Program and Evaluation Plan:

An Intervention to Increase Childhood Vaccination Rates in the Chapel Hill Area

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Abstract

Childhood vaccination rates in North Carolina are currently well below the rate needed to confer herd immunity. As a result, there were three measles outbreaks in the State in 2013. The goal of this intervention is to increase vaccination coverage for children aged 19-35 months through an educational program for parents who initially refuse vaccination in the Chapel Hill area.

This paper provides the program and evaluation plans for the intervention. It opens with a systematic review of the literature, addressing similar interventions and their evaluation. The program plan addresses the development of the intervention; its goals and its implementation. The evaluation plan is a way to assess whether the intervention is being implemented as planned, as well as the efficacy of the intervention. The paper is a guide to the development, implementation and evaluation of the intervention, and provides an approach to dissemination.

Introduction

Childhood vaccination has been a controversial issue for many years. The controversy intensified in 1998 when the Lancet published a study by Andrew Wakefield linking the measles, mumps and rubella (MMR) vaccine to colitis and autism spectrum disorders (Wakefield). This study has since been declared fraudulent and retracted because Wakefield had manipulated evidence for personal and financial gain; his medical licence was revoked (Godlee, Smith and Marcovitch).

Scientific and medical societies have systematically rejected these findings, but the media has propagated the findings of Wakefield's original paper. Fiona Godlee, the editor of the BMJ, states that "The original paper has received so much media attention, with such potential to damage public health, that it is hard to find a parallel in the history of medical science. Many other medical frauds have been exposed but usually more quickly after publication and on less important health issues" (Godlee). Multiple studies examining the link between childhood vaccines and autism have been conducted; none support the link. Vaccines are considered safe and effective ("Vaccine Safety").

There are laws in place to encourage parents to vaccinate their children. In order to attend day care or school in North Carolina, children must receive all of the doses of vaccines protecting against 10 diseases. This is mandated by the North Carolina Immunization Law (Orange County; "School Vaccination Requirements"). The 10 diseases are: diphtheria, tetanus, pertussis, hepatitis B, influenza, measles, mumps, rubella, polio, and varicella ("School Vaccination Requirements").

Despite this law, not enough children are vaccinated. As of 2007, 77.3% of children aged 19-35 months had met the State requirements for vaccination coverage. As of 2012, this number

dropped to 76.2%. These numbers are well below the target of 91.3% (North Carolina Institute of Medicine). As a result of the gap in coverage, there have been several outbreaks of preventable diseases. In 2013, there were 3 measles outbreaks in North Carolina alone. All of the outbreaks were in Orange County; almost all of the cases were in unvaccinated individuals (Iannelli). This highlights a need to increase childhood vaccination rates in the Chapel Hill area. The intervention outlined in this paper could potentially increase vaccination coverage for children in the Chapel Hill area.

The purpose of this paper is to describe a program and evaluation plan for an intervention that aims to increase childhood vaccination rates by changing the knowledge, attitudes, and behavior of parents who do not wish to vaccinate their children. The first section of this paper is a systematic review. Four articles are included in the review. They all examine the implementation and evaluation of educational programs geared towards parents who refuse routine vaccinations for their children. The second section focuses on the program plan. This section covers the background and the context for the intervention. Theory frameworks that relate to the intervention are presented, followed by the goals and objectives. The section concludes with the activites involved in the program implementation. The third section is the evaluation plan. It opens with the rationale and approach to evaluation. The evaluation design and methods are then presented, followed by the evaluation planning tables. This section ends with a discussion of the ethical issues involved in the evaluation and the plan for dissemination. This program may serve as a template for an intervention that other pediatric clinics can use to increase childhood vaccination rates.

Systematic Review

Introduction

The purpose of this literature review is to identify programs developed with the goal of increasing childhood vaccination rates. I will specifically look into educational programs, as opposed to policy changes. The successes and failures of these programs will help guide the development of my program; I want to build on what has already been done if possible.

Methods

Research Question:

My research question for this literature review is: What educational programs geared towards parents who refuse routine vaccinations for their children have previously been implemented and evaluated?

Search Strategy:

A search was performed in PubMed using the terms: "(vaccine OR vaccination) AND (parent OR parents) AND (education OR intervention OR program OR instruction OR teach) AND (evaluation OR effective OR effectiveness) NOT HPV". This yielded 423 results.

To narrow the search to programs in developed countries, I used the list of search terms for low and middle income countries provided by Mellanye Lackey; I will refer to this list as the LMIC list. This list can be found on the "Global Health Toolkit" page of the UNC Health Sciences Library website ("Global Health Toolkit"). I then performed another search using the terms: "(vaccine OR vaccination) AND (parent OR parents) AND (education OR intervention OR program OR instruction OR teach) AND (evaluation OR effective OR effectiveness) NOT HPV" NOT the LMIC list. This narrowed the search to 268 articles, of which 246 were in English.

Based on titles and abstracts, there were 7 articles that met the inclusion and exclusion criteria, listed below (Bjornson, Scheifele and Gold; Gowda et al.; Gust et al.; Jackson et al. "Randomised cluster trial"; Mayer, Housemann and Piepenbrok; Shourie et al.; Suryadevara et al.). The Suryadevara article presents an evaluation of their intervention's effectiveness; however, no details are provided about what the "education intervention" entails so this article was not included in the literature review. The Gust article was omitted because it focused on comparing the attitudes of parents who want an exemption to the attitudes of parents who want to vaccinate their children. The authors briefly addressed the effectiveness of presenting the parents with a brochure, but that is not in line with the intervention that I wish to develop. The intervention in the Mayer article aimed to increase access to vaccines, which is not a factor that I will address in this intervention.

Inclusion criteria were that (a) the study was performed in the USA or another developed country, and (b) the children were considered generally healthy (that is, not severely mentally or physically ill or immunocompromised).

Articles were excluded if they (a) were about the human papilloma virus, (b) were performed in developing or low income countries because of differences in resources and baseline knowledge of parents, (c) were about teenagers or children older than 5 years, which is the cut off for kindergarten, or (d) involved education as part of home visits, because those are not done in this country and the visits are done by nurse-midwives in other countries. There were no restrictions on the year published.

Articles to be used:

I will use the following four articles for my literature review: Shourie et al; Jackson et al. "Randomised cluster trial"; Gowda et al; and Bjornson et al. A summary table of these studies is provided in the Appendix.

Results

Article 1: Shourie et al.

The first article is titled "A cluster randomised controlled trial of a web based decision aid to support parents' decisions about their child's Measles Mumps and Rubella (MMR) vaccination" by Shourie and colleagues.

Program Description:

This study was conducted in order to determine the effectiveness of an online decision aide versus a pamphlet versus usual care in increasing first-time parents' informed decision about vaccinating their child against MMR. The administration of the first MMR vaccine was a secondary outcome measure.

Participants were recruited through five Primary Care Providers in northern England between May 2009 and September 2010. A total of 220 first time parents with children 3-12 months old who were being offered the first time dose of the MMR vaccine were recruited. There were 50 parents in the decision aid arm, 93 in the pamphlet arm, and 77 in the control arm. Parents were included if they reported that they were "hesitant" about vaccinating their child or if they prefered an alternative vaccine schedule.

The program consisted of three arms: the first was an online decision aid and usual care; the second was a pamphlet and usual care; and the third was usual care. The first arm was the intervention of interest, or the cases. The online decision aid was based on the Australian MMR decision iad and modified to better fulfill the International Patient Decision Aids Standards

(IPDAS) criteria. The intervention is described in detail in a different study (Jackson et al. "Evaluating a web based decision aid"). Parents were given the link to the web-based decision aid as well as a personal username and password.

The IPDAS instrument is an internationally validated tool that is often used to assess the quality of decision aids. The IPDAS Checklist is comprised of 10 quality dimensions, each with their own specific criteria. This checklist can be used to rate the quality of a decision aid (Elwyn).

The pamphlet given to the second arm was the Health Scotland leaflet titled "MMR your questions answered." Although this pamphlet does not meet IPDAS criteria, previous research by the same authors found that this pamphlet reduces decisional conflict (this will be explained in detail later) (Jackson et al. "Randomised cluster trial").

The third arm, usual care, was the control group. Based on a phone survey, the authors determined that this usually consists of an appointment for the first dose of the MMR vaccine when the child is 12-13 months and a pamphlet (usually the one listed above). Parents are also offered a consultation if they have any concerns.

Evaluation:

There were no statistically significant differences between the three groups at baseline. Most participants were educated white mothers in their early 30's who were married or in a stable relationship. All outcomes in this study were self-reported through a questionnaire, which was given prior to the intervention and 2 weeks after the intervention.

The primary outcome in this study was decisional conflict, which "assesses a parent's perception that their decision was informed, in accordance with their values, and can be acted upon." It is measured using a 16-item validated scale, with scores ranging from 1 (no conflict) to

5 (extremely high levels of conflict). A score below 2 on this Decisional Conflict Scale corresponds to informed decision making. According to the authors, a score below 2 should, in theory, correlate to a decisional conflict level that is low enough to catalyze behavior change.

Parents in the decision aid group experienced the largest reduction in decisional conflict following the intervention. Parents in both the decision aid group and the pamphlet group had a mean decisional conflict score below 2. Parents in the usual care group did not experience a change in the mean decisional conflict score.

The authors also found that higher decisional conflict post intervention was associated with higher decisional conflict pre-intervention, as well as higher anxiety and trade-off beliefs that favor the harms over the benefits of the MMR vaccine.

The secondary outcomes included knowledge about the MMR vaccine, attitudes towards vaccination against MMR, trade-off beliefs on benefits versus harms of MMR immunization, and anxiety. There were small changes in each of these variables, presented in Table 3. The most notable findings among the secondary outcomes, however, had to do with the administration of first dose of MMR vaccine: 100% in the decision aid group, 91% in the pamphlet group, and 99% in the control group chose to vaccinate their children.

The authors postulate that this is because the decision aid involved a deliberation process, where parents had to think about their child getting vaccinated versus potentially contracting the disease; this allowed parents to make an informed decision consistent with their values and attitudes. The pamphlet did not help parents to go through this deliberation process, so their decision was not as informed. Therefore the conviction of parents in vaccination was not as strong and did not lead to behavior change.

The strengths of study are that it was a randomized controlled trial and that these findings are consistent with previous research. One weakness is that vaccination administration was measured at 15 months, even though the vaccine can be administered up to 24 months by the country's standards; more time could result in increased vaccine uptake in the pamphlet and control groups. Furthermore, only 16% of the practices contacted provided parents to partake in the study and only 55% of the parents completed complete case analysis for the primary outcome. These factors increase the chances of selection bias and decrease the generalizability of the findings. For my program, I am not as concerned with the generalizability because this study focuses on the population that I would like to target.

Article 2: Jackson et al.

The second article is titled "Randomised cluster trial to support informed parental decision-making for the MMR vaccine" by Jackson and colleagues.

Program Description:

This is a cluster randomised control trial designed to evaluate the effect of a parent-centered multi-component intervention on informed decision making of parents about the MMR vaccine. The three-pronged intervention included a presentation of balanced information, group discussion and a coaching exercise.

Parents were recruited from 6 primary care centers and 6 childcare organizations in Leeds, England between May and July 2006. The parents had to have a child eligible for the first or second dose of the MMR vaccine, meaning that the child could be anywhere from 6 months to 5 years old. A total of 92 parents were recruited, 44 in the intervention arm and 48 in the control arm.

The intervention consisted of a pamphlet ("MMR your questions answered") sent to the participant's house and a two-hour parent meeting lead by a researcher and a parent recruited from the community. These leaders received a half day of training. The meeting started with a presentation of balanced information, followed by a group discussion and a coaching exercise.

Participants in the control group were sent the "MMR your questions answered" pamphlet. Note that this pamphlet is the same one that was used in the Shourie study.

Evaluation:

Questionnaires were sent to all participants by mail. The first one was sent and collected prior to randomization. The same questionnaire was sent out one week after the intervention and again at three months after the intervention. The questionnaire was developed with the help of an expert on decision making and used in a pilot study with 5 parents prior to this study.

The two groups did not differ at baseline.

The primary outcome was decisional conflict, measured using the 16-item Decisional Conflict Scale, the same one that was used in the Shourie study. The mean decisional conflict level in both groups prior to the intervention was above 2 (2.35 for the intervention group and 2.45 for the control group). It dropped below 2 at one week post intervention (1.9 for both groups) and remained below two at three months (1.85 for both groups). There was no statistically significant difference in the mean decisional conflict scores between the two groups at any time.

There were several factors that were associated with a decreased likelihood of change in decisional conflict; namely, if the parent had made an MMR decision for an older child in the past and higher levels of concern about the potential side effects of the vaccine. Attitude and concern beliefs also affected the likelihood of change in decisional conflict.

The secondary outcomes were all self-reported measures as well. There was a statistically significant difference in the percentage of parents who took their children to get vaccinated; 93% in the intervention group and 73% in the control group. The other secondary outcomes were intention to vaccinate child, knowledge about MMR and the measles disease, attitude towards MMR, parents' beliefs about the MMR options, and anxiety. There were "small changes in the predicted direction were evident for the intervention arm for" all of these factors.

One strength of this study lies in the use of the pamphlet as a control. This decreases the likelihood of bias due to the Hawthorne effect, a phenomenon whereby individuals change their behavior because they know that researchers are observing them. This was a randomized control trial, with two groups that were very similar at baseline.

The small sample size is a weakness in this study, however. There is also no comparison to standard of care, so it is impossible to say if this intervention works better than current practices. The lack of standardization of the intervention's procedures also raises concerns. The authors do not say if the information that they presented was taught to the leaders and then presented to the subjects in a standardized manner. If this program is to be applied to another clinic, there needs to be some standardization of this process so that the results can be reproducible.

Article 3: Gowda et al.

The third article is titled "A pilot study on the effects of individually tailored education for MMR vaccine-hesitant parents on MMR vaccination intention" by Gowda and colleagues.

Program Description:

This intervention pilot study compared two educational interventions in parents who are hesitant about MMR vaccination: web pages that were individually tailored to parents' specific

vaccination concerns or web pages that contained generalized information about the MMR vaccine.

The researchers recruited parents from 9 pediatric primary care clinics within the University of Michigan Health System and from the University's clinical trial recruitment website. All participants screened positive for hesitancy over MMR vaccination; that is, they reported that they "did not want" or "were unsure" about vaccinating their child against MMR. A total of 77 parents were enrolled in the study, with 41 in the control group and 36 in the intervention group. Participants were recruited between June and December 2011.

Patients randomized to the tailored intervention arm began by filling out a baseline survey before starting the intervention. This information was used to tailor web pages to each participant. The web pages were tailored to name, race, specific concerns about vaccination, and past experiences (personal or other) with vaccination. Participants could view the web pages for as long as they wished.

The untailored intervention arm was used as the control group. The web pages that this group viewed were similar in appearance to the tailored web pages, but the information was just general data about the MMR vaccine taken from the MMR Vaccine Information Statement (VIS) issued by the Centers for Disease Control and Prevention. These VIS sheets are considered the standard of care, and physicians are required to provide them to patients prior to giving a vaccine.

Evaluation:

Results were obtained using a computer based survey administered before and after the intervention; this means that all data were self-report measures. There were no statistically significant differences in the sociodemographic data between the two groups at baseline. The

proportion of parents who planned to get the MMR vaccine at baseline was equal between the two groups. There was a higher proportion of parents in the controls who indicated that they were “unsure/neutral” about the MMR vaccine. However, a lower proportion of parents in the controls indicated that they had a negative attitude towards MMR vaccination.

The primary outcome was intention to vaccinate, which was assessed using an 11-point scale that has been used in other studies (Dempsey et al.; Zimet et al.). Two analytic approaches were used. One approach used a categorical scale to easily compare results with other studies, while the other used a continous scale to assess magnitude of change. A score of 4 or below was considered as a “negative intention”, a score of 5 as “neutral/unsure”, and a score above 5 as a “positive intention”.

Overall, there was a statistically and clinically significant increase in the proportion of parents who intended to vaccinate their children: from 34% before the intervention to 52% afterwards. The tailored group had a larger increase in the percentage of parents who intended to vaccinate their children post intervention compared to the untailored group. After the intervention, 58% of parents in the tailored group said they intended to vaccinate, compared to 46% in the untailored group. The difference between the two groups was not statistically significant though, the study sample was too small. Furthermore, more parents in the tailored group moved out of the “unsure/neutral” category. The linear analysis is congruent with these findings.

Secondary outcomes revealed differences in the ways that the two groups used the website. The authors measured the number of pages accessed; parents in the untailored group accessed, on average, 5 pages while those in the tailored group accessed 7 pages. They also found that the most commonly viewed page in the untailored group was about the side effects of

the MMR vaccine; in the tailored group it was about whether the "MMR vaccine was safe or not." The average time spent per page was similar for both groups; around 30 seconds. The average time spent on the site overall, however, was different. The untailored group spent less time on the website (an average of 141 seconds) compared to the tailored group (221 seconds).

One strength of this study is that the authors examined the efficiency of tailoring messages to vaccine hesitant parents, taking the heterogeneity of beliefs among of this population into account. The secondary outcomes are useful for understanding how parents use the tools. The target population in this study matches the target population in my intervention. These results are consistent with findings from other studies.

The largest weakness in this study is the small number of participants. The authors did not look at behavior change either. Furthermore, the control group is not the current standard of care. It is impossible to say, based on these findings, how this tailored intervention compares to the current standard of care. The 11-point scale had been used previously to assess parental vaccination intention for the HPV vaccine, and not the MMR or other childhood vaccines. The authors do not comment on how well this scale works for childhood vaccinations. This could potentially decrease the internal validity of their findings.

Article 4: Bjornson et al.

The final article is titled "Assessment of parent education methods for infant immunization" by Bjornson and colleagues.

Program Description:

This study was an assessment of the effects of an educational video versus human counseling (an oral presentation) on parents' knowledge about childhood immunizations. The

diphtheria, tetanus, pertussis, polio and haemophilus influenza type b vaccines were addressed in this intervention.

Participants were recruited at prenatal classes in Vancouver and Richmond, Canada. Both fathers and mothers were recruited; these classes consisted mostly of first-time parents but parents with older children were not excluded from the study. A total of 227 participants were included, 128 in the case group and 99 in the control group. The authors do not give the dates of the intervention, but the article was published in the November-December 1997 issue of the Canadian Journal of Public Health.

The intervention consisted of a 14-minute video that was developed "with professional assistance," although no further details on the development of this video are provided. The video covers the facts about the diseases listed above and the related vaccines. A pediatric infectious disease specialist narrated the video; the video also included visual aids such as pictures of children with the disease and text. Next, a nurse-counselor answered a mother's questions about topics that were not previously addressed, such as giving acetaminophen after the shot.

The oral presentation covered the same information as in the video. Nurses gave the presentations, and no visual aids were used. Each presentation differed slightly but the content was standardized.

Evaluation:

Data were collected using a questionnaire, filled out in person right before and right after the intervention. A pilot study was performed prior to this study in order to refine the questionnaire. It consisted of 16 questions and took about 5 minutes to complete; the presentations covered all of the material in the questionnaires.

There were no statistically significant differences between the mean scores of the two groups at baseline, or when stratified by each individual question.

After the intervention, the difference between mean total scores was not statistically significant. Both groups' mean scores improved after the intervention. This was true for each individual question, except for one question about the duration of the DPT-P vaccine. There were no significant differences in the scores in either group when stratified by gender of the parent.

This study has a much larger sample size than any of the other studies. Another strength is the standardization of the oral presentations to each other and to the video, increasing the internal validity of the study. Vaccines other than the MMR were addressed.

The generalizability of this study comes into question, however. The study population consisted of highly motivated parents; parents who attend prenatal classes and arrived early to take part in this study. This is not representative of the entire population of parents, and may not represent the study population that I am targeting. Another major drawback is the timing of the intervention relative to the vaccination. The parents' opinions may change when they are faced with the immediate decision to vaccinate or not. Doing an intervention closer to the outcome of interest would increase the internal validity of the study. There is also no comparison to the standard of care. Furthermore, this intervention was done in Canada. This difference, however, is less concerning to me than the others as the Canadian population is very similar to that of U.S. in terms of culture, values, economics, and many other factors.

Discussion

All of these articles assess the effectiveness of interventions aimed to increase the knowledge about vaccination and the confidence of parents to vaccinate. Shourie et al found that a web-based decision aid and a pamphlet were equally efficacious at decreasing parental

decisional conflict; however, a much higher percentage of parents in the decision aid group actually vaccinated their children. The results of the Jackson study also showed no statistically significant difference in mean decisional conflict score at any time between their intervention group and their control (pamphlet) group. These authors also found that more parents in the intervention group had their children vaccinated (Jackson et al. "Randomised cluster trial"; Shourie et al.).

Both of these studies show beliefs that are inconsistent with behavior; in both cases the intervention led to more behavior change than the control despite the fact that both groups reported the same level of decisional conflict, which attempts to measure a health belief. The authors attribute these discrepancies to an inadequate sample size. They argue that a higher-powered study would lead to decisional conflict scores that adequately predict behavior change (Jackson et al. "Randomised cluster trial"; Shourie et al.). This could be the result of a poorly designed scale though; it could be missing questions that address key components that link health beliefs and health behavior. Furthermore, both of these studies were performed in England, where childhood immunizations are not a requirement for admission to kindergarten. This legal parameter could lead to significant changes in beliefs and behaviors between American and British parents, but it is impossible to predict exactly what those changes could be.

The Gowda study also assessed web based interventions. The authors found that tailoring the intervention increases the proportion of parents who intend to vaccinate their children. They did not measure the proportion of parents who followed through on these intentions. Their findings were clinically significant but not statistically significant, a fact that they attribute to small sample size (Gowda et al.).

The final article included in this review was published a few years earlier than the others, in 1997. It was a good article to include because it addresses immunizations other than the MMR vaccine. The authors found no statistically significant difference between interventions delivered in person or by video, indicating that direct provider-to-patient interactions do not necessarily increase the effectiveness of educational interventions (Bjornson, Scheifele and Gold).

Program Plan

Background

State and National Policies

The North Carolina Immunization Law mandates that children must receive all of the doses of vaccines protecting against 10 diseases in order to attend day care or school. Medical contraindications and religious exemptions are recognized and permitted (Orange County; "School Vaccination Requirements"). The required vaccinations are Diphtheria, Tetanus, acellular Pertussis (DTaP); Hepatitis B (Hep B); Haemophilus Influenzae Type B (Hib); Measles, Mumps, Rubella (MMR); Polio; and Varicella (VAR) ("School Vaccination Requirements").

The Advisory Committee on Immunization Practices (ACIP) developed a schedule for providers and parents to follow for childhood vaccinations. Many practitioners follow these guidelines and the American Academy of Pediatrics endorses them. They are in fact the basis for the NC Immunization Law ("The Advisory Committee"; "Immunization Policy Statement").

The vaccines listed previously have been proven safe and effective by both the Centers for Disease Control and Prevention and the U.S. Food and Drug Administration. Multiple clinical trials have been conducted before the vaccines are put on the market, and "government agencies and their partners have established several coordinated systems to monitor the safety of vaccines after they have been licensed for public use" ("Vaccine Safety"). Furthermore, cost is usually not a limiting factor in access to vaccines. The Universal Childhood Vaccine Distribution Program (UCVDP) provides vaccines to children even if they are uninsured or they cannot afford them. The vaccines are supplied only in accordance with the ACIP schedule ("Immunization Policy Statement"). The Vaccines for Children program also supplies free vaccines to children

who are without insurance, with insurance that does not cover the vaccines, eligible for Medicaid, Native Americans, and Alaskan Natives (Orange County).

Local Policies

The University of North Carolina's Child and Adolescent General Clinic issued an Immunization Policy Statement in 2010 that addresses parents' choices not to vaccinate their children. If parents chose to forgo vaccinating their children after physicians tell them about the importance of immunizations and the policies outlined above, then the clinic refuses to treat those families and tells them that they must seek care elsewhere. The clinic justifies its choice stating that "in this case the benefits of standard vaccination to public and individual health outweigh the benefits of meeting individual preferences for a very small group of patient families" ("Immunization Policy Statement").

Healthy People Goals

As of 2007, 77.3% of children aged 19-35 months had met the State requirements for vaccination coverage. As of 2012, only 76.2% of this group met State requirements. One Healthy North Carolina 2020 Objective is to increase this percentage to 91.3% (North Carolina Institute of Medicine). There are several Healthy People 2020 Objectives related to childhood vaccinations listed in the "Immunization and Infectious Diseases" (IID) section. One of the goals, IID-7, is to "achieve and maintain effective vaccination coverage levels for universally recommended vaccines among young children". This goal is sectioned by vaccine type and includes specific goals for the 6 vaccines required by NC law. The target for each of the vaccines is 90% coverage. The DTaP and Hib vaccination coverages are well below this target. The next Healthy People 2020 Objective, IID-8, is to increase the percentage of children in this age group who are covered. The following goal, IID-9, aims to decrease the percentage of children in this

group who have received no vaccinations. Finally, IID-10 is to maintain vaccination coverage in kindergartners at 95% or above ("Immunization and Infectious Diseases").

Program Context

The goal of this program is to increase vaccination coverage for children aged 19-35 months through an educational program for parents who initially refuse vaccination in the Chapel Hill area. Although it is impossible to predict the challenges that will arise when implementing this new health program, there are potential issues that can be addressed ahead of time.

Political Environment

Vaccination of children is currently a controversial issue. Recent outbreaks of vaccine-preventable diseases, such as measles and pertussis, have brought the issue of vaccine exemption to the forefront of public health officials in the United States (Carrillo-Marquez and White). In North Carolina alone, there were three measles outbreaks in 2013. The first outbreak was in Orange County in the beginning of May, with 21 people contracting the disease and 44 additional people requiring quarantine. Later in the year, there were 19 more cases in Stokes County and Orange County that could be traced to an individual who traveled to India. This happened again when a different individual returned from India; eight people in Stokes County and Orange County contracted the disease. The large majority of cases were in unvaccinated individuals (Iannelli). Common reasons that parents give for exemptions are mostly based on fears about side effects and components in the vaccines; fears about long-term complications such as autism also drive parents away from vaccinating (Carrillo-Marquez and White).

Consistency with Local, State, and National Priorities

Several of the Healthy People 2020 Objectives address the need to increase vaccination rates in children 19-35 months ("Immunization and Infectious Diseases"). Healthy People North Carolina also endorses increasing coverage to 91.3% by 2020; coverage was 77.3% in 2007 and 76.2% in 2012 (North Carolina Institute of Medicine). Locally, however, immunization coverage is not listed as one of the top 10 public health priorities, as voted by 5 committees (Orange County).

Acceptability to Providers and Recipients

This difference between local priorities and low levels of vaccine coverage highlights a disconnect between providers and recipients. The very nature and goal of the program could threaten participation of parents with very strong beliefs against vaccination. The program needs to avoid, or at least minimize, complete alienation of this group of parents. The focus groups will help identify plans that these parents are most likely to deem acceptable. This will increase the chances of changing their practices.

I will also research other programs that have been implemented to determine which plan may be most effective for this situation.

Possible Financial Resources

There are two programs that supply vaccines to children who are uninsured or whose insurance does not cover the cost of the vaccines. These programs are the Universal Childhood Vaccine Distribution Program (UCVDP) and the Vaccines for Children Program ("Immunization Policy Statement"; Orange County).

Technical Feasibility

Several programs have been implemented in other countries, specifically in England, Australia and Canada. These programs have led to more positive attitudes of vaccine-hesitant or vaccine-resistant parents towards vaccinating their children. These studies are reviewed and evaluated in the Literature Search section of this paper. I will modify these programs to better fit my intervention, thereby saving time and conserving resources and energy. This will also increase the chances that my intervention will successfully achieve its goals.

Vaccine-hesitant and vaccine-resistant are terms that refer to the attitudes of parents towards vaccinating their children. Vaccine-hesitant parents are those that are not sure about their beliefs towards vaccination and have therefore not decided whether they will vaccinate their children or not. Vaccine-resistant parents are those that have a negative attitude towards childhood vaccination and therefore are not planning to vaccinate their children.

Stakeholders and Other Factors

Key stakeholders include parents in the Chapel Hill area, regardless of whether they have vaccinated their children. Once a threshold proportion of children have been vaccinated, then the whole community is protected; this is known as herd immunity. Therefore, the more children who are vaccinated, the greater the protection for everyone in the community. UNC is another key stakeholder, as the UNC Pediatric Clinic will lose fewer patients if fewer patients refuse vaccination.

There are several options for places to implement this program. I could start at the UNC Pediatric Clinic; they also share the goal of increasing the percentage of children who are vaccinated. I need to determine if they have any educational programs already in place, how invested physicians are in changing parents' beliefs and attitude toward vaccinating their children, and if there are nurse educators or social workers on staff who could assist me with my

program. I could also expand the program to a clinic with a lower compliance rate. A possible barrier could be that the clinics do not welcome such a program for fear of alienating their patients.

Program Theory Frameworks

Program Theories

For my program, I plan to focus on the application of intrapersonal and interpersonal theories; that is, cognitive-behavioral models, since many of the current interventions focus at the community level.

Health Belief Model

The Health Belief Model (HBM) is a good model on the individual level that addresses behaviors that raise health concerns, such as refusing vaccination. This model delves into an individual's thought process driving their behavior by looking into his or her attitude towards the health problem, how serious they feel the problem is, and if there is something they can do to address that problem. The HBM is structured around six main concepts: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cue to action and self-efficacy. When benefits outweigh costs, there is a change in behavior (National Cancer Institute).

This theory can help identify reasons that parents are opting out of vaccination. The program can then be tailored toward the concepts with which individuals are struggling. This should tip the balance towards benefits to change. For example, if parents believe that their children have little or no chance of contracting measles (low perceived susceptibility), the intervention could include a focus on educating them about their level of risk.

Several studies about the rates of childhood immunization use the HBM. Chen and his colleagues used a survey based on the HBM to understand why influenza vaccination rates in children were below the desired threshold (Chen et al.). Another study by Flood et al found that

the HBM provides an appropriate framework for determining why parents chose not to vaccinate their young children against influenza (Flood et al.). The HBM was also used in a study by Mergler and colleagues that looked into the association between parental beliefs about vaccination and provider beliefs (Mergler et al.).

Social Cognitive Theory

The Social Cognitive Theory (SCT) works an interpersonal level; it evolved from the Social Learning Theory (SLT) and the two terms are sometimes used interchangeably. It proposes that health behaviors are a product of the interaction between personal factors and environmental factors. These two factors, in turn, are affected by health behaviors; the three factors evolve together in an intricately dynamic process to shape a person's health beliefs. This model is structured around six concepts: reciprocal determinism, behavioral capability, expectations, self-efficacy, observational learning (modeling), and reinforcements (National Cancer Institute).

This could be a useful theory to complement the HBM. If there are community hubs or employers that are anti-vaccination, I could include these leaders in the intervention in order to change some of the environmental factors.

Goals and Objectives

Goal: The goal of this program is to increase the knowledge about childhood vaccination for parents of children age 19-35 months who are vaccine-resistant or vaccine-hesitant who live in or near Chapel Hill. Once these parents understand vaccines better, they should have a more positive attitude towards vaccination. This change, in turn, will lead to behavior change; that is, increased vaccination rates in this population.

Short Term Objective 1: By June 10, an online decision aid will be finalized and ready for potential participants to use.

Activities: The decision aid will be based on the one used in the study by Shourie, Jackson, Cheater et al., if possible. The study will be modified if necessary to better fit the target population, as the survey was developed in Great Britain and the national standards may differ between these two countries. If possible, the authors of the study will be contacted to work in a collaboration.

Short Term Objective 2: By July 31, recruit at least 50 eligible parents from online discussions forums to participate in the intervention.

Activities: I will find anti-vaccination groups on Facebook and Twitter and post a pre-written invitation to participate in the intervention. I will search for groups in the Chapel Hill and Carborro areas. Parents with children in the appropriate age range who respond will be invited to participate in the intervention.

Short Term Objective 3: By August 15, at least 50 participants will have completed the decision aid and at least 75% will score higher on the knowledge assessment survey after the intervention than they did before the assessment. Furthermore, at least 75% will score higher on the attitude assessment scale that is included in the survey.

Activities: Parents who responded to the social-media recruitment and who are eligible will be sent a link to the online intervention, as well as a username and password. I will have access to this username and password in order to perform a detailed qualitative analysis.

Short Term Objective 4: By the end of the summer of 2014, the intervention and its results will be presented to the UNC Pediatric clinic to begin integrating the decision aid into this clinic.

Activities: Dr. Tom Belhorn, a pediatrician at UNC, is already aware of this project. Once the intervention is complete, he can help to coordinate a meeting for me to present my findings and propose how to integrate the decision aid into the clinic's practices. I could present my findings in person at a physician conference, I could also present during weekly grand rounds for residents.

Short Term Objective 5: By the end of the year 2014, at least 50% of the participants in the original intervention will have their children vaccinated against the recommended diseases at the recommended doses.

Activities: The participants will be contacted and sent a questionnaire about whether they vaccinated their children, and if so, which vaccines they received and how many of each vaccine they received.

Short Term Objective 6: By the end of the summer of 2015, I will expand the intervention to other pediatric clinics in North Carolina.

Activities: The findings will be presented to the Department of Pediatrics at Wake Forest Baptist Medical Center in Winston-Salem, NC. I am a medical student there, so I can work with my attendings to expand the program to Wake Forest and other clinics if they have connections. The findings will also be presented to Blue Ridge Pediatric and Adolescent Medine in Boone, NC. I shadowed Dr. Lanny "Chip" Monroe for several weeks and I can contact him. I will work with these practices so that the intervention can be optimally integrated into their work.

Long Term Objective 1: Increase childhood vaccination coverage in North Carolina to 91.3% by 2020.

Activities: This is consistent with the Healthy People 2020 Objectives and the Healthy People North Carolina Objectives. Increasing the knowledge of vaccine-hesitant and vaccine-resistant parents will lead them to change their mindset and behavior about vaccinations. The intervention will also allow pediatric practices to be better able to address parents' concerns about vaccination without increasing the time of the doctor-patient visit, thus allowing physicians to focus on other aspects of the patient's care.

Program Implementation

Activities

I will implement several activities aimed at increasing knowledge of childhood vaccination in vaccine-resistant parents in the Chapel Hill area. Once these parents understand vaccines better, they should have a more positive attitude towards vaccination. This change, in turn, will lead to behavior change; that is, increased vaccination rates in this population. In order to achieve the first short term objective, the decision aid used in the study by Shourie, Jackson, Cheater et al. will be modified if necessary to better fit the target population. Parents will use the decision aid to increase both their knowledge of and their attitudes towards childhood vaccinations.

The activities for the second short term objective center around the recruitment of parents to participate in the program. I will find anti-vaccination groups on social media sites such as Facebook and Twitter. I will narrow the search to groups in the Chapel Hill and Carrboro areas; I will post a pre-written invitation to participate in the intervention. Parents with children who meet the inclusion criteria will be invited to participate in the intervention.

The activities for the third short term objective include sending a link to the eligible parents who responded to social media prompts. They will be given a username and password, which I will keep track of in order to perform a detailed qualitative analysis.

The fourth short term objective's activities will be conducted with the help of Dr. Tom Belhorn, a pediatrician at UNC. He will help coordinate a meeting in which I can present my findings and propose how to integrate the decision aid into the clinic's practices. I can also present my findings at a physician's conference or to residents during weekly grand rounds.

The change in behavior of participants will be assessed to address the fifth short term objective. A different questionnaire will be sent to participants 6 to 12 months following the intervention to determine whether they vaccinated their children. The specific vaccines, as well as the number of doses, administered will be determined.

The activities for short term objective number six focus on the expansion of the program to other clinics in North Carolina. Specifically, I can contact the Department of Pediatrics at Wake Forest Baptist Medical Center in Winston-Salem and Dr. Monroe at Blue Ridge Pediatric and Adolescent Medicine in Boone. I will work with these practices to integrate the intervention into the clinics.

All of these activities should lead to meeting the long term objective. Increasing the knowledge of vaccine-hesitant and vaccine-resistant parents will lead to attitudinal change. In turn, a change in behavior should follow so that the Healthy People 2020 Objective and Health People North Carolina Objective of increased childhood vaccination can be met. This intervention will also allow pediatric clinics to better address parents' concerns about vaccinations in a timely manner that is tailored to individual parents.

The relationships between all these elements of the program are summarized in the logic model in the Appendix.

Budget Proposal

This intervention is a zero-based budgeting project. I will be in charge of most of the work so there will be no personnel or training costs. Because the decision aid will be a web-based tool, and the parents will be contacted via the web, there will be no equipment or transportation costs.

Timeline:

6/10/2014: Finalize online decision aid for vaccine-hesitant and vaccine-resistant parents.

7/31/2014: Recruit at least 50 eligible parents from online discussion forums to participate in the intervention.

8/15/2014: At least 50 participants will have completed the decision aid and I will have all the data available for analysis.

9/15/2014: The results will be presented to the UNC pediatric clinic, with the ultimate goal of integrating the intervention into the practices of the clinic.

12/31/2014: The vaccination rates of the participants will be measured; at least 50% of the participants will have their children vaccinated against the recommended diseases at the recommended doses.

8/31/2015: The results will be presented to the pediatric clinics in Winston Salem and Boone, with the ultimate goal of integrating the intervention into the practices of the clinics.

1/1/2020: Childhood vaccination rates in North Carolina will be measured for the Healthy People and Health People North Carolina projects; the target rate of 91.3% will be met.

Evaluation Plan

Rationale and Approach to Evaluation

This section will delineate the reasons that this intervention will be evaluated. Evaluation is a necessary component of any successful public health program. It is important to address not only the rationale behind the evaluation, but also the role of the evaluator and the key stakeholders and their questions. Addressing potential problems that may arise in the implementation of the evaluation is another key part of developing the intervention.

Today, there is a lot of pressure for evaluations to show that public health programs are effective and positively influencing the target community. However, it is just as important to collect data in order to improve the program (W.K. Kellogg Foundation). The Joint Committee on Standards declared that the four key standards of evaluation are utility, feasibility, propriety, and accuracy (Patton; Centers for Disease Control and Prevention).

This vaccination intervention should be evaluated for several reasons. It will serve to determine its effectiveness; it will determine which aspects were successful and which ones were not. These results will be published, as well as a clear statement of the purpose and methods. This will ensure transparency and a common understanding of the program among all stakeholders (Centers for Disease Control and Prevention). Improvement of the intervention is an important goal of the evaluation; data will be collected, and applied, to work towards this goal (W.K. Kellogg Foundation). Another aim of the evaluation is to expand the intervention to other similar community settings in North Carolina. The publication of the program's effectiveness will lead to increased support and acceptance of the intervention (Centers for Disease Control and Prevention). One section of the evaluation will address which parts of the intervention can be

modified so that it can be adapted in different settings. The evaluation will also address the potential challenges of the program's dissemination.

Because of the purposes of the evaluation, it is crucial that the evaluator has a full knowledge of the intervention in its entirety. I will serve as an internal evaluator so that the evaluation will be an active, participatory process. An in-depth understanding of the program is a necessary part of both the improvement and expansion processes. An internal evaluator is a cost-effective way to evaluate; I will be able to receive a lot of informal feeback because I am involved in all aspects of the program (W.K. Kellogg Foundation). I will also be able to serve as an advocate for the intervention (Centers for Disease Control and Prevention). Key skills of an evaluator include the ability to listen, negotiate, and consolidate multiple perspectives. They need to possess the analytical skills to perform the evaluation, and it is crucial that they are flexible and able to solve problems (W.K. Kellogg Foundation).

Stakeholders should be involved in the evaluation throughout the entire process. This will help increase its utility, as active participation of key stakeholders will allow them to better understand the evaluation. Open lines of communication throughout the entire process will lead to better results. The evaluators will know the stakeholder's key questions and will be able to communicate their findings in the stakeholder's preferred style. In return, the stakeholders will not be surprised by any of the results when the report is published and they will be able to act on the results much sooner (Bamberger). The key stakeholders in the vaccination intervention are parents in the Chapel Hill area, those that are pro-vaccination as well as those that are vaccine-hesitant and vaccine-resistant, and the UNC Pediatrics Clinic. Both groups will be interested in decreased incidence of vaccine-preventable diseases. Pro-vaccination parents and the UNC clinic will be interested in increased vaccination rates until herd immunity is achieved. The former

group is interested in increased protection for their own children, and the latter group in keeping more patients. Addressing the concerns and questions of the anti-vaccination group will be equally important; they will be interested in side effects and whether they feel as if their right to refuse vaccination is respected.

There were also be potential challenges of evaluating the intervention. Underutilization is a major problem in evaluation research. Patton summarized this challenge as "narrowing the gap between generating evaluation findings and actually using those findings for program decision making and improvement (Patton). Active involvement of stakeholders will help to counteract this problem.

Other common challenges in evaluation include budget, time, data, and political influences (Bamberger). I will be the evaluator, and will not need a budget. To make sure that I have enough time, I will start early with the evaluation; I will begin collecting data as soon as I implement the intervention. Childhood vaccination has become a highly politicized topic in the media recently, so I will keep the wording of my reports as factual and objective as possible.

The final potential problem is that I will be functioning as an internal evaluator. Because there is no external evaluator, I will not have an outside perspective of the intervention. I will also be learning the skills as I am evaluating; external evaluators tend to have more expertise and access to equipment (W.K. Kellogg Foundation).

Evaluation Design

To help ensure a successful evaluation, the evaluation study design and methods need to be carefully considered. For this intervention's evaluation, I will use an integrated and interdisciplinary approach. The design will be mostly quasi-experimental. Data will be collected prospectively. Assessments will be given to all participants before and after the intervention. The

outcomes are unbounded outcomes because are not linked to a specific time or event, which means that they may exist before and after the intervention (Issel). The outcomes for this intervention include participants' knowledge, attitude and behavior regarding vaccination.

This design is not experimental because participants will not be randomly assigned into two groups; there is no control group in this study because all participants will receive the intervention. I will be assessing the effect of an "exposure" on a certain population, with the exposure being the intervention. However, I am manipulating the exposure; that is, I created and delivered the intervention to a group of participants whom I selected based on prespecified criteria. For this reason, the design is a mix of quasi-experimental and observational (Issel).

My outcome documentation design will be a one-group pretest and posttest design, which is uncomplicated and inexpensive compared to other designs. The one-group pretest and posttest design consists of collecting data from participants before the intervention and again after the intervention. This will allow me to assess the magnitude of change in the set indicators in the participants by comparing scores before the intervention to those after it. I will also be able to assess change on a population level, which will help with the expansion of the intervention (Issel).

History and maturation threats will be minimized by collecting data immediately before and immediately after the intervention. The assessments will be given online and will be identical before and after the intervention, minimizing the threat of instrumentation. However, this design does not have much power to determine causality because there is no control group. It can show the magnitude of change that occurred but it cannot attribute this change to the intervention; that is, it is impossible to say with any certainty that the intervention caused the change. Despite these weaknesses, the design is satisfactory for program documentation.

Evaluation Methods

A variety of evaluation study methods will be used. Quantitative methods allow for numerical analysis. I will be able to quantify the impact of the intervention on individual participants and on the group as a whole. Not all of the data that will be collected can be measured or counted; furthermore, quantitative data may not allow participants to fully express their views. For these data I will used qualitative methods. These data can be used to further develop the program theory for this intervention. Qualitative methods allow for a more personalized approach, giving a voice to participants and stakeholders. One drawback of these methods is that they are more time-consuming than quantitative methods (Issel).

The combination of quantitative and qualitative methods will increase the credibility of the results, as results can be compared and integrated to strengthen the conclusions. It also addresses some of the limitations of each individual method. Some challenges to mixed methods include increased time and resources and the possibility of conflicting results. The major drawback, however, is analyzing the data. The results need to be synthesized to draw a meaningful conclusion (Issel).

Quantitative methods that will be used include an activity log to determine if a set of discrete activities were done. Questionnaires without open-ended questions will also be used in some cases. These will allow for quick collection of data in a reliable and standardized manner (Issel). The pre- and post-intervention assessment survey is also a quantitative method. Organization records will include both quantitative and qualitative data.

Several qualitative methods will be used. Individual in-depth interviews and focus groups will allow individuals to give direct input about specific aspects of the intervention and its implementation. These methods are inexpensive. The former will allow for expression of

individual views, personal thoughts and values; the latter will allow for expression of collective views. Observation will allow me to collect data on interpersonal interactions, sequence of events, causes and effects, and new behaviors or events. . Questionnaires with open-ended questions allow for quick and inexpensive data collection (Issel). I will also ask for feedback after every presentation in order to determine what should be improved.

Evaluation Planning Tables

Short Term Objective 1:

By June 10, an online decision aid will be finalized and ready for potential participants to use.

Evaluation Questions	Participant	Evaluation Method
By June 10, was the online decision aid ready to use?	Project coordinator	Activity log
Was permission obtained from the authors of the original decision aid?	Project coordinator; Authors of the original decision aid	Activity log
Was the decision aid pilot tested on someone in the medical field who is aware of vaccination facts and NC laws in order to second check accuracy?	Project coordinator; Volunteer medical personnel	Activity log
Was the decision aid pilot tested on somone representative of the target population in order to test for usability?	Project coordinator; Volunteer parent	Activity log
Was the decision aid modified to reflect laws and values that are specific to the population in North Carolina?	Project coordinator Volunteer medical personnel Volunteer parent	Questionnaire
What improvements can be made to the decision aid? Why were these changes made?	Project coordinator Volunteer medical personnel Volunteer parent	Individual in-depth interview

Short Term Objective 2:

By July 31, recruit at least 50 eligible parents from online discussions forums to participate in the intervention.

Evaluation Questions	Participant	Evaluation Method
By the end of July, how many parents who meet the inclusion/exclusion criteria were recruited?	Project coordinator	Organizational records
What online discussion forums were used to recruit parents?	Project coordinator	Organizational records
From how many different forums were parents recruited?	Project coordinator	Organizational records
How many participants were recruited from each of these forums?	Project coordinator	Organizational records
What reasons did parents who participated state as their motivation(s) to participation?	Participants	Focus group Questionnaire with open-ended questions
What reasons did parents who did not participate state as their aversion(s) to participation?	Eligible parents who did not participate	Questionnaire with open-ended questions
What challenges arose when recruiting patients?	Project coordinator	Organizational records
What aspects of recruitment worked well, and why?	Project coordinator	Organizational records

Short Term Objective 3:

By August 15, at least 50 participants will have completed the decision aid and at least 75% will score higher on the knowledge assessment survey after the intervention than they did before the intervention. Furthermore, at least 75% will score higher on the attitude assessment scale that is included in the survey.

Evaluation Questions	Participant	Evaluation Method
By the middle of August, how many participants have completed the decision aid?	Project coordinator	Organizational records
How many people started the survey but did not complete it? If possible, ask them why they did not complete it.	Project coordinator; Participants	Organizational records Individual interviews
What difficulties did participants experience while filling out the survey? What did they like about the survey?	Participants	Focus groups
How long did it take, on average, to complete the survey?	Participants; Data from decision aid	Organizational records Focus groups
By the end of June, what percentage of participants scored higher on the knowledge assessment survey after the intervention than they did before the intervention?	Data from decision aid	Pre and post intervention assessment surveys
What specific areas of knowledge saw the highest improvement? Why?	Data from decision aid	Pre and post intervention assessment surveys Focus groups
What specific areas of knowledge saw the lowest (or minimal) improvement? Why?	Data from decision aid	Pre and post intervention assessment surveys Focus groups
By the end of June, what percentage of participants scored higher on the attitude assessment scale than they did before the intervention?	Data from decision aid	Pre and post intervention assessment surveys
Which specific attitudes saw the highest improvement? Why?	Data from decision aid	Pre and post intervention assessment surveys Focus groups
Which specific attitudes saw the lowest (or no) improvement? Why?	Data from decision aid	Pre and post intervention assessment surveys Focus groups
What changes were made to the intervention? Why?	Project coordinator	Organizational records

Short Term Objective 4:

By the end of the summer of 2014, the intervention and its results will be presented to the UNC Pediatric clinic to begin integrating the decision aid into this clinic.

Evaluation Questions	Participant	Evaluation Method
By the end of summer 2014, were the intervention and its results presented to the UNC Pediatric clinic?	Project coordinator	Organizational records
What aspects of the presentation went well? Which aspects went poorly?	Project coordinator	Organizational records
What was the reception of the UNC Pediatric clinic to the presentation?	Staff at the UNC Pediatric clinic	Feedback after presentation Observation Interviews
Who are the people to contact and what strategies can be used to start implementing this intervention in the UNC Peds clinic?	Staff at the UNC Pediatric clinic	Observation Interviews
Has this intervention been used in the UNC Pediatric clinic? If so, with how many patients?	Staff at the UNC Pediatric clinic (project coordinator for this site)	Interviews
Which aspects of the implementation of the intervention worked well in this setting?	Staff at the UNC Pediatric clinic	Observation Interviews
What barriers were there in implementing the intervention in this clinic? How were they overcome?	Staff at the UNC Pediatric clinic (project coordinator for this site)	Observation Interviews
What changes were made to the intervention and its implementation? Why?	Staff at the UNC Pediatric clinic	Observation Interviews
Did any unexpected outcomes occur, either from the presentation or the implementation? Why?	Project coordinator Staff at the UNC Pediatric clinic	Observation Interviews

Short Term Objective 5:

By the end of the year 2014, at least 50% of the participants in the original intervention will have their children vaccinated against the recommended diseases at the recommended doses.

Evaluation Questions	Participant	Evaluation Method
By the end of the year 2014, what percentage of the participants have had their children vaccinated (all the recommended vaccinations)?	Project coordinator; Participants; State Immunization Registry	Organizational records Surveys
By the end of the year 2014, what percentage of the participants have had their children vaccinated (some the recommended vaccinations)? Which vaccines have been most common or overlooked?	Project coordinator; Participants; State Immunization Registry	Organizational records Surveys
Of parents who vaccinated who could be contacted, what did they state were major motivating factors for choosing to vaccinate?	Participants	Open-ended questionnaire Interviews
What barriers did participants experience in vaccinating their children? How were they overcome?	Participants	Open-ended questionnaire Interviews
Of the parents who refused to vaccinate who could be contacted, what reasons did they give for not vaccinating?	Participants	Open-ended questionnaire Interviews

Short Term Objective 6:

By the end of the summer of 2015, I will expand the intervention to other pediatric clinics in North Carolina.

Evaluation Questions	Participant	Evaluation Method
By the end of summer 2015, were the intervention and its results presented to other pediatric clinics in NC? If so, how many?	Project coordinator	Organizational records

What aspects of the presentation went well? Which aspects went poorly?	Project coordinator	Organizational records
What was the reception of the clinic to the presentation?	Staff at the clinic	Feedback after presentation Observation Interviews
Who are the people to contact and what strategies can be used to start implementing this intervention in the clinic?	Staff at the clinic	Observation Interviews
Has this intervention been used in the clinic? If so, with how many patients?	Staff at the clinic (project coordinator for this site)	Interviews
Which aspects of the implementation of the intervention worked well in this setting?	Staff at the UNC Pediatric clinic	Observation Interviews
What barriers were there in implementing the intervention in this clinic? How were they overcome?	Staff at the clinic (project coordinator for this site)	Observation Interviews
What changes were made to the intervention and its implementation? Why?	Staff at the UNC Pediatric clinic	Observation Interviews
Did any unexpected outcomes occur, either from the presentation or the implementation? Why?	Project coordinator Staff at the UNC Pediatric clinic	Observation Interviews

Long Term Objective 1:

Increase childhood vaccination coverage in North Carolina to 91.3% by 2020.

Evaluation Questions	Participant	Evaluation Method
In 2020, what is the childhood vaccination coverage percentage in North Carolina?	"Healthy North Carolina" report	Surveys
How many clinics in North Carolina have implemented this intervention?	Project coordinators across the State.	Surveys
How many parents have participated in this intervention?	Project coordinators across the State.	Organizational records
What percentage of participants vaccinated their	Project coordinators across the State.	Organizational records

children following the intervention?		
What aspects of the intervention worked well in these multiple sites? Why?	Project coordinators across the State.	Organizational records Interviews
What barriers were there to its implementation? How were they overcome?	Project coordinators across the State.	Organizational records Interviews
Did any unintended outcomes occur?	Project coordinators across the State.	Organizational records Interviews

Institutional Review Board and Ethics

It is important to conduct research ethically, especially if the research involves human subjects. In order to protect human rights, Institutional Review Boards (IRB) were created. Before any research involving human subjects can begin, the project must be approved by an IRB to ensure that human rights are not violated. At UNC, the Office of Human Research Ethics is responsible for ensuring that all research associated with the university is ethical; it is therefore responsible for running the IRB (The University of North Carolina).

The ultimate goal of this intervention involves vaccinating young children, who are considered a special vulnerable population. They are not old enough to understand the intervention or vaccination (Issel). However, this intervention is aimed at adults who have the capability to provide informed consent to participate in the intervention. They have the right to refuse to participate in the study, and they can still decline to vaccinate their children if they do participate.

Furthermore, childhood vaccinations are the standard of care and have been proven safe and effective ("Vaccine Safety"). Should parents chose to vaccinate their children after participating in this intervention, they will be protecting their children against several fatal illnesses. They will expose their children to some potential harms from the side effects of the vaccines, but overall they will be decreasing the chance of illness and death.

The IRB guidelines about patient confidentiality will be strictly followed (The University of North Carolina). No personal information about the participants or the participants' children will be shared or published. I will need to document a way to contact the parents for individual interviews and focus groups, but that information will not be used outside of that purpose. Very little personal information will be collected; most of the questions will be geared toward knowledge of, attitudes towards, and behaviors regarding childhood vaccination. I will complete the Human Subjects Training prior to initiating the intervention ("Ethics Training").

I will obtain informed consent from all participants. I need to do this for several reasons. The first reason is to be compliant with IRB procedures. The second is that I will try to publish my findings. The results will be shared outside of the context of the intervention and its analysis, which means that it is research and not simply evaluation (Issel). UNC provides a common consent form that I can use as a template. This form includes a statement that what I am doing is research, the purpose of the research, and the role of the participant. It also includes a description of risks and benefits, as well as a statement about the protection of the participant's confidentiality. I will also include the information of someone that they can contact for any questions about the project or their rights. Finally, I will emphasize that participation is voluntary ("General FAQ").

Other potential ethical issues include exposures and confidentiality of the staff involved, "financial arrangements, conflicts of interest, level of competence, and deadlines" (Issel). I forsee no ethical dilemmas arising from any of these factors in this intervention or its evaluation.

There are three types of IRB reviews: exempt, expedited and full board. The intervention and evaluation should not involve more than minimal risk, so I do not need to apply for a full board review. On the other hand, I am not exempt because I plan to publish my findings and

disseminate them to other pediatric clinics so that they may use this intervention. I will therefore apply for an expedited IRB application. My research and evaluation falls under Category 7 of the expedited review types. This involves "research on individual or group characteristics or behavior … or research employing survey, interview, oral history, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies" (The University of North Carolina).

Plan for Dissemination

It is important to intentionally plan for the dissemination of the evaluation findings. Dissemination will increase the utility of the evaluation. Simply publishing the results does not necessarily mean that the stakeholders will access those results and act on them. I will need to actively engage the stakeholders so that they understand the results and how to use them (Centers for Disease Control).

Several of the objectives for this intervention focus on the dissemination of the evaluation findings. Short term objective 4 focuses on presenting to the UNC Pediatric clinic. As stated under the activites for this objective, I will have help from Dr. Tom Belhorn, a pediatrician in this clinic. He will help me set up an appropriate time and place to present the findings. The presentation will also provide guidance on how the clinic can integrate the intervention into its practices. I am also planning on presenting my findings to other clinics throughout North Carolina, as stated in short term objective 6. I am a medical student at Wake Forst Baptist Medical Center in Winston-Salem, so I can present there. I also worked with a pediatrician, Dr. Lanny Monroe, at Blue Ridge Pediatric and Adolescent Medicine in Boone. I can contact him to set up a presentation there.

Conclusion

Childhood vaccination rates have been falling over the past few years across the country. North Carolina is not immune to this trend. As of 2007, only 77.3% of children met the school requirements for vaccination. As of 2012, this number dropped to 76.2%. An estimated 91.3% of children need to be vaccinated in order to confer herd immunity (North Carolina Institute of Medicine). Even if the latter number is incorrect, the percentage of unvaccinated children in the State is high enough to allow for outbreaks of preventable, and potentially fatal, diseases. In 2013, there were three outbreaks of measles (Iannelli).

The intervention described in this paper provides a relatively easy and low-cost method to address this problem. It specifically targets parents who do not wish to vaccinate their children and those who are undecided about the issue. It explores the knowledge and attitudes of these parents towards vaccination, as well as their behavior. These factors are measured before and after the intervention to determine if the intervention effected any change.

The systematic review emphasized the importance of measuring both attitudes and behavior, as the results can sometimes be inconsistent with each other. Web-based interventions resulted in more parents vaccinating their children compared to parents in the control groups. The attitudes of parents were measured using a decisional conflict scale; both the cases and controls reported the same level of decisional conflict. The intervention described in this paper will therefore measure both attitudes and behavior.

The evaluation plan is integrative and interdisciplinary, with a quasi-experimental design. A combination of quantitative and qualitative methods are used and integrated to increase the credibility of the results. The overall goal of the evaluation plan is to determine if the

intervention is meeting its goals and objectives. The evaluation will also allow me to determine how to improve the intervention and its implementation.

Because the issue of childhood vaccinations is so politically charged at this time, it will be very important for me to avoid alienating the group of parents that I wish to recruit. The systematic review showed that it is possible to avoid this potential weakness; the web-based interventions did result in increased childhood vaccinations. Another potential problem is that there is no control group in this study, which will preclude me from determining whether the intervention caused any change in knowledge, attitude, or behavior. The fact that the surveys will be administered right before and right after the intervention will help strengthen the connection between the intervention and the outcomes.

Childhood vaccinations are an important public health issue at the moment. A multifaceted, multidisciplinary approach is necessary to alleviate the burden of disease from preventable illnesses. This intervention is just one of many ways to help increase childhood vaccination rates.

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Appendix

Appendix A – Summary of Literature Review

Program and Goal	Target Population	Program/Intervention Description	Evaluation Strategy	Results	Strengths and Weaknesses
Article: A cluster randomised controlled trial of a web based decision aid … **Author**: Shourie et al **Goal**: determine the effectiveness of an online decision aid vs a pamphlet vs usual care in increasing first-time parents' informed decision about vaccinating their child against MMR.	First time parents with children 3-12 months old who were being offered the first dose of the MMR vaccine in five Primary Care Providers in northern England - 220 total participants - 50 in decision aid group - 93 in pamphlet group - 77 in control group	**Online decision aid + usual care:** - Based on the Australian MMR decision aid - Parents were given the link to the web-based decision aid and a personal username and password **Pamphlet + usual care:** - "MMR your questions answered" **Controls:** - Usual care by pediatricians; usually an appointment and sometimes a pamphlet	Questionnaire sent 2 times - Prior to intervention - 2 weeks post intervention **Primary Outcome:** - Decisional conflict, measured using the Decisional Conflict Scale, a 16-item scale previously validated by these authors - 1: lowest score, no conflict - 5: highest score, extremely high levels of conflict - < 2: corresponds to informed decision making **Secondary Outcomes:** - Administration of first dose of the MMR vaccine - Knowledge of the MMR vaccine - Attitudes towards vaccination against MMR - Trade-off beliefs on benefits versus harms of MMR vaccination - Anxiety	**Primary Outcome:** - Parents in both the decision aid group and the pamphlet group had a mean decisional conflict score below 2 - Parents in the decision aid group experienced the larges reduction in decision al conflict - Control group: no change in the mean decisional conflict score **Secondary Outcomes**: - Administration of first dose of MMR vaccine: - 100% in decision aid group - 91% in the pamphlet group - 99% in the control group - Small changes in each of the other variables	**Strengths:** - RCT - Findings consistent with previous research **Weaknesses:** - Vaccine administration measured at 15 months - Low percentage of practices that were contacted participated - Low percentage of parents in these practices participated

Program and Goal	Target Population	Program/Intervention Description	Evaluation Strategy	Results	Strengths and Weaknesses
Article: Randomized cluster trial to support informed parental decision-making for the MMR vaccine **Author**: Jackson et al. **Goal**: Evaluation of the effect of a parent-centered multi-component intervention on informed decision making of parents about the MMR vaccine	- Parents were recruited from 6 primary care centers and 6 childcare organizations in Leeds, England. The parents had to have a child eligible for the first or second dose of the MMR vaccine; that is, 6 months to 5 years old. - 92 total participants - 44 in the intervention group - 48 in the control group	**Intervention:** - Pamphlet titled "MMR your questions answered" was sent to the participant's house - Two hour parent meeting led by a researcher and a parent recruited from the community **Controls:** - "MMR your questions answered" pamphlet	Questionnaires sent by mail 3 times: - Prior to randomization - 1 week after the intervention - 3 months after the intervention **Primary Outcome**: - Decisional Conflict Scale, described in the Shourie article **Secondary Outcomes:** - MMR vaccination - Intention to vaccinate child - Knowledge about MMR and measles - Attitude towards MMR - Parents' beliefs about the MMR options - Anxiety	**Primary Outcome**: - At baseline ,the score was >2 - 2.35 for intervention - 2.45 for controls - At 1 week ,the score was 1.9 for both groups - At 3 months ,the score was 1.85 for both groups **Secondary Outcome**: - Statistically significant difference in the proportion of parents who took their children to get vaccinated - 93% for intervention - 73% for controls - "small changes in the predicted direction were evident for the intervention arm for" all the other outcomes	**Strengths:** - RCT - Use of pamphlet as control decreased probability of "Hawthorne" effect **Weaknesses:** - Small sample size - No comparison to standard of care

Program and Goal	Target Population	Program/Intervention Description	Evaluation Strategy	Results	Strengths and Weaknesses
Article: A pilot study on the effects of individually tailored education … **Author**: Gowda et al **Goal**: Comparison of 2 educational interventions in parents who are hesitant about MMR vaccination: individually tailored web pages and untailored web pages.	-Parents recruited from 9 pediatric primary care clinics within the University of Michigan Health System or using the University's clinical trial recruitment website. -All participants screened positive for hesitancy over MMR vaccination. - 77 total participants - 36 in the intervention group - 41 in the control group	**Intervention:** - Parents filled out a baseline survey before starting - This information was used to tailor information to each participant; characteristics such as name, race, specific vaccination concerns, and past experiences were used. **Controls:** - Web pages similar in appearance to intervention web sites, but contained general data about the MMR vaccine	Computer based survey administered before and after the intervention. Parents reported how they felt about the MMR vaccine: positive, unsure/neutral, or negative. **Primary Outcome**: Intention to vaccinate - 11 point scale - Analysed in both a categorical and a linear manner - ≤4: negative - 5: neutral - >5: positive **Secondary Outcomes:** - Number of pages accessed - Most commonly viewed page - Average time spent per page - Average time spent on site	**Primary Outcome**: - Overall intention to vaccinate: - 34% before - 52% afterwards -Intention to vaccinate after the intervention: - 58% in tailored group - 46% in untailored group. - Not statistically significant **Secondary Outcome:** - Number of pages accessed: - 7 in tailored group - 5 in untailored group - Most commonly viewed page: - Tailored about safety - Untailored about side effects - Average time spent per page -~30 sec for each group - Average time spent on site: - Tailored: 221 sec - Untailored: 141 sec	**Strengths:** - Took heterogeneity of beliefs among vaccine-hesitant parents into account - Secondary outcomes help explain how parents use the website - Target population matches the target population for my study **Weaknesses:** - Small number of participants - No comparison to standard of care - Scale not validated for childhood immunizations

Program and Goal	Target Population	Program/Intervention Description	Evaluation Strategy	Results	Strengths and Weaknesses
Article: Assessment of parent education methods for infant immunization **Author**: Bjornson et al **Goal**: **A**ssessment of the effects of an educational video versus human counseling (an oral presentation) on parents' knowledge about childhood immunizations	- Participants recruited at prenatal classes in Vancouver and Richmond, Canada. - Mostly of first-time parents but parents with older children were not excluded from the study - 227 total participants - 128 in the intervention group - 99 in the control group	**Intervention:** - 14 minute video that was developed "with professional assistance" - Covers facts about diphtheria, tetanus, pertussis, polio and haemophilus influenza type b infections and vaccines - Narrated by pediatric infectious disease specialist - Ends with a conversation between a nurse and mother covering topics not previously addressed **Controls:** - Oral presentation by nurse that covered the same information as in the video	Questionnaire administered right before and right after the intervention. - 16 questions - Assessed the knowledge of the parents about the diseases and vaccines	- Both groups' mean scores improved after the intervention - No statistically significant difference between the groups' mean scores after the intervention - No statistically significant difference between the groups' mean scores when stratified by question (with the exception of one question about the duration of the DPT-P vaccine) - No statistically significant difference between the groups' mean scores when stratified by gender	**Strengths:** - Large sample size - Standardization of the oral presentations to each other and the video - Addresses vaccines other than the MMR **Weaknesses:** - Only includes highly motivated parents - Intervention a long time before administration of vaccine - No comparison to standard of care

Appendix B – Logic Model

Assumptions for Logic Model
North Carolina Immunization Law mandates that children must receive all doses of the following vaccines in order to attend day care or school, barring medical and religious exemptions: DTaP, HepB, Hib, MMR, polio, and VAR. The ACIP developped a schedule for these vaccines, which is endorsed by the AAP ("The Advisory Committee"; "Immunization Policy Statement").
These vaccines have been proven both safe and effective by the CDC and the FDA, as well as by multiple clinical trials ("Vaccine Safety").
State and national guidelines are in place to increase childhood vaccination rates ("School Vaccination Requirements").
As of 2007, 77.3% of children aged 19-35 months had met the State requirements for vaccination coverage, well below the target of 91.3% (North Carolina Institute of Medicine). **As of 2012, this number dropped to 76.2%**

Inputs	Activities	Outputs	Outcomes	Impacts
Verified online decision aid discussed in article by Shourie et al. Support from University of North Carolina's School of Public Health. Cost of vaccines will not be an issue, as most insurance policies cover the recommended vaccines. The Universal Childhood Vaccine Distribution Program and the Vaccines for Children program provide vaccines to children who are uninsured or underinsured.	Modify online decision aid that has been verified in a different setting. Contact developers of this decision aid.	More tailored and efficient decision aid. More detailed and reliable answers to patients' questions.	Develop an effective online decision aid.	Change the mindset of the community: less resistance to vaccination. Elimination of outbreaks of vaccine-preventable communicable diseases.
	Recruit participants through online social media in the Chapel Hill area. Send decision aid to eligible parents. Completion of decision aid and monitoring of knowledge and attitudes, as well as vaccination rates. Send follow-up survey to participants to determine vaccination rate.	Increased knowledge about vaccines. More positive attitudes towards childhood vaccinations.	Full participation from at least 50 eligible parents in the Chapel Hill area. The decision aid will result in increased knowledge about and better attitudes towards vaccines for the majority of participants. Increase vaccination rate of participants' children to at least 50%.	
	Presentation of results to UNC Pediatrics physicians and residents to begin integration into UNC clinics.	Increased vaccination knowledge, more positive attitudes and higher rates at UNC Pediatric Clinic.	Integration into UNC pediatric clinics.	
	Presentation (and integration) of results to the Department of Pediatrics at Wake Forest Baptist Medical Center in Winston Salem and to Blue Ridge Pediatric and Adolescent Medicine in Boone.	Increased vaccination knowledge and rates at Wake Forest Baptist Hospital and in northwestern North Carolina.	Expansion of intervention to other pediatric clinics in North Carolina. Increase childhood vaccination coverage in North Carolina to 91.3% by 2020.	

Appendix C – Supplemental Materials

MMR Decision Aid

The Online decision aid can be found at this website: http://www.leedsmmr.co.uk/

I have contacted Cath Jackson and Julie Leask. They have both given me their permission to evaluate this decision aid as long as I acknowledge them in anything I write about the study.

Decisional Conflict Scale

The decisional conflict form is presented below. It is publicly available and was obtained from:
https://decisionaid.ohri.ca/docs/develop/Tools/DCS_English.pdf
(www.ohri.ca/decisionaid. AM O'Connor, Decisional Conflict Scale. © 1993 [updated 2005].)

Traditional Decisional Conflict Scale (DCS)

My difficulty in making this choice

A. Which of these statements reflects your beliefs? Please check ☑ one.

- ☐ I do not want to vaccinate my child.
- ☐ I am unsure if I want to vaccinate my child.
- ☐ I would like to vaccinate my child.

B. Considering the option you prefer, please answer the following questions:

	Strongly Agree [0]	Agree [1]	Neither Agree Nor Disagree [2]	Disagree [3]	Strongly Disagree [4]
1. I know which options are available to me.	☐	☐	☐	☐	☐
2. I know the benefits of each option.	☐	☐	☐	☐	☐
3. I know the risks and side effects of each option.	☐	☐	☐	☐	☐
4. I am clear about which benefits matter most to me.	☐	☐	☐	☐	☐
5. I am clear about which risks and side effects matter most to me.	☐	☐	☐	☐	☐
6. I am clear about which is more important to me (the benefits or the risks and side effects).	☐	☐	☐	☐	☐
7. I have enough support from others to make a choice.	☐	☐	☐	☐	☐
8. I am choosing without pressure from others.	☐	☐	☐	☐	☐
9. I have enough advice to make a choice.	☐	☐	☐	☐	☐
10. I am clear about the best choice for me.	☐	☐	☐	☐	☐
11. I feel sure about what to choose.	☐	☐	☐	☐	☐
12. This decision is easy for me to make.	☐	☐	☐	☐	☐
13. I feel I have made an informed choice.	☐	☐	☐	☐	☐
14. My decision shows what is important to me.	☐	☐	☐	☐	☐
15. I expect to stick with my decision.	☐	☐	☐	☐	☐
16. I am satisfied with my decision.	☐	☐	☐	☐	☐