professionals of all types should be looking for ways to increase immunization and close the vaccination gaps in hopes of creating a healthier and less costly United States population.
**Purpose of Research**

The purpose of this research is to study the effects of an educational intervention regarding vaccinations in parents of preschool age children in San Diego County. The hope is that providing parents with accurate information on vaccinations and dispelling myths regarding them will increase individual knowledge and willingness to vaccinate. If increased knowledge and willingness occurs on an individual level, it is possible that further studies could lead to increased immunization coverage across the United States. Using a quantitative pre-test/post-test design, data will be collected with the goal to support the hypothesis that the educational intervention will increase both knowledge and willingness to vaccinate.

**Research Question**

The proposed study will have one research question that focuses on one independent variable and two dependent variables. The research question that will be utilized is as follows: Is an educational program on vaccines effective in increasing parental knowledge and willingness to vaccinate in parents of preschool age children in San Diego County?

**Research Variables**

The independent variable in this particular study is the educational intervention on vaccinations that will be provided to the selected participants. The dependent variables that will be assessed through pre-test and post-test design will be knowledge on childhood vaccines and the willingness to vaccinate children. A more thorough discussion of how a relationship between these variables will be assessed will be provided later on in this paper.
Chapter 2: Literature Review

A literature review was performed utilizing three databases, CINAHL, PubMed, and Google Scholar. The key terms used were education, intervention, childhood, vaccine, vaccination, immunization, coverage, consequences, parental, gap, herd immunity, attitudes and knowledge. The resulting literature was reviewed, selected by relevance to the research topic, and then sorted into categories based on the themes of each study.

Defining and Understanding Herd Immunity

Herd immunity is used to describe the proportion of immune individuals in a population needed to protect said population from an outbreak of an infectious disease. This critical number of individuals has been applied to many different diseases including measles, pertussis, chicken pox, rubella and polio, and has been used by pro-vaccine advocates to demonstrate the need for increased vaccination coverage. The use of herd immunity is meant to protect the most individuals possible. Therefore, the idea is to vaccinate and therefore immunize all individuals that are capable of receiving vaccines. Reaching the proportion of people necessary to make outbreak impossible, herd immunity also then protects individuals who are unable to be vaccinated due to age, disease, or immunocompromise by diminishing their chances of being exposed. This is an important concept in vaccine programs, and the method behind the periodic eradication of polio, measles, smallpox and rinderpest (Fine, Eames & Haymann, 2011).

The Consequences of Undervaccination

In an article on the role of intentionally undervaccinated children in the spread of disease, Sugerman et al. (2009) studied a measles outbreak in San Diego in 2008. The authors mapped out vaccination-refusal rates in various schools, and then analyzed the patterns of measles transmissions across San Diego County. In this particular outbreak, a 7-year-old boy had
returned to California after a trip to Switzerland infected with measles. This child was intentionally unvaccinated and therefore susceptible to the virus. The authors identified everyone who was exposed and made ill by this initial infected child. This outbreak was found to have exposed 839 people, with 12 contracting the measles virus and falling ill. Each of the persons identified were then interviewed and vaccination status was determined. All of the 12 infected individuals were unvaccinated, 11 intentionally and one being under the required age for vaccination (Sugerman et al., 2009).

The authors concluded that this one unvaccinated individual resulted in a small outbreak fueled by pockets of undervaccinated children, and $176,980 worth of medical and containment effort costs. They continued by stating that lower vaccination rates are worrisomely correlated with higher pertussis and measles incidences. The authors concluded by reiterating that maintenance of high vaccination coverage must be made a priority so as to avoid having vaccine preventable diseases become endemic once again (Sugerman et al., 2009).

**Why Parents are Not Vaccinating**

As previously discussed, the unfortunate publishing of Dr. Andrew Wakefield’s study linking vaccinations to autism lead to the beginning of vaccine hesitancy and fear mongering. However, many studies have been performed with the purpose of discovering why parents choose not to vaccinate their children. In a short editorial on vaccine hesitancy, Professor Barry Bloom (2014) from Harvard states that misinformation from anti-vaccine groups, ill-informed peers, and celebrities is not the only culprit for decreasing vaccination coverage. In addition to these deterrents, it has recently been shown that current public health campaigns regarding vaccines may increase misconceptions and that interventions intending to correct false information about vaccinations may be counterproductive. He concludes that discovering the
true reasons why parents are not vaccinating or undervaccinating their children is the key to increasing immunization coverage (Bloom, 2014).

In 2012, LaVail and Kennedy performed a research study on parental attitudes and vaccination behaviors. The authors chose to look at how confidence in the safety, efficacy and value of vaccines related to the likelihood of parents vaccinating their children. Utilizing a mail-out questionnaire, the researcher’s collected self-reported data from 376 parents with children 6-years-old and younger. The researchers found that parents who were confident in all or any of these characteristics of vaccines were more likely to vaccinate their children. Therefore, it was concluded that potentially part of the issue with underimmunization is that parents are not confident in the safety, value and efficacy of vaccines (LaVail & Kennedy, 2012).

Vaccine hesitancy is a term that has recently become popular in the discussion of vaccination. Parents who are vaccine hesitant typically are those who have delayed a vaccine, refused a vaccine, or allowed their children to be vaccinated despite feeling as though it was not the right thing to do. In a 2011 study, Healy and Pickering researched the concerns of parents who were experiencing vaccine hesitancy. The concerns of parents regarding vaccines vary depending on their own personal experiences as well as their knowledge on the subject. In this study, it was found that parents are fearful that vaccines will cause the infection they are meant to protect from, and that “natural” immunity is healthier than that caused by immunization. In addition, the fear of vaccines is often greater than the fear of infectious diseases due to the fact that vaccine preventable diseases are not seen as often as they were in the past (Healy & Pickering, 2011).

While the media is quick to report misinformation about the adverse events associated with vaccines, the deadly effects of diseases are less likely to make headlines. Lastly, the
researchers also discuss the recent sentiments that thimerosol, the preservative used in some vaccines, causes mercury poisoning in children. While this has not been proven, the FDA did remove thimerosol from all vaccines in the childhood vaccination schedule except some influenza vaccines. The authors concluded by stating that parental concerns often lead to vaccine hesitancy and that it is the job of healthcare professionals to understand parental concerns and the vast amount of incorrect information they are inundated with on a daily basis (Healy & Pickering, 2011).

**Interventions to Increase Vaccination Coverage**

Vaccination is currently a hot topic not only in the media, but also in research. For this reason, there are many studies regarding the reasoning behind not vaccinating as well as parental response to interventions meant to increase vaccination. While there are very few studies on the entire childhood vaccine schedule, there are many studies that focus on particular vaccines.

In one such study, an improvement initiative was implemented with the intent to increase HPV vaccination rates in preteen girls. The authors performed a quasi-experimental study at a small private pediatric practice in an urban setting. A two-part intervention, this study included both electronic reminders for healthcare providers, as well as an educational brochure for parents. The researchers found that HPV immunization increased from 24.1 percent to 75 percent after the implementation of the improvement initiative. In addition, 65.2 percent of the parents in the sample stated that the educational brochure helped them make the decision to vaccinate their children with the HPV vaccine. It was concluded that HPV vaccine completion rates can be greatly improved when healthcare providers are reminded, and parents are given the information necessary to make informed health decisions for their children (Cassidy, Braxter, Charron-Prochownik & Schlenk, 2014).
While the previous study showed an increase in vaccine series completion, not every study has such positive results. However, studies on educational interventions do support the idea that parents are in need of accurate information. In their study on educating parents who were considering or had already filed an exemption to school immunization, Gust et al. (2009) found that while their methods did not increase actual vaccination, it did get positive feedback from the parents who participated.

In a survey and interview style study, the authors sent both surveys and educational brochures to parents who were identified as those who would potentially file exemptions to school immunization. It was found that parents in this population had negative attitudes towards vaccines, the CDC, and their healthcare provider. However, in a focus group interview following the study, the parents in the intervention group claimed that the brochure sent to them did increase their knowledge on vaccinations and also increased their trust in the CDC. In addition, they found the information given helpful and thorough. Therefore, despite the authors not necessarily changing the participant’s minds on vaccination completely, they were able to provide them with information they deemed helpful and improved their opinions of the CDC (Gust et al., 2009).

In a final article reviewed that studied an intervention for increased vaccination in children, Patwardhan et al. (2011) researched the effectiveness of an electronic record reminder in a pediatric rheumatology clinic. This study focused on the influenza vaccine, which is recommended in the childhood vaccination schedule for all children older than 6 months (CDC, 2014). The authors of this study performed a chart review of patients attending a specific rheumatology clinic, and then implemented an automatic best practice reminder to alert healthcare professionals when a child had not received the influenza vaccine. In a two-year
span, the researchers found that vaccination rates in the sample population increased from 5.9 percent to 25.5 percent. While this study did not include an educational intervention geared towards parents, it did remind healthcare workers to educate parents and make their best attempt to encourage vaccination for their patients (Patwardham, Kelleher, Cunningham, Menke, Spencer, 2011).

The previously discussed literature review was used to identify gaps in the literature regarding childhood vaccination, as well as make informed decisions on research design and study aims.

**Theoretical Framework**

**Health promotion model.** For this study, Nola Pender’s Health Promotion Model (HPM) will be used as a theoretical framework. The purpose of this theory is to help nurses understand what determines the health behaviors of their clients and how to counsel and promote healthy lifestyles based on these behaviors. This theory is particularly applicable in research on vaccine refusal and hesitancy as it delves into what drives people to make poor health decisions and how the healthcare professional can be involved in aiding them to make better health choices (Pender, 2011).

The educational intervention that will be discussed in more detail later on in this proposal will be created around certain components of the Health Promotion Model (Appendix A). For example, Pender’s theory discusses how prior related behavior and experiences as well as personal factors affect and influence health behaviors. This will be taken into account when participants seem to have learned from the educational intervention, but are still unwilling to vaccinate their children. In addition, Pender theorizes that perceived benefits and barriers are important drives in the choices people make when it comes to health. The educational
intervention being proposed will thoroughly discuss the benefits of vaccination and help parents weigh them against the true, scientifically supported adverse events.

Lastly, similar to the HPM, this study will take into account that interpersonal and situational influences are often at play when parents choose not to vaccinate their children. Therefore, the intervention in this study must not only be convincing and well-supported, but must be presented in a manner that is influential without making participants feel guilty or as though they are wrong and the researcher is right (Pender, 2011).
Chapter 3: Methodology

As the literature review has suggested, one of the driving forces behind parents being hesitant to vaccinate is misinformation. Previous studies on various individual vaccines have proven that interventions that provide parents with accurate and useful information can be effective in increasing the willingness to vaccinate. However, there is a gap in the literature regarding the entire childhood vaccination schedule. For this reason, this study would provide parents of preschool age children with a thorough but time-efficient education on said schedule, as well as the myths surrounding vaccines, the diseases vaccinated for, and the true adverse events associated with vaccination. The purpose would be to determine if this educational intervention is effective in increasing parental knowledge and willingness to vaccinate.

The success of this study would support vaccination education to be performed on a larger level. While this study would only occur in San Diego County, a successful educational program could be adapted for areas throughout the United States. From here, further studies could be done to determine if increased willingness to vaccinate increases vaccination coverage. If this is the end result, the United States could potentially not only reach its Healthy People 2020 goal of 90% vaccine coverage, but also reduce the number of vaccine preventable deaths and even eradicate the diseases that cause them.

Research Question and Hypothesis

There is one primary research question for this study. As previously stated, the research being proposed will hopefully answer the question “is an educational program on childhood vaccines effective in increasing parental knowledge and willingness to vaccinate in parents of preschool age children in San Diego County?” The hypothesis is that an educational program on childhood vaccines will increase parental knowledge and willingness to vaccinate in parents of
preschool age children. This hypothesis is directional and will be supported by data collected by a pre-test/post-test design.

**Operationalizing Research Variables**

The independent variable in this study will be the educational program itself. This program will be a 30-minute presentation developed by the researcher regarding the childhood vaccination schedule, the diseases vaccinated for, the myths surrounding vaccinations and the true adverse effects associated with vaccines. The dependent variables in this study are knowledge and willingness to vaccinate.

**Knowledge.** In the case of this study, knowledge is an interval-level variable that will be represented by raw test score, or number of questions answered correctly. The pre- and post-test will contain the same information-based questions on the content that will be covered in the 30-minute presentation. As the hypothesis in this study is directional, the assumption is that test score (knowledge) will be lower in the pre-test than it will be in the post-test following the educational intervention.

**Willingness to vaccinate.** Willingness to vaccinate will also be assessed as an interval-level variable, determined by questions on the pre-test and post-test that utilize a likert scale to gauge how likely a parent is to vaccinate their child. Again, the directional hypothesis of this study creates the assumption that participants will be more willing to vaccinate their children after they have received the educational intervention.

**Research Design**

This study will be performed as a quantitative, pre-test/post-test design with a non-randomized sample. A paired T-test will be used to analyze the data collected from a pre-test and post-test that will both be administered to every parent who partakes in the educational
intervention. Data will be collected at one time for each participant (Appendix B). Collecting before and after-intervention data on the same participants allows for the assessment of increased knowledge and willingness to vaccinate in each individual. If there is a statistically significant difference between the pre-test and post-test scores, the directional hypothesis stated earlier will be supported.

**Setting.** The educational intervention and data collection will occur at the facilities of 22 private preschools around San Diego County that state they are willing to participate. Consent, pre-test, intervention, and post-test will all occur at a one-time administration at each facility. The preschools must be willing to donate their space, as well as childcare during the time that the intervention will be performed. Therefore, it is likely that the educational program and data collection will occur during normal school hours. Participants will be given information on how they can access the results of the study once it has been completed.

**Sampling.** The participants for this study will be recruited on site at each of the 22 chosen private preschools. The preschools were chosen based on data provided by shotsforschool.org, a website developed by the California Department of Public Health that provides information on the up to date (UTD) vaccination percentages of children attending certain schools. The 22 selected preschools were chosen based on the criteria that they had greater than ten students, and their mean UTD percentage was less than 70 percent (shotsforschools.org, 2014). Approval will be sought from those in charge at the preschools to not only gain access to the parents with children enrolled at their school, but also so that they can collaborate in recruiting parents to participate in the study.

**Target population.** The target population for this study includes parents (male or female) of preschool age children at one of the selected private preschools in San Diego County.
This population was chosen as each of the preschools has a UTD percentage less than 70 percent, and therefore it is likely that many of the parents at these schools are vaccine hesitant. In addition, in San Diego County, the highest percentage of unvaccinated students is in the group that attends private schools (California Department of Public Health, 2014). Therefore private preschools, where the children attending are generally aged two to five, were chosen so as to attempt to gain the greatest good in providing an educational intervention and potentially increased vaccinations in young children who could be “caught up” in their vaccines.

**Sample size.** The sample size required for this study was calculated using G*Power statistical software using a one-tailed, matched pairs T test (Appendix C). The literature review of similar studies had effect sizes that were quite variable. As this particular intervention covers a lot of information related to a very controversial topic, the effect size chosen will be on the lower end of the range seen in relatable studies. Therefore, an effect size of 0.20 was chosen at the recommendations of Polit and Beck (2012) that nursing research utilize an effect size between 0.20 and 0.40. Continuing with recommendations from this nursing research manual, a conventional alpha of 0.05 and a power level of 0.80 were also chosen (Polit & Beck, 2012). Utilizing these numbers, the G*Power program determined population size to be 156 participants. Performing the educational intervention at multiple preschools should make this sample size easily attainable.

**Inclusion and exclusion criteria.** For this study, inclusion criteria are adults over age 18 that are parents of preschool age children (two to five) that attend one of the 22 selected private preschools. The preschools must have more than 10 students attending their school and have a population of children whose total UTD percentage is less than 70 percent. The parent participants must read and understand the English language and be able to participate in the
entire study including the pre-test, 30 minute presentation and post-test. Exclusion criteria include parents who have other children present at the time of the intervention, as this could be a distraction. In addition, any participant who has a disease, illness, injury or congenital issue that affects mental competence will be excluded from the study. Lastly, any participant who has a learning disability that affects their ability to take a written test or absorb information will be excluded from the study as this could affect their ability to increase their knowledge independent of the true effectiveness of the educational intervention.

**Demographic data.** No demographic data will be collected on participants so as to assure them that their information is truly confidential. Identification will be solely based on ID numbers that will be different for each individual, but the same for each matched pre-test and post-test. Demographic data was deemed unnecessary for this study as the results of the study can only be generalized to a very specific subpopulation of parents with children attending private preschools in San Diego County.

**Instruments.** For this study, two instruments will be used to assess vaccine knowledge as well as willingness to vaccinate. The first tool was developed by Zingg and Siegrist (2012) to evaluate parental knowledge of vaccines (Appendix D). An eleven question survey, the authors found that their tool had a Loevinger’s scalability coefficient of $H = .48$, and a reliability of $p = .80$. Therefore this tool has been deemed usable in a previous study (Zingg & Siegrist, 2012).

The second tool that will be used is one developed in 2012 and utilized in a study in 2014 by Pelullo, Marino, Abuadili, Signoriello and Attena. The authors developed individual questionnaires to evaluate various attitudes towards vaccination, including willingness to vaccinate (Appendix E). While the authors of this study did not publish the validity and reliability statistics of their instruments, they did state that the questionnaire was developed and
pilot tested before use. Their likert scale question regarding vaccination will be used to assess willingness to vaccinate before and after the educational intervention (Pellulo et al., 2014).

**Data Collection and Management**

After attending the ethics class given by the Institutional Review Board, approval will be sought by the board itself for permission to perform the study at the chosen locations. Informed consent will then be obtained from the parents who attend the educational intervention and participate in the study. Pre-tests and post-tests will be handed out together before the educational intervention has begun. The pre-test will then be administered immediately before the intervention is started, and will then be collected by the researcher/educator. They will be placed immediately into an envelope, which will be kept on the researcher’s person until the end of the intervention. The participants will then sit for the 30-minute educational intervention. Upon completion of the educational program, participants will be asked to complete the post-test, which will contain the same questions as the pre-test. The post-tests will then be placed in a separate envelope and kept on the investigator’s person. All pre-tests and post-tests from all the sites will be kept in a locked box at California State University San Marcos so as to ensure confidentiality.

**Data Coding.** As previously stated, participants will be known only by the coordinated ID number that will be placed on each matching pair of pre-test and post-test. ID number will be the first column entered into SPSS 20 to identify participants. Knowledge will not need to be coded for as it will be represented by a raw test score. The variable of willingness to vaccinate will be coded according to likert scale answers (0 = strongly disagree, 1 = disagree, 2 = neutral, 3 = agree, and 4 = strongly agree).
**Statistical Analysis.** A paired T test will be used in SPSS 22 to determine the T-statistic for each set of data regarding knowledge and willingness to vaccinate. Matched pair T-tests are used when one group is tested at two different points in time. In addition to this assumption, the measurement scale of the variables must be interval. Lastly, the data collected must be normally distributed or at least not too badly skewed. If the data collected turns out to be skewed, a Wilcoxon matched-pairs test will be used instead of a T test (Plichta & Kelvin, 2013).

**Biases**

All studies contain biases depending on the type of study and how it is conducted. In this particular study, there is the initial bias of convenience sampling. As the participants are non-randomized and simply are those parents at the selected preschools who are willing to volunteer, there is an inherent bias towards parents who are more motivated to participate in an educational study. Therefore, there may be built-in differences between these parents and the others with children attending these preschools. In addition, there is a high likelihood of response bias due to the passion of the researcher/educator on the topic of childhood vaccination. With this bias, participants wish to please the researcher and therefore respond to the intervention in favor of what they believe the researcher is looking for in an outcome. Lastly, in most studies there is the possibility of the Hawthorne effect. This effect is one seen where participants that are aware they are part of a study alter their behavior, or in this case their answers on their tests due to the fact that they are part of a study (Polit & Beck, 2012).

**Limitations**

Limitations of this study are mostly related to generalizability. Because the sample is taken from a very specific population in one particular region, the results will not be generalizable to a large population. The study will need to be replicated in various populations.
for it to be widely generalizable and therefore for the results to be seen as truly important. However, this study is easily replicable making future generalizability a good possibility.

**Threats to Internal Validity**

Threats to internal validity are variables outside of the study that could potentially affect the dependent variables. In the case of this study, previous experiences with vaccination and outside misinformation on vaccines are potential threats to internal validity. While participants may truly increase their knowledge due to the intervention, they may still be unwilling to vaccinate their children due to fear acquired by outside information from individuals with greater emotional pull, or by previous experiences with vaccination that were unsavory. These potential threats cannot be controlled for and therefore will remain threats to the study’s outcomes. In addition, the IQ and learning capabilities of participants could also be threats to the internal validity of this study. This will be controlled for by looking simply at the change in the positive direction for both knowledge and willingness to vaccinate for each subject as opposed to how high each participant scores on the pre-test or post-test (Polit & Beck, 2012).

**Ethical Considerations**

This study involves a sample of participants that are older than 18-years-old, and most likely are not impoverished or vulnerable populations, as their children are able to attend private preschools. In addition, the ethical class provided by the IRB will be attended before the study is carried out. Approval will have been gotten from the IRB to perform the study therefore safeguarding the fact that the study design will have been deemed ethical beforehand.

At the time the study is enacted, informed consent will be collected from every individual that chooses to participate in the study. All participant data collected will be kept confidential by not collecting participant’s names or demographic information. Lastly, the pre-tests and post-
tests that are collected will be kept in a locked location at California State University San Marcos.

Conclusion

With once eradicated diseases making a comeback in the United States, vaccinations have become a priority for healthcare providers and researchers alike. The importance of immunizations is such that vaccine coverage is one of the many goals set by Healthy People 2020. With the concept of herd immunity in mind, the Office of Disease Prevention and Health Promotion set childhood vaccine coverage goals for 2020 at 90 percent (HealthyPeople.gov, 2014).

While it is common knowledge in the medical community that underimmunization is a serious public health problem, it is not known how to go about changing the minds of parents who are inundated daily with misinformation from the media and popular celebrities. The damage done by the campaigns such as “Green Our Vaccines”, and the erroneous data of Dr. Wakefield linking autism to vaccines has made the task of reeducating the public extremely difficult (How the anti-vaccine movement is endangering lives, 2014). However, it is likely that it begins with bringing the truth to the people who make the decisions for a large portion of the population: parents.

The answer to the issue of inadequate vaccine coverage will be one of great proportion. However, as is often the case, the solution to this problem must be researched in smaller populations before it can be applied to the entire country. It is this concept that drives the previously discussed research proposal. If using an educational intervention is effective in increasing knowledge and willingness to vaccinate in the selected population, this research design can then be replicated in other populations. While an effective outcome in this study may
seem small, it could be the beginning of meeting the countrywide goal of 90 percent vaccination coverage, and most importantly saving millions of lives.
Chapter 4: Grant Elements

Potential Grants and Feasibility

There are many grants available for public health topics such as vaccination. The following are three grants that were considered for this particular project.

Office for the Assistant Secretary for Health. A second possible grant is one provided by the Department of Health and Human Services. All applicants except those engaging in lobbying activities are eligible for this grant. The grant itself is giving to projects that foster transparent, accurate, and appropriate information and communication regarding vaccines and vaccination (Grants.gov, 2016).

This grant is very feasible for this particular project. All of the necessary eligibility criteria are met, and the grant application is easily accessible through grants.gov. The only reason that this grant was not chosen is that the award floor is set at $200,000, which is more than is necessary for the project at this stage.

National Institute of Health Small Research Grant Program. This program, run by the Department of Health and Human Services, is meant for small research projects that are self-contained. In addition, they are aimed at studies that can be completed in two years and have limited levels of necessary funding. This particular grant opportunity is certainly feasible for this particular study. The project is small, with minimal paid personnel, and the definite ability for the research to be finished within two years. However, this grant program requires applicants to meet the research subject needs of existing Institutes and Centers (I&Cs) within the National Institute of Health (NIH, 2016).

The downfall of this grant is that this particular study does not perfectly fit the subjects of any one Institute and Center. The two I&Cs that relate to the topic of vaccinations are the
National Institute of Allergy and Infectious Disease, and the National Institute of Child Health and Human Development. While there is a possibility that this grant would be awarded to this study, there is a grant that is a far better fit (NIH, 2016).

**Pfizer Independent Grants for Learning & Change.** Provided by Pfizer Pharmaceuticals has a specific grant under the Independent Grants for Learning & Change that relates directly to the goal of this research study. The clinical area is specified as Pediatric Immunization. This grant is meant to provide researchers with financing for studies that focus on improving immunization series completion in communities that have low rates of vaccine completion. The grant description states that studies related to system-based changes and educational efforts for providers and/or patients, are both acceptable.

This grant is not only feasible, but absolutely perfect for this study on pediatric immunization. Every stipulation is met, and it is very possible that the grant would be awarded for this research study. For this reason, this grant was chosen over those previously discussed (Pfizer, 2015).
## Detailed Budget for Initial Year of Study

<table>
<thead>
<tr>
<th>Budget Category</th>
<th>Dollar Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Personnel</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Salary</strong></td>
<td></td>
</tr>
<tr>
<td>Principal Investigator/Educator (~70-75 hours @ $70.00/hr)</td>
<td>$5,000</td>
</tr>
<tr>
<td>Benefits (48% salary)</td>
<td>$2,400</td>
</tr>
<tr>
<td>Research Assistant (~50 hours @ $20.00/hr)</td>
<td>$1,000</td>
</tr>
<tr>
<td>Benefits (48% salary)</td>
<td>$480</td>
</tr>
<tr>
<td><strong>Consultants</strong></td>
<td></td>
</tr>
<tr>
<td>Statistician (20 hrs @ $150/hr)</td>
<td>$3,000</td>
</tr>
<tr>
<td><strong>Subtotal Personnel</strong></td>
<td>$11,880</td>
</tr>
<tr>
<td><strong>Materials &amp; Supplies</strong></td>
<td></td>
</tr>
<tr>
<td>Printing (~2,000 pages @ 0.10 per copy)</td>
<td>$200</td>
</tr>
<tr>
<td>Pens, large opaque envelopes (240 @ 60/$5.00 &amp; 50 @ 50/$20.00)</td>
<td>$40</td>
</tr>
<tr>
<td>Continental breakfast platters from Panera Breads (22 @ ~$150.00)</td>
<td>$3,300</td>
</tr>
<tr>
<td>Portable multimedia projector</td>
<td>$150</td>
</tr>
<tr>
<td><strong>Subtotal Materials &amp; Supplies</strong></td>
<td>$3,690</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
</tr>
<tr>
<td>Domestic Travel (gasoline for employees)</td>
<td>$500</td>
</tr>
<tr>
<td>IRB Fees</td>
<td>$1,000</td>
</tr>
<tr>
<td><strong>Subtotal Other</strong></td>
<td>$1,500</td>
</tr>
<tr>
<td><strong>TOTAL DIRECT COST</strong></td>
<td>$17,070</td>
</tr>
<tr>
<td>Indirect Costs (@10%)</td>
<td>$1,707</td>
</tr>
<tr>
<td><strong>TOTAL COSTS</strong></td>
<td>$18,777</td>
</tr>
</tbody>
</table>
Budget Justification

Personnel

Marisa Deptala, R.N, BSN. Marisa Deptala will serve as the principal investigator and educator on this research study. She is a registered nurse who at the time of the study will be a certified family nurse practitioner after finishing her MSN at California State University, San Marcos in May 2016. She has a background in progressive care unit/telemetry nursing, and urgent care nursing. The research study was the subject of her thesis for her graduate degree.

Marisa Deptala will be responsible for Institutional Review Board presentation, as well as the overall direction of the project, and actual presentation of the educational intervention. Marisa Deptala will be provided with $5,000 in compensation for the approximately 70-75 hours of work that is estimated to be necessary to complete the first stage of this project. She will also receive benefits at the suggested CSU San Marcos cost of 48 percent.

One research assistant will be selected from those that apply from the California State University San Marcos School of Nursing. The assistant will be provided with $1,000 for the approximately 50 hours of work that is estimated to be necessary for this position. The selected assistant will also receive benefits of 48 percent of salary.

Consultant

The only consultant that will be hired for this research study is a research statistician. The statistician will assist in the statistical design, methods, and techniques necessary to analyze the collected data. The technician will receive $150/hr for a total of 20 hours.

Material and Supplies

Materials include office supplies including pens, all of the copies of the consent forms, pretests, posttests, and flyers, and the envelopes to hold the consent forms and tests from each
site. In addition, a portable multimedia projector will be purchased in case none are available at the preschool sites for the presentation. Lastly, supplies will include a variety of breakfast foods and coffee provided by Panera Breads to provide as incentive for the short educational intervention.

**Domestic Travel**

As all of the private preschools are located in San Diego, the only compensation necessary for travel is money for gasoline for car communicating. An estimate of $500 has been provided for total travel expenditure.

**IRB fees**

The Institutional Review Board (IRB) is necessary to protect the rights and welfare of human research subjects. All studies involving human subjects must be presented to the IRB and receive permission to perform the research study in question. This process has fees associated with it.

California Department of Public Health. *2013-2014 Child Care Assessment Results*. Retrieved from


CDC. (2014). “Measles Cases and Outbreaks”. Retrieved from

http://www.cdc.gov/measles/cases-outbreaks.html


http://www.grants.gov/web/grants/search-grants.html


http://nursing.umich.edu/faculty-staff/nola-j-pender


Philadelphia: Wolters Kluwers, Lippincott Williams & Wilkins.


Appendix A

Nola Pender’s Health Promotion Model
Research Design

Single Group Pre-test/Post-test One-Time Intervention

Non-randomized Sample

$O_1 \ Y \ O_2$

$O_1$ = pre-test
$X$ = educational intervention
$O_2$ = post-test
Appendix C

G*Power Calculation of Sample Size

![G*Power screenshot](image-url)
**Appendix D**

**Knowledge Questionnaire**

<table>
<thead>
<tr>
<th>Items</th>
<th>Response distribution</th>
<th>Item scalability</th>
</tr>
</thead>
</table>
| 1. Vaccines are superfluous, as diseases can be treated (e.g. with antibiotics. (-)) | Study 1: 75% correct, 17% incorrect, 8% do not know
                      Study 2: 84% correct, 6% incorrect, 10% do not know | $H_L = .44$       |
| 2. Without broadly applied vaccine programs, smallpox would still exist. | Study 1: 75% correct, 7% incorrect, 18% do not know
                      Study 2: 85% correct, 5% incorrect, 10% do not know | $H_L = .48$       |
| 3. The efficacy of vaccines has been proven.                          | Study 1: 73% correct, 12% incorrect, 15% do not know
                      Study 2: 77% correct, 9% incorrect, 14% do not know | $H_L = .53$       |
| 4. Children would be more resistant if they were not always vaccinated against all diseases. (-) | Study 1: 43% correct, 36% incorrect, 21% do not know
                      Study 2: 46% correct, 35% incorrect, 19% do not know | $H_L = .46$       |
| 5. Diseases like autism, multiple sclerosis, and diabetes might be triggered through vaccinations. (-) | Study 1: 35% correct, 16% incorrect, 50% do not know
                      Study 2: 44% correct, 12% incorrect, 44% do not know | $H_L = .39$       |
| 6. The immune system of children is not overloaded through many vaccinations. | Study 1: 30% correct, 30% incorrect, 40% do not know
                      Study 2: 36% correct, 23% incorrect, 42% do not know | $H_L = .44$       |
| 7. Many vaccinations are administered too early, so that the body's own immune system has no possibility to develop. (-) | Study 1: 24% correct, 40% incorrect, 37% do not know
                      Study 2: 29% correct, 34% incorrect, 36% do not know | $H_L = .48$       |
| 8. The doses of the chemicals used in vaccines are not dangerous for humans. | Study 1: 24% correct, 37% incorrect, 39% do not know
                      Study 2: 26% correct, 44% incorrect, 29% do not know | $H_L = .42$       |
| 9. Vaccinations increase the occurrence of allergies. (-)            | Study 1: 24% correct, 35% incorrect, 41% do not know
                      Study 2: 33% correct, 31% incorrect, 36% do not know | $H_L = .41$       |
| 10. By means of gene technology, vaccinations that feature fewer side effects can be produced.* | Study 1: 31% correct, 13% incorrect, 56% do not know
                      Study 2: 43% correct, 9% incorrect, 48% do not know | $H_L = .53$       |
| 11. Vaccinations cannot generate the diseases they are meant to prevent.* | Study 1: 30% correct, 41% incorrect, 28% do not know
                      Study 2: 27% correct, 48% incorrect, 25% do not know | $H_L = .48$       |

(Zingg & Siegrist, 2012)
Appendix E

Willingness to Vaccinate Questionnaire

Table 3
Parents’ attitudes and beliefs about vaccinations, Italy, 2013 (n=1,039)

<table>
<thead>
<tr>
<th></th>
<th>I am favourable toward vaccination</th>
<th>Vaccinations are safe</th>
<th>Vaccinations are effective in reducing the risk of disease</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Agree strongly</td>
<td>617</td>
<td>59.4</td>
<td>500</td>
</tr>
<tr>
<td>Agree somewhat</td>
<td>370</td>
<td>35.6</td>
<td>466</td>
</tr>
<tr>
<td>I don’t know</td>
<td>12</td>
<td>1.1</td>
<td>15</td>
</tr>
<tr>
<td>Disagree somewhat</td>
<td>32</td>
<td>3.1</td>
<td>37</td>
</tr>
<tr>
<td>Disagree strongly</td>
<td>8</td>
<td>0.8</td>
<td>21</td>
</tr>
<tr>
<td>Totala</td>
<td>1,039</td>
<td>100</td>
<td>1,039</td>
</tr>
</tbody>
</table>

Notes: Numbers for each item may not sum to the total study population because of missing values.

Table 2
Parents’ intentions to vaccinate their children, Italy, 2013 (n=1,039)

<table>
<thead>
<tr>
<th>Would you immunise your child if vaccination were not mandatory?</th>
<th>n</th>
<th>%</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certainly</td>
<td>721</td>
<td>69.4</td>
<td>66.6–72.2</td>
</tr>
<tr>
<td>Probably</td>
<td>234</td>
<td>22.5</td>
<td>20.0–25.1</td>
</tr>
<tr>
<td>Probably not</td>
<td>35</td>
<td>3.4</td>
<td>2.2–4.4</td>
</tr>
<tr>
<td>Certainly not</td>
<td>30</td>
<td>2.9</td>
<td>1.8–3.9</td>
</tr>
<tr>
<td>I don’t know</td>
<td>19</td>
<td>1.8</td>
<td>1.0–2.6</td>
</tr>
<tr>
<td>Total</td>
<td>1,039</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

CI: confidence interval for proportions.

(Pellulo et. Al, 2014)
Appendix F
IRB Application

California State University
SAN MARCOS

Application for Approval for Research Involving Human Subjects:
Full or Expedited Review

Submission Procedures:
1. The researcher completes application
2. If the researcher is a student, their faculty advisor must review the application and sign the application in IRBNet. Additional instructions can be found on the last page of this application. **
3. The researcher submits the application and accompanying documents to IRBNet. http://www.csun.edu/ocr/irb/forms.html

For assistance completing this form, please review the resources located at www.csun.edu/irb.
If you have any questions, please refer to the IRB website or contact the IRB staff at (760) 750-4029 or irb@csun.edu.
Please answer each section completely and as concisely as possible. Use lay terms as IRB members have diverse backgrounds.

- [ ] Full Review
- [ ] Expedited Review
Projected Start Date: July, 2016

Project Title: The Effectiveness of an Educational Intervention in Increasing Parental Knowledge and Willingness to Vaccinate

Faculty/Staff Investigator:

<table>
<thead>
<tr>
<th>Name</th>
<th>Susan Andera</th>
<th>Department/College</th>
<th>School of Nursing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone Number</td>
<td></td>
<td>E-mail</td>
<td></td>
</tr>
<tr>
<td>Date CITI Completed</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Student Investigator: (If the student is the primary investigator) **

<table>
<thead>
<tr>
<th>Name</th>
<th>Marisa Depta</th>
<th>Department/College</th>
<th>School of Nursing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone Number</td>
<td>805-448-5570</td>
<td>E-mail</td>
<td><a href="mailto:brickwork@cougars.csun.edu">brickwork@cougars.csun.edu</a></td>
</tr>
<tr>
<td>Date Training Completed</td>
<td>Jan 6, 2016</td>
<td>CITI</td>
<td>IRB Workshop</td>
</tr>
</tbody>
</table>

Faculty Advisor Name: Susan Andera | Department/College: School of Nursing

| Phone Number  | 805-448-5570                  | E-mail             | brickwork@cougars.csun.edu |
| Date CITI Completed | Jan 6, 2016                |                    |                   |

Checklist: Check which of the following items are included, as applicable:

- [ ] Certification of Human Subjects Protection training for each researcher and the faculty advisor.
- [ ] Letter/email of organizational support (Required if recruiting or interacting with participants at a specific site or through a specific organization outside of CSU). If sent in an email, must include organization and position of the person who approved.
- [ ] Recruitment flyer(s) or advertisements, scripts for radio or TV.
- [ ] Survey(s), questionnaires, or interview questions. If this is an online survey, please provide a pdf copy of the survey.
- [ ] Consent and/or child assent form(s) or information sheet(s). For online surveys, provide a pdf copy of the introduction/information screen(s).
  1. Provide unique forms for each population in your research.
  2. Use official letterhead or the masthead found in the samples on the IRB website.
  3. Include contact information for the Researcher, faculty mentor, and IRB office.
  4. Be sure the information in your consent/information sheet MATCH your application information.
- [ ] Students Researchers ONLY: Faculty advisor has approved the project and has signed the application in IRBNet.
- [ ] Ed. D Students ONLY: Attach the required UCSD-CSUSM-JDP IRB Cover Sheet. Please be sure to sign the form, scan it, and submit it with your application as a separate document.

Revised 10/13/2015    Page 1
1. Purpose of Project and Project Background

Describe your research question, including why the question is important, and how your study will attempt to answer it. Include how your literature review supports this with at least three citations. (Do not exceed one page—Use lay language.)

Vaccine preventable diseases have been making a come back in the United States in the past decade. Research suggests that the outbreaks of Pertussis and Measles that the U.S. has been experiencing are due to small pockets of unvaccinated individuals. Misinformation from the media and celebrities who are part of the Anti-Vaccine movement are driving parents to question immunization, and therefore choose to undervaccinate their children or even keep them from being vaccinated at all. This proposed study’s aim is to introduce an educational program on childhood vaccines so as to provide parents with accurate information on vaccine preventable diseases and the benefits of being immunized.

2. Recruitment Procedures & Participant Population

A) List the expected number of participants for each population group included in this study. 156

B) Describe all characteristics relevant to being selection of participants. (e.g., demographics, ethnicity, vulnerabilities, etc.) Explain why you are targeting this specific population.

The educational intervention and data collection will occur at the facilities of 22 private preschools around San Diego County that state they are willing to participate. Consent, pre-test, intervention, and post-test will all occur at a one-time administration at each facility. The preschools must be willing to donate their space, as well as childcare during the time that the intervention will be performed. Therefore, it is likely that the educational program and data collection will occur during normal school hours. Participants will be given information on how they can access the results of the study once it has been completed.

The target population for this study includes parents (male or female) of preschool age children at one of the selected private preschools in San Diego County. This population was chosen as each of the preschools has a UTD percentage less than 70 percent, and therefore it is likely that many of the parents at these schools are vaccine hesitant. In addition, in San Diego County, the highest percentage of unvaccinated students is in the group that attends private schools (California Department of Public Health, 2014). Therefore private preschools, where the children attending are generally aged two to five, were chosen so as to attempt to gain the greatest good in providing an educational intervention and potentially increased vaccinations in young children who could be “caught up” in their vaccines.

For this study, inclusion criteria are adults over age 18 that are parents of preschool age children (two to five) that attend one of the 22 selected private preschools. The preschools must have more than 10 students attending their school and have a population of children whose total UTD percentage is less than 70 percent. The parent participants must read and understand the English language and be able to participate in the entire study including the pre-test, 30 minute presentation and post-test.
C) Indicate whether anyone might be excluded from participating and explain why.

Exclusion criteria include parents who have other children present at the time of the intervention, as this could be a distraction. In addition, any participant who has a disease, illness, injury or congenital issue that affects mental competence will be excluded from the study. Lastly, any participant who has a learning disability that affects their ability to take a written test or absorb information will be excluded from the study as this could affect their ability to increase their knowledge independent of the true effectiveness of the educational intervention.

D) How will you find, recruit, or identify potential subjects? How will you select, from the volunteers, the final group of participants? Submit flyers, posters, or other oral or written invitations used to recruit potential participants.

The participants for this study will be recruited on site at each of the 22 chosen private preschools. The preschools were chosen based on data provided by shotsforschool.org, a website developed by the California Department of Public Health that provides information on the up to date (UTD) vaccination percentages of children attending certain schools. The 22 selected preschools were chosen based on the criteria that they had greater than ten students, and their mean UTD percentage was less than 70 percent (shotsforschools.org, 2014). Approval will be sought from those in charge at the preschools to not only gain access to the parents with children enrolled at their school, but also so that they can collaborate in recruiting parents to participate in the study. Written invitations will be provided to the preschools to offer to parents regarding voluntary participation in the study.

E) Will you be offering an incentive?

☐ Yes ☐ No

If yes, please explain procedure for any incentives that will be offered. Include how much participants must do to be eligible to receive credit.

The incentive to participating in the study will simply be providing coffee and refreshments during the educational intervention itself. Any parent who is present for the intervention will be allowed to partake in consumption of the provided food and beverages.


   Explain for each population participating in your research.
   See the IRB web page on Informed Consent. See also Language Requirements.

A) How and when will you explain the study and the required elements of Informed Consent? Will you be doing this or will it be handled by a research assistant?

A research assistant will be present at each site to aid in the dispersal and collection of any handouts or forms. Each parent who presents for the educational intervention will first be given a handout that explains the study. This handout will be kept by each participant so that they may refer to it in the future if they wish to contact the researcher about results or publication. In addition to the handout, an informed consent will be provided and each participant will be expected to provide a signature. These forms will be collected for proof of informed consent.
B) How much time will participants have to consider participating between the explanation described above, the receipt of the consent document, and the beginning of study?

The participants will have approximately 10 to 15 minutes to read over the handout and sign the informed consent before the educational intervention will begin. If they choose not to participate in the study after reading the description, they may leave at this time. This may vary per site as the intervention will formally begin when all informed consents have been collected.

C) If there are subjects under the age of 18, how will the study be explained to them? How will parental consent and child assent be handled?

No subjects under 18 will be allowed to participate in this study.

D) If you are requesting a Waiver of Consent or a Waiver of Documentation of Consent, explain why this waiver is needed. Outline alternative procedures for obtaining consent or providing study information (e.g., information sheet, introduction screen for web survey, etc.).

N/A

E) Indicate the primary language(s) of your participants. If any participants’ is not fluent and comfortable with English, explain how you will ensure that participants’ understanding of the activity for which they are giving consent.

The primary language of the participants will be English. If the participant is not comfortable with English, they will be excluded from participating in the study.

4. Procedures and Methodology

Provide descriptions of each distinct procedure and each population group.

A) Provide a step-by-step explanation of your research activities and methodologies that involve human subjects. Be thorough.

The participants in this study will be subjected to a pre-test and post-test that is approximately 14 questions in length. In between these tests, they will be expected to sit for a 30 minute educational intervention that provides information on childhood vaccines, the diseases they prevent, the misconceptions surrounding vaccines, and the true typical side effects of vaccines. No invasive intervention will be applied.
B) Where will the research be conducted? Describe any risks or confidentiality issues related to using this location.

The educational intervention and data collection will occur at the facilities of 22 private preschools around San Diego County that state they are willing to participate. Consent, pre-test, intervention, and post-test will all occur at a one-time administration at each facility. The preschools must be willing to donate their space, as well as childcare during the time that the intervention will be performed. Therefore, it is likely that the educational program and data collection will occur during normal school hours. The confidentiality issues related to using this location is that many of the participants will likely know each other. However, both the pre-tests and post-tests will be collected by the research assistant and immediately placed in an envelope so that participants answers will be kept confidential. In addition, pre-tests and post-tests will be passed out together with each set being assigned an ID number. This number will be the same for the pre-test and post-test that corresponds with each individual participant. Once collected, these documents will not be associated with any participants name or demographic information. Therefore neither outsiders or the researcher will be able to identify whom the pre-tests and post-tests belong to.

C) State the specific dates/timeframe in which you plan to conduct your research.

5. Participant Debriefing or Feedback.
   If deception is involved in your research, participants should be debriefed about the nature of the study as soon as possible. Participants should be given the opportunity to request a copy of the results of the study/your final report.

A) Describe any feedback or information you will offer participants.

As there is no deception in this study, a debriefing will not be necessary. However, participants will be given cards with contact information so as to request results of the study.

6. Risks
   List risks for each population participating in the research and for each methodology. Please be sure the risks listed here match the risks mentioned in your consent letter or information sheets. Consider all risks very carefully. For more information on risks, see Examples of Risk.

A) Explain potential risks to your participants. Risks may be physical, psychological (e.g., strong emotional reactions to research questions), or inconveniences (e.g., time required).

In this study, there will be few risks for any parents who choose to participate. There will be the inconvenience of time as the educational intervention itself will be approximately 30 minutes. Luckily, with the site being at each individual preschool, this should not be an inconvenience. Due to the current controversial nature of vaccinations in the United States, the most likely risk other than time constraints will be strong emotional reactions to the information presented. While all information will be presented in a factual manner, there is the possibility that disagreement could occur.
B) Vulnerable Subjects: Select which, if any, of the following vulnerable subjects will be involved in your research.

- Pregnant women, human fetuses, neonates (see Federal Guidelines, 45CFR26, subpart B)
- Prisoners (see Federal Guidelines, 45CFR26, subpart C)
- Children (see Federal Guidelines, 45CFR26, subpart D)
- Other Vulnerable Populations such as persons with cognitive disabilities, economically or educationally disadvantaged persons, etc.

C) Describe and special risks to vulnerable populations or your population profile

There is the possibility that pregnant women will participate in this study. However, as this study's intervention is educational and will not include any invasive procedures, there are no special risks to this population.

D) List risks related to confidentiality of data. What could happen if an unauthorized person accessed the data? For instance, participant's identify or personal information could be known by others

As previously stated, the pre and post-tests will not include names but will instead be linked by identification number. Therefore an unauthorized person accessing the data would not allow them to gain any knowledge on any of the participants.

E) Will any personal identifying data be recorded? If so, what information will be recorded? (e.g., Social security number, drivers license number, student id, address, phone number, birth date, personal email address)

No. No personal identifying data will be collected.

7. Safeguard Procedures to Minimize Risks.

A) Please respond to each risk that you listed in #6 above. State how you will minimize each risk and protect confidentiality.

As previously stated, the information provided in the educational intervention will presented in the most succinct, direct, and factual manner as possible to avoid time constraints and emotional distress.

B) How you will safeguard data? Where/how will data be stored? Who will have access to the data? How will access be limited?

Collected tests will be placed immediately into an envelope and sealed. They will then be kept in a locked box at California State University San Marcos before and after data is analyzed.
C) List referrals and/or resources that may be offered if a participant has a strong emotional response or a physical injury (e.g., clinics or shelters, medical or psychological referrals).

Due to the nature of this study, it is extremely unlikely that either of these possibilities will occur. However, participants will be informed at the beginning of the study that if they begin to feel at all offended or uncomfortable that they are allowed to ask questions or even excuse themselves from the study.

8. Study Benefits

A) Discuss any potential individual and/or societal benefits. Note, often there is no direct benefit for the participants. However, the study may contribute to the literature and/or future research.

The purpose of this research is to study the effects of an educational intervention regarding vaccinations in parents of preschool age children in San Diego County. The hope is that providing parents with accurate information on vaccinations and dispelling myths regarding them will increase individual knowledge and willingness to vaccinate. If increased knowledge and willingness occurs on an individual level, it is possible that further studies could lead to increased immunization coverage across the United States. According to evidence-based practice outcomes, “for each birth cohort that is immunized with the standard schedule, 33,000 lives are saved, 14 million cases of disease are prevented, healthcare costs are reduced by $9.9 billion, and $33.4 billion in indirect costs are saved “ (Gromek, 2013).

B) Do the benefits from this study exceed the risks to participants? Please explain.

Yes. As already state, the design of this study leaves very little room for risk to participants. However, the benefits could potentially lead to further studies that save thousands of lives and millions of dollars.

9. Researcher(s) qualifications and experience.

A) Briefly outline the primary researcher(s)’s qualifications and experiences relative to the subject of this research.

I am a master’s student at California State University of San Marcos as well as a registered nurse. I have had education on vaccination schedules as well as their importance. In addition, I will have the support of two professors who are doctorally educated.
B) If this is a student project, include faculty sponsor's qualifications.
Susan Andera has a doctorate in nursing practice and is a faculty member at the California State University, San Marcos.

C) If using student or research assistants, please state how you will ensure that these assistants are trained and qualified to assist. All assistants should complete the CITI training on the protection of human participants in research.
Any research assistants will be used simply to help set up intervention sites, to help participants sign consents, assemble refreshments, and collect pre-tests and post-tests. They will all be expected to complete CITI training.