

A. Cover Page

**Project ID #:** 27449113

**Program Title:** Establishing and Evaluating a School and University Campus-Based Approach to Implementing Serogroup B Meningococcal (MenB) Disease Recommendations in Older Adolescents and Young Adults

**Main Collaborators:** University of Florida (UF), Department of Pediatrics and Department of Health Outcomes and Policy (HOP), Alachua County Health Department (ACHD), Alachua Medical Reserve Corps (MRC), Alachua County School System (ACSS), University of Florida Student Health Care Center (SHCC) and Avnee Rawal Fund for Pediatric Health

**ABSTRACT:**

**Background:** Meningococcal B (MenB) disease disproportionately affects 16-23 year olds. Uptake of immunizations in this age group is poor with multiple recognized barriers. There is a new national recommendation that a MenB vaccine series may be administered to youth 16-23 years of age.

**Methods:** We plan a multi-level intervention including; awareness, education, empowerment and accessibility to MenB vaccines for 16-23 year olds in high schools and a local university within Alachua County Florida. Primary intended outcomes are; a) the adaptation of available education materials on meningococcus infection and immunization for use with 16-23 year olds to diminish vaccine uptake barriers and b) increased uptake (initiation and series completion) and knowledge of meningococcal B vaccine in the target audience. We will use pre- and post-intervention surveys and vaccine uptake data from Florida SHOTS immunization database to measure knowledge, attitudes and vaccine uptake in this population.

**Results:** Expected results are to reach MenB immunization of 20-30% of the 16-18 year olds in high schools in Alachua County by the end of the first year (~= the numbers achieved for MenACWY 2<sup>nd</sup> shots in this same age group) and a similar % uptake in the 18-23 year olds. Ideally this uptake of vaccine will correlate with an increase in knowledge, empowerment and awareness of the importance of Men B vaccine through the multi-level intervention effects on the community, parents and peers of adolescents and young adults.

**Conclusions:** A multi-level intervention, including school-level immunization accessibility increases uptake and knowledge of MenB vaccine in parents of and individuals 16-23 years old.

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C. Reviewer Comments:

**Description of the intervention:** We plan a multi-level intervention with 4 components; awareness (county-wide publicity regarding meningococcal disease and the importance of MenB vaccine in prevention of disease in the higher risk population of 11-23 year olds), education (online, written and in-person), empowerment (through peer educators and vaccine decision making review) and enhanced accessibility to immunization with MenB by taking the vaccines directly to the youth in school, on and off the university campus, with a facilitated consent process. (See pages 7-12 for the detailed description of the interventions.)

**How the partnerships work?** UF Pediatrics and HOP will oversee the education and empowerment curriculum, surveys, implementation of the education and immunization events and data management and analysis. The ACSS will facilitate communication with students and parents regarding awareness, education, empowerment and access to MenB vaccine within the high schools. School nurses along with staff from the ACHD, MRC and UF physicians and peer educators will staff the education and immunization events to provide MenB vaccine and collect surveys and register immunizations in Florida SHOTS database. The UF SHCC will similarly collaborate using their nurses and clerical staff with staff from ACHD, MRC and UF to implement the education and immunization events for undergraduates at UF. ACHD oversees all vaccine storage and delivery. The Avnee Rawal Fund will collaborate with all the groups to optimize the awareness, education and empowerment components for the community and target audiences. They will oversee the website, publicity and assist in survey and consent collection utilizing tangible incentives.

**Method for implementing Cat B recommendations?** We will use a multi-level intervention to support a restructuring of care that makes the MenB vaccine more accessible to all 16-23 year olds by bringing vaccine to convenient locations in the high schools and universities. The restructuring is supported by interventions targeted at three levels of the socio-ecologic framework: awareness is targeted at the community, the education campaign is targeted at parents, peers, and students, and the empowerment campaign is targeted at students. (See page 7 for the theoretical model and pages 7-9 for the interventions.)

**Description of evaluation plan?** We will evaluate our multi-level intervention with a group non-randomized experimental two-year trial. The interventions will be conducted in the eight high schools and one university (UF) in Alachua county where investigators have ongoing collaboration for implementing vaccines in schools. We will recruit a control county from the 19 remaining counties within Florida that also have a college or university. In both intervention and control schools, we will collect MenB vaccination records from the Florida state immunization registry (Florida SHOTS) and evaluate the influence of our interventions on MenB vaccine attitudes and knowledge with a pre-post survey of parents (high school students) and students (college students). For our primary vaccine uptake outcomes, we will estimate the change in the probability of vaccination initiation and completion over time using fully saturated regression models including an INTERVENTION\*TIME interaction. Similar models will be used to estimate the change in vaccine knowledge and attitudes over time. We will estimate all models as mixed effects models to account for within school clustering and repeated measures over time. (See page 10 – study design.)

**Description of plan for dissemination:** We will leverage the second year of the project to disseminate and evaluate the dissemination of our multi-level intervention to the control

county. The Blueprint for dissemination (page 17) will guide our dissemination process which will include creation of clear implementation materials, aid for the control county establishing stakeholder collaborations, aid and mentoring for the control county by the intervention county during their intervention implementation. A full description is on page 16.

## **D. Main Section**

### **D.1.1 Overall Goal**

In the U.S., serogroup B meningococcal disease (MenB) disproportionately affects adolescents and young adults.<sup>1</sup> Therefore, the Centers for Disease Control and Prevention (CDC) released a recommendation that a MenB vaccine series *may be* administered to adolescents and young adults aged 16-23.<sup>2</sup> Efforts to increase uptake of MenB vaccines must understand and address clinician, patient, and caregiver awareness, attitudes, knowledge and decision making related to immunization. **The overarching goal of this project is to establish and evaluate a high school and university-targeted multi-level intervention program to increase MenB vaccine uptake.** This goal directly addresses the current Category B serogroup B meningococcal (MenB) ACIP recommendations and the intent to increase MenB immunization in an older adolescent / young adult population (16-23 years of age). Our multi-level intervention will address four main elements in vaccine decision-making guided by the socio-ecologic framework: (1) awareness of the vaccine by the community, (2) education of parents, peers, and individual youth, (3) youth empowerment to make health decisions, and (4) accessibility of the vaccine. This project will leverage the established collaboration between several institutions (university, county health department, county school board and a community advocacy group) in Alachua County for influenza vaccination to implement and evaluate a unique model for increasing Men B vaccine uptake among 16-23 year olds.

### **D.1.2 Key Objectives**

- 1) Adapt nationally suggested meningococcal B vaccine materials to focus on the barriers and facilitators to immunization most salient in Alachua County.
- 2) Evaluate effectiveness of our intervention in increasing uptake (initiation and series completion) and target audience knowledge of the meningococcal B vaccine
- 3) Prepare materials for dissemination and evaluate the dissemination process in one other county.

Our team is well prepared to accomplish these aims because of prior experience conducting vaccination campaigns in Alachua high schools and the University of Florida, prior experience educating patients, parents and providers about vaccinations, and the major stakeholders' experience with previous collaboration with each other and their commitment to the project.

## **D.2 Current Assessment of Need in the Area:**

Alachua County, Florida has a population of approximately 259,000, with approximately 47,000 undergraduate students (32,000 enrolled at UF and 15,000 enrolled at Santa Fe College). There are 8 public and private high schools with total enrollment of ~ 7,600 students with approximately 4,500 16-18 year olds. Approximately 22% of the county's population is between ages 13-23. This makes the threat of epidemic MenB infection initiating in an adolescent / young adult population real for Alachua County. The Alachua County Department of Health has administered approximately 400 doses of MenB vaccine --since October 2015. For Alachua County, the state immunization registry, FloridaShots, reports 291 Men B vaccinations given in 2015 and 307 vaccinations given in 2016 through May 10<sup>th</sup>, 2016.

If one considers the national data for MenACWY vaccination in the age group 13-17, 78.8% of adolescents aged 17 years received 1 dose of MenACWY, and only 28.5% received the complete 2-dose series. Florida is below the national average for MenACWY vaccination with 72.2% receiving 1 dose.<sup>3</sup> Data from Florida SHOTS for Alachua County, reports the total number of doses of MenACWY given by year; 2013- 2932 doses, 2014 – 3409 doses, 2015 – 3212 doses and through May 10<sup>th</sup> 2016 -680 doses. (Data was taken directly from the Florida SHOTS database by Alachua County zip codes and year through the Alachua CHD.) The University of Florida requires 1 MenACWY dose for students living on campus at entry to UF. UF also recommends the MenACWY series for students living on campus but does not have a recommendation for MenB vaccine for enrollment at UF. (Personal communication- Dr. Guy Nicolette)

This indicates a clear gap in protection for adolescents and young adults who do not have protection against meningococcal disease related to any serotype including only a limited number of youth who have received the complete series more likely to afford longer duration protection. Furthermore, very few community members will have protection against MenB since the MenB vaccination recommendation is new and the total numbers of Men B immunizations is low. Crowded housing both on and off campus, active and passive smoking and antecedent viral infections are known risk factors for meningococcal disease. In addition, bar and nightclub patronage and alcohol use have been associated with higher risk for disease. All of these risk factors are present in our community, thus an outbreak of meningococcal disease could occur.<sup>4</sup>

The reasons to undertake this project in Alachua county include; a) need to increase awareness and uptake of MenB vaccine to provide adolescents and young adults with protection against MenB disease; b) there are existing community collaborations successfully providing immunizations for the Control Flu Program in Alachua County, working to increase influenza immunization by going to local K-12 schools and UF campus to immunize individuals, which can be utilized for the MenB project; c) the strong initiative and support of the Alachua County Health Department in providing immunizations for the county citizens and d) our desire to create and evaluate a model for implementing current MenB immunization recommendations. We will offer 16-18 year olds, who have had only 1 shot of MenACWY vaccine, the booster dose during our immunization events to improve coverage for all the important meningococcal

serotypes. This model, when shown to be successful, could be disseminated to other counties and locations specifically for MenB immunization. Furthermore the model could also be applied to other adolescent and young adult vaccines (MenACWY, Tdap, HPV, etc.).

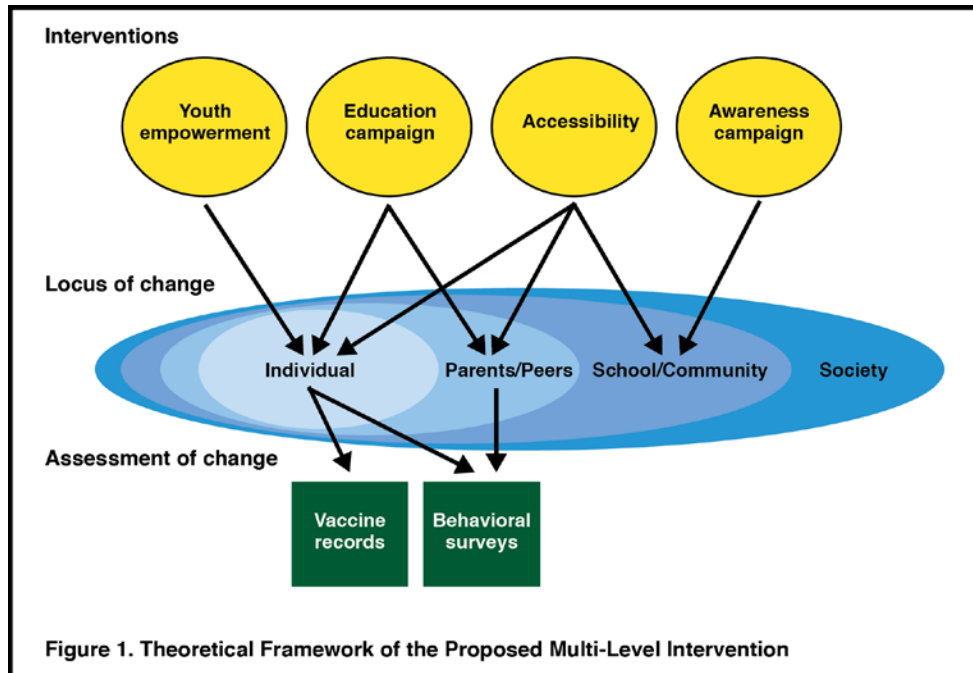
### D.3 Project Design:

Our project is a multilevel intervention targeted at three of the social-ecologic framework's components to promote universal vaccination of MenB among 16-23 year olds.

#### D.3.1 Theoretical framework:

The proposed intervention is guided by the social-ecologic theory of behavior that hypothesizes individual health behaviors are influenced by the individual, their close relationships, the community, and society.<sup>5</sup> Similar to the most successful and sustainable interventions,<sup>6</sup> our proposed intervention targets all levels of influence and addresses both distal and proximal factors (Figure 1).

Three of our intervention components (educational campaign, youth empowerment peer-led sessions, and increased accessibility with in-school vaccination days) are targeted directly at individual influences because proximal influences often produce the largest changes. Next, parents and peers are



targeted by both the educational campaign and the increased accessibility of the vaccine within schools. Parents play an important role for youth health decisions, especially among the 16-17 year olds.<sup>7</sup> Peer influence is one of the strongest influences on adolescent and young adult decisions.<sup>8</sup> The project will address school and community level influences, with the accessibility of the vaccine within schools, demonstrating the school support of the vaccine, and by conducting community educational events as part of our awareness efforts. Finally, while we will not intervene on societal influences MenB vaccine receipt (i.e., Centers for Disease Control and Prevention's recommendations and national attitudes about vaccination), we will adjust our effectiveness analysis for society influence with measured individual vaccine attitudes,

propensity to behave consistent with national guidelines, and awareness of MenB vaccine recommendations.

#### D.3.2 Intervention components:

For goal 1, we will adapt the intervention components from prior research by the study team on influenza vaccination and from national resources on MenB vaccine to meet the needs of students, parents, and the Alachua county community.

##### *D.3.2.1. Awareness:*

We will conduct an **awareness campaign** throughout Alachua County to alert medical practitioners, parents, high school students, university students, and the community in general to the significance of Serogroup B meningococcal disease in the United States, the occurrence of outbreaks on college campuses, the increased risk for individuals 11-23 years of age and the availability of Meningococcal B vaccines and current recommendations for their use. In conjunction with the successful Control Flu program in Alachua County, we will attend community fairs and create local advertisements. The Control Flu program has already developed the infrastructure for attending these events and broadcasting these advertisements. The additional collaborators, (Dr. Ryan, Paul Myers, Guy Nicolette, Karen Clarke) who are also part of the Control Flu program, will coordinate these efforts.

To inform the material included in the awareness campaign, we will conduct semi-structured interviews with members for each of the key stakeholder groups: students, parents, and medical practitioners. We anticipate conducting 9-12 interviews to assess specific perceptions, attitudes, existing knowledge and barriers to MenB vaccine. Qualitative information from these groups will also be used to adapt the other intervention components.

##### *D.3.2.2 Education:*

The **education component** will be both web-based and in-person to meet the individual needs of different learners. Educational information will be provided both before and during the in-school vaccination days. We will develop a parent and a student (18-23 years old) version of the educational curriculum. We will adapt national resources of patient –focused materials and guidelines from the Centers for Disease Control and Prevention (CDCP), Advisory Committee on Immunization Practices (ACIP), National Foundation of Infectious Diseases (NFID), Department of Health and Human Services (DHHS), American Academy of Pediatrics (AAP) and National Vaccine Advisory Committee (NVAC) for the indications and use of Meningococcal B vaccines. First, our team of physicians and health behavior researchers will use the results from the stakeholder semi-structured interviews (conducted for the awareness campaign) to adapt the national materials to the most relevant barriers and facilitators for Alachua County. We will get feedback on the acceptability and usefulness of the materials from focus groups with the target populations (parents and students). We will conduct 3 focus groups of parents and 3 focus groups of students each with 6-8 participants. We will analyze the focus group data following grounded theory.<sup>9</sup> Adaptations will be made to the materials between and following completion of the focus groups.

#### *D.3.2.3 Empowerment*

A guided program for adolescents and young adults on “Decision-Making for your Health” will be offered at the same time as the vaccination days to assist youth in finding, assessing and utilizing health information (online and printed) to guide their personal decision-making for their health. The program will be a transition from parent-directed decision-making to patient/youth-directed decision-making focusing on immunizations as an essential component of health amongst many decisions regarding health facing youth (alcohol, tobacco and drug use, sexual activity, diet and exercise, motor vehicle safety, etc.) Peer educators (UF medical school students or UF undergraduates) will participate in education events, answer questions of the adolescents/young adults and their parents and facilitate development of decision making for healthcare by the youth through demonstration of accessing health information, use of an app for figuring out what vaccines they might need (What vaccines do you need? <http://www2.cdc.gov/nip/adultimmsched/> ) (this is intended only to guide the decision making process for youth as it does not currently contain a recommendation for MenB vaccine) and one-on-one discussions with the youth concerning examples of their personal healthcare decision making.<sup>10</sup>

#### *D.3.2.4 Accessibility*

Because so few older adolescents and young adults attend regular well visits<sup>11</sup>, we will restructure the immunization system by offering MenB on the high school and university campuses through a collaborative program between the University of Florida, Alachua County Health Department and the Alachua County School System. These immunization opportunities will include Immunization Fairs, Immunization Booths at local health fairs, Immunization after school programs and Immunization afternoons and evenings to reach the youth at times and places convenient for them. The opportunities will include; online resources for education and empowerment, in-person guidance re: vaccine education and decision-making, question and answer booths and a streamlined consent and immunization process. For any youth with signed consent for immunization(their own for 18-23 year olds and parental consent for 16-17 year olds); we will immunize them with MenB vaccine, monitor them for 15 minutes post immunization and record the immunization in Florida SHOTS database.

This is similar to the successful Control Flu Program in Alachua County, immunization events with streamlined education and consent process and actual administration of the vaccine to those youth consenting (or with appropriate parent consent). We will also offer students booster shots (for 16-18 year olds if they need them) of MenACWY and HPV at the same time. All vaccines will be offered free of charge and administration of the vaccines will be billed to student’s health insurance. Each vaccine administered will be recorded in Florida SHOTS and by the Alachua County Health Department (monitor # doses given during these events).

In the high schools, information/consent packets re: Men B immunization access will be e-mailed to students/parents and sent home with students in paper form prior to immunization events including; an information sheet on meningococcal disease, vaccine information sheets for MenB vaccines, answers to commonly asked questions about the vaccine, the site for



information for the Adolescent Adult Vaccine Quiz,<sup>10</sup> a specific consent form for administration of the Men B vaccine and demographic information for facilitating insurance reimbursement for the immunization administration. In the university, through specific colleges, individual dormitories and student groups (Pre-Med Interest Group, Students for Vaccines and others) within the university similar information/consent packets will be distributed prior to immunization events. This will facilitate the youth bringing in their signed consent form or allow them to already be familiar the information and consent form and sign a consent form at the event prior to immunization. Insurance information is also collected before or at the time of immunization. The youth will be asked to complete an “exit survey” (similar to the post-education survey) while waiting the post-immunization 15 minutes; to identify the specific intervention components which influenced their decision to be immunized with MenB vaccine.

## **D.4 Methods**

### **D.4.1 Study sample (Target audiences)**

#### *D.4.1.1 Adolescent / young adults (16-23 years of age)*

We will recruit adolescents from eight county high schools and young adults attending University of Florida. Recruitment of 16-18 year olds in high schools will occur in after-school or lunch time immunization opportunities in a fashion similar to the school-located influenza vaccination (SLIV) program in Alachua County. Recruitment of 18-23 year olds will occur via immunization opportunities both on campus in dorms and health outreach by the University Student Health Care Center and off university campus through health fairs and similar immunization events. The Alachua County Health Department, Medical Reserve Corps of Alachua County, University of Florida and Avnee Rawal Foundation will collaborate to provide, awareness, education, empowerment and accessibility via these events. The students are “used to” being approached via the Control Flu Program. We feel the use of peer educators in the educational events will allow them to get information regarding vaccines from informed peers and we will also give a tangible incentive to students completing the survey.

#### *D.4.1.2 Parents of students (high school and college)*

We will recruit parents through electronic and written information distributed to students/young adults from the high schools, and university. This will include; Information about meningococcal disease, Men B disease and vaccine protection, immunization schedule for adolescents and young adults, vaccine information sheets (VIS), notifications of the immunization and education opportunities, a survey about their knowledge and attitudes and consent forms to be signed for Men B immunization. The parents routinely receive information from the high schools and university concerning immunizations and health concerns. We believe that many parents will be interested in the education and immunization opportunities offered and we will provide tangible incentives for completion of the survey.

#### *D.4.1.3 Healthcare professionals*

We will recruit healthcare professionals from the Pediatric After Hours Group, Alachua County Medical Society, University of Florida Student Health Care Center and the Medical Reserve Corps of Alachua County. Healthcare professionals will participate in focus groups and in the education and immunization opportunities for adolescents and young adults. Health professionals within our community often want to be able to share their own thoughts, experiences and opinions as well as glean new information useful to them in their day-to-day work. Within UF, the medical reserve corps, private pediatricians we already have a group of professionals who will appeal directly to the other professionals for their participation and input through the surveys.

*D.4.1.4 Alachua County community members*

The community will participate the awareness campaign potentially increasing their knowledge of meningococcal infection, disease and vaccination. Additionally there is the potential for less exposure to invasive meningococcal strains in the community with larger portions of the population being immunized. Furthermore, the social-ecological model suggests raising community support will increase vaccinations among the specific target populations and other members of the community (e.g. 18-23 year olds not attending UF).

**D.5 Study Design**

The design of the proposed study is a group, non-randomized experimental trial (Table 1). The interventions are targeted at the Florida high schools and universities. The intervention will be conducted in the eight Alachua county public and private high schools and the University of Florida where the investigators have established supportive relationships with stakeholders and have conducted immunization campaigns previously.<sup>12</sup> The intervention condition includes an

months	Aug- Sept 2016	Sept- Nov 2016	Jan-Feb 2017	Mar- Apr 2017	Aug - Sept 2017	Sept- Nov 2017	Jan-Feb 2018	Mar- Apr 2018
<b>Intervention:</b> <b>Alachua county schools</b> Interventions Immunization data Behavioral survey	$O^{VC0}$ $O^{S1}$	$X^{AWA}$	$X^{EDU}$ $X^{EMP}$ $X^{ACC}$	$O^{VC1}$ $O^{S2}$	$O^{VC2}$	$X^{AWA}$	$X^{EDU}$ $X^{EMP}$ $X^{ACC}$	$O^{VC3}$ $O^{S3}$
<b>Control:</b> <b>Control country schools</b> Interventions Immunization data Behavioral survey	$O^{VC0}$ $O^{S1}$			$O^{VC1}$ $O^{S2}$	$O^{VC2}$	$X^{AWA}$	$X^{EDU}$ $X^{EMP}$ $X^{ACC}$	$O^{VC3}$ $O^{S3}$

$X^{AWA}$  = county-level awareness campaign conducted with Control Flu Program,  $X^{EDU}$  = educational materials for parents and students,  $X^{EMP}$  = youth empowerment program on health decision-making,  $X^{ACC}$  = accessible vaccine in school common areas,  $O^{S1}$  = pre-intervention behavioral survey,  $O^{S2}$  = post-intervention behavioral survey,  $O^{S3}$  = long-term post-intervention behavioral survey,  $O^{VC0}$  = review of Florida immunization registry data for all MenB doses received prior to the intervention,  $O^{VC1}$  = review of Florida immunization registry data for all MenB doses received during the intervention time period,  $O^{VC2}$  = review of Florida immunization registry data for time period from post-intervention to six-months following intervention,  $O^{VC3}$  = review of Florida immunization registry data for time period from six months post-intervention to immediately following second year of intervention.

individual-level, a peer-level, and community-level component. In the second year of the study, the interventions will be repeated in Alachua county schools to investigate cumulative effects of repeated delivery.

For the control condition, we will recruit high schools and a university or college within a separate Florida county. This recruitment is feasible based on the presence of five Florida counties with similar size colleges or universities to University of Florida (Leon, Miami Dade, Orange, Hillsborough, Palm Beach, and Broward), and over 15 other counties with colleges and multiple high schools within the county. The investigative team has experience with other research collaborations across the state, the university Student Health center director is in close communication with other directors at other colleges/universities around the state specifically regarding the current vaccine recommendations for college age students, the high school superintendents have active collaborations for curriculum and programs for the health of their students across counties and co-investigator, Mr. Myer, is in frequent communication and collaboration within the FDOH as Acting Deputy Secretary for county health systems. These active connections and collaborations will facilitate our capability to recruit an appropriate “control county” from around the state. The “control county” will be recruited early on, participate in behavioral surveys in year 1, participate in their own vaccine data collection and analysis in the same method as in Alachua County in year 2, will receive an intervention toolkit to be utilized in the second year of the project (including education and on-site vaccination opportunities) as part of our dissemination evaluation. Alongside purposeful selection of our control schools, individual level data will be used to calculate propensity scores that we will use to adjust for possible confounding and selection bias between the intervention and control counties. This adjustment will strengthen the causal inference of our findings.

#### D.5.1 Implementation Process Evaluation

We will assess the implementation of each of our intervention components with several measures of exposure, participation, and fidelity.

##### *D.5.1.2 Awareness campaign*

D.5.1.2.1 Participation. We will estimate the reach of the awareness campaign by estimating the number of community members that attend each event, track the number of materials taken by community members, and track the coverage of our local advertisements.

D.5.1.2.2 Recognition, usefulness, and acceptability. With a few questions in the post-intervention behavioral survey, we will evaluate the parent and student recognition of our campaign slogans and main objectives. We will also ask whether parents and students found this information use and acceptable.

##### *D.5.1.3 Educational component:*

D.5.1.3.1 In-person participation and information sufficiency. During all vaccination events, we will track the number of students and parents accessing the educational

materials. We will also track which questions are asked of our education staff so we can further improve the materials to meet the needs of the target audience.

D.5.1.3.2 Usefulness and acceptability. With a few questions in the post-intervention behavioral survey, we will evaluate if parents and students found the education materials provided with the consent, on the website or offered in-person useful.

#### *D.5.1.4 Empowerment component*

To evaluate the empowerment component, we will assess participation. During all vaccination events, we will track the number of students and parents accessing the empowerment materials and near-peer facilitators. We will also track the average amount of time each student spends with the near-peer facilitators to help estimate the number of facilitators needed at each event.

#### *D.5.1.5 Accessibility:*

To measure the accessibility process, we will measure the rate of vaccination among attendees and the overall percentage of students vaccinated.

D.5.1.5.1 Rate of vaccination among eligible attendees. During all vaccination events, we will estimate the percent of attendees who obtain vaccination by dividing the number of 16-23 year olds who receive a dose of MenB vaccine by the number of 11-23 year olds attending the event.

D.5.1.5.2 Percentage of students vaccinated. We will estimate the percentage of students vaccinated with at least one dose of the MenB vaccine through our program by dividing the number of students receiving a vaccine dose by the number of students enrolled. In the second year, we will also estimate the percentage of the student population receiving a second dose or completing the series.

#### *D.5.1.6 Comparative usefulness of sources:*

All students who receive a vaccine will be invited to take a brief survey offered on iPads that will include questions on which main source of information (parent instructions, educational materials, awareness events, empowerment, and accessibility) they used to decide to get the vaccine. This information will allow us to estimate which intervention elements may be the most salient to students. While far short of a design to evaluate the influence of each intervention component; the survey will provide some understanding of the core intervention components needed to achieve the project's effect and will aid in adaptation efforts for dissemination.

### **D.5.2 Outcome Evaluation:**

We will evaluate the short-term and long-term effects of our multi-level intervention on uptake and knowledge of MenB vaccine. Outcomes will be measured through vaccination records from the Florida immunization registry and behavioral survey for students and parents.

#### *D.5.1.2 Uptake of MenB vaccine:*

Our primary outcome is uptake of the MenB vaccination among participants in intervention compared to control schools. With parent or student permission (those  $\geq 18$  years) to access vaccine records, collected when agreeing to participate in the behavioral survey, we will send the list of consenting individuals to the Florida immunization registry and obtain individual records of MenB vaccine received from the month prior to our intervention (August 2016) through the end of our intervention efforts (April 2018). Consent for the vaccination records will extend through the full study period, resulting in no missing data for our primary outcome. With this data, we will estimate rates of initiation and series completion between participants in the intervention and control condition. State immunization registry data has the advantage of being available for both intervention and control counties and is inclusive of vaccine doses received at most clinics, through our program, financed by Vaccines for Children, and received at the Department of Health. All vaccines administered by our in-school program will be tracked separately and will be standardly reported to the state immunization registry.

#### *D.5.2.2 Knowledge and attitudes about MenB vaccine*

Our secondary objective is to assess change in knowledge and attitudes about the MenB vaccine due to our interventions, we will administer behavioral surveys approximately 1 month before beginning any intervention activities, immediately following completion of intervention activities, and following the second intervention year. The survey will be a brief (5-10 minutes) self-administered survey including questions about demographics, vaccine attitudes, beliefs, and knowledge (general and MenB vaccine-specific), perceived likelihood of infection, perceived severity of MenB, and perceived effectiveness of the MenB vaccine. All survey items will be adapted or adopted from prior vaccine-related surveys. The post intervention survey will also include questions about familiarity with or participation in intervention activities. To prevent participant disclosure, we will send each survey with a unique and random study identifier. We will keep the files with the link between identifiers, names, and contact information separate from the files with study identifiers and questionnaire responses. At no time will data and identifiers be stored together.

For high school students, we will survey a random sample of 2,500 parents (1,250 Alachua County and 1,250 control county) of 16-18 year olds because parents play a large role in health decisions of teens and the parent is needed for consent for the vaccine for all youth less than 18 years.<sup>13</sup> The students' parents will be recruited from random samples within each school to allow schools to maintain the list of students. If possible, we will collect enrollment lists from each school and randomize from the entire student population in Alachua County and a second sample in the control county.

In conjunction with the Control Flu Program material mail-out, in August to September 2016, we will mail parents of each selected student a packet including an invitation to complete the survey, a consent letter explaining completing the survey is interpreted as consent to also collect the youth's Florida SHOTS records for MenB vaccine, the survey, and a tangible incentive (equivalent to ~\$5). One week later, all non-responders will receive a postcard reminding them

of the survey and a link to complete the survey on-line. Two weeks after the original mailing, we will send an email reminder with an electronic link to the survey to all parents who have not responded. We will include the principal of the school as a co-signer of the letter to parents. Following the same procedures, parents who participate in the first survey, will be sent the post-survey survey immediately following intervention activities in March to April 2017. This survey will be accompanied by a tangible incentive (~ \$10 value). To compare effects of exposure to the program for a second year versus the first year in control schools, we will survey all participating parents again in March to April 2018. This survey will be sent to responders to at least one of the two previous surveys and include a \$15 incentive. The multiple modes of data collection will likely not effect self-reporting of behaviors: there were no differences by mode of collection (i.e., Internet or mail) in a previous trial with long-term follow-up of a cohort of over 5,000 high school students in Chicago.<sup>13</sup>

For university students, we will survey a random sample of students 18-23 years old: 1,250 at University of Florida and 1,250 at the control university. We will follow the previously successful strategy of contacting students used by co-investigators (Dr. Ryan, Paul Myers, Guy Nicolette) for influenza vaccination efforts. Specifically, we will work with individual colleges and dormitories in the University to identify and send an email with a link to an electronic consent, survey and immediately available \$5 incentive (e.g., electronic gift card to university stores, Amazon electronic gift card, etc.). Pre-intervention survey responders will receive the immediate post-intervention survey and a \$10 incentive for completion. A third survey will be sent with a \$15 incentive. If response rates are low, we will consider selecting additional students for our sample or forgoing the random sample for a convenience sample by bringing tablets to student gathering locations.

To maximize survey response rates, we will follow best practices for conducting surveys including personalizing questions, providing hand stamped return envelopes, including unconditional incentives, and sending reminder postcards.<sup>14</sup> Postcards will include a link to the survey website. Additionally, we will email participants links to the survey website following best practices (e.g., including a picture and not mentioning the survey in the subject line).<sup>14</sup>

### **D.5.3 Analysis**

For each age group (high school and university), we will estimate the effect of the intervention on vaccine initiation, vaccine completion, beliefs knowledge and attitude. For our primary vaccine uptake outcomes, we will estimate the change in the probability of vaccination initiation and completion over time using fully saturated regression models including an INTERVENTION\*TIME interaction. Similar models will be used to estimate the change in vaccine knowledge and attitudes over time. We will estimate all models as mixed effects models to account for both within school clustering as well as repeated measures over time. All models will be estimated using PROC MIXED in SAS v9.3. PROC MIXED allows for the specification of Kronecker product covariance structures necessary to account for multiple levels of clustering. Our models will assume a covariance structure of the Kronecker product of a compound symmetric matrix for students nested within school and an AR(1) matrix for survey measurements nested within students over time. To maintain an additive interpretation of the

interaction term and allow for the necessary Kronecker product covariance structures, we will estimate the impact of the intervention on vaccine initiation and completion using a linear probability model in PROC MIXED. As a sensitivity analysis, these estimates will be verified with a mixed effects logistic model specifying the appropriate additive contrasts using PROC NLMIXED.

To account for selection bias and confounding, we will use propensity score weighting to balance demographics and general vaccine attitudes across study condition at baseline. We will estimate stabilized propensity weights using logistic regression models. Extreme weights, those in the top and bottom 1%, will be trimmed as necessary to maintain stability of model estimates.

#### D.5.4 Power Considerations

For our primary outcomes of vaccine uptake, we estimated the necessary sample size for high school students via Monte-Carlo methods. Given our planned sample size, we will achieve statistical power of 0.8 with a change in the vaccination rate of 15% (5% to 20%). Our statistical power rises in excess of 0.9 with a change in the vaccination rate of 20% (5% to 25%) (Figure 2).

We estimated the required sample size by generating data according to our previously discussed analysis model and conducting a Wald-test of the INTERVENTION\*TIME interaction. We replicated this process 10,000 times across different sample sizes to determine the minimum sample size required to achieve a

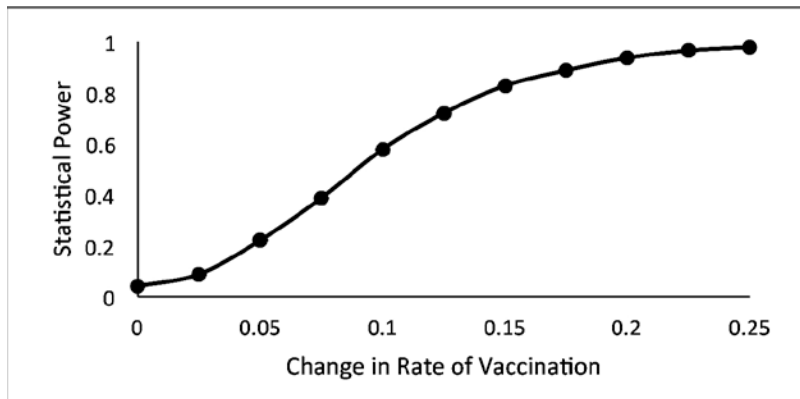


Figure 2. Statistical power of intervention to detect a difference as vaccination increases

statistical power of 0.8. Based on prior collected data, we assumed a vaccination rate of 5% at baseline and in the control condition. We simulated an increase in the vaccination rate of 5% for each of our intervention measurements, resulting in a vaccination rate of 20% by the end of the intervention period. We adjusted for non-independence by using a calculated effective sample size (ESS) for all simulations. The ESS was approximated by extending the approach of Faes et al to account for multiple levels of clustering by using a Kronecker product covariance matrix.<sup>15</sup> ESS was calculated assuming a covariance structure defined by the Kronecker product of compound symmetric matrix for students nested within cluster and a first-order autoregressive matrix for measurements nested within students over time. Based on our prior behavioral intervention trials with high-school students, we assumed a first order autocorrelation of 0.2 across four measurements and a school-level intra-class correlation of 0.01 across 16 schools. After accounting for both the within cluster correlation and autocorrelation, 1,500 high school students will be needed to achieve study aims. Assuming a

response rate of 60% from the first survey, we will recruit 2,500 high school students' parents. We accounted for only the response rate to the first survey because consent to the first survey includes consent to review MenB vaccination records in Florida shots. Thus, we will be able to evaluate our primary outcome, MenB vaccination, for all responders of the first survey. To be conservative, we assume a similar sampling design for our 18-23 year olds and will also recruit 2,500 university students.

## D.6 Dissemination Plan

We will achieve our third key objective, of dissemination of the materials with a dissemination strategy guided by the Blueprint of Effective Strategies in Dissemination (Table 2).<sup>16</sup> The materials and coordination for dissemination will occur during the spring and summer 2017. We will disseminate and evaluate the dissemination in school year 2017-2018 (see Table 1).

Blueprint Strategy	Dissemination Strategy Steps
1. Highlight evidence and simplicity	One-page summary for stakeholders
2. Align intervention with stakeholder strategic goals	Tailor stakeholder summary to stakeholder goals
3. Integrate opinion leaders	External opinion leaders and identify leaders within each school and participating organization
4. Coalition of campaign sponsors	Aid connection of a similar coalition as established in Alachua county
5. Threshold of participating organizations	Leverage experience in Alachua and plans for future expansion to other counties and states
6. Practical implementation tools	Develop intervention toolkit, aid in first implementation of each component, and provide technical assistance
7. Create learning networks	Set up and organize peer-mentoring of control county implementers by Alachua county implementers
8. Incorporate evaluation and goals	Perform process and effectiveness evaluation Allow schools to select their own goals

First, based on our effectiveness trial conducted in school year 2016-2017, we will develop a one-page description of the processes and results of our multi-level intervention. The one-page description will be targeted to stakeholders and highlight the simplicity and effectiveness of the intervention. Second, we will tailor our one-page description to each stakeholder. For example, the schools will be interested in how the vaccination intervention will reduce the chances of an outbreak, student serious injury (e.g., leg amputations, loss of fingers, scarring), and student death. University and college campuses will likely be most persuaded by stories from student health directors at University of California Santa Barbara or University of Oregon who have experienced cases of MenB. Third, we will integrate opinion leaders from within and outside the community to help with participation of schools, students, and parents. Main leaders of opinions regardless of the control county selected will be Avnee Rawal Fund for Pediatric Health and the University of Florida clinical investigators on the proposed project (Drs. Lawrence and Ryan). Within each county we will identify important opinion leaders at each school and participating organization to help champion the project. Fourth, we will support replication of a coalition similar to the one established in Alachua County by helping connect



the control county school system to their county health department, the Avnee Rawal Fund for Pediatric Health, the university student health services, and the university infectious disease department. Fifth, we will only have experience with one prior county participating and will not be able to use peer pressure of the majority of counties participating to encourage participation in the intervention as the blueprint suggests. We will, however, be able to leverage the experience of Alachua as an exemplar county and communicate that the long-term plans of the campaign include expanding to additional Florida counties and counties in other states. Thus, the targeted control county has an opportunity to be a lead community. Sixth, based on improvements suggested for the process measures collected during the first year of the intervention, we will develop an intervention toolkit. The toolkit will cover all the necessary resources needed, the time commitments of staff, the steps to carry out the implementation, and all of the intervention resources (adapted education materials and near-peer led empowerment). The toolkit development will focus on clarity of design and concepts. We will provide staff to help run the first of each intervention component by the control county and provide technical assistance throughout the intervention period. Seventh, we will connect the main implementers in Alachua with the main implementer in the control county. The Alachua implementers will serve as peer-mentors to share experiences, challenges, and lessons learned. Regular communication between the two groups in the form of monthly calls will be encouraged to help the control county with implementation. Eighth, we will perform the same rigorous process and effectiveness analysis in the control county as in the intervention county (see Table 1). Additionally, based on the results of the first year implementation, we will allow each school to set their own goals for effectiveness and process measures. Finally, we will ask stakeholders to complete a brief semi-structured interview at the end of the control county implementation of the intervention to assess the value of each strategy. We will use the proposed strategy to guide dissemination to additional counties within and outside of Florida.

#### **D.7 Strengths of this project**

The project specifically addresses the Category B recommendations for MenB vaccination by facilitating education and decision making for youth and improving accessibility to the vaccine. The drop off in MenACWY second shots in the series (or even HPV booster shots) has been ascribed to the lack of frequent routine well visits in older adolescence when teens can receive these boosters. The awareness, education and empowerment elements will help youth understand the importance of meningococcal infection and risk for individuals 11-25 and the benefits of protection via both the MenACWY and MenB vaccines. The facilitated accessibility, “taking the vaccine” to them should decrease the barriers of time and needing to make an appointment for immunizations. Empowerment is the most unique aspect of our project, but the combination of the four elements (awareness, education, empowerment and accessibility) is a unique plan for addressing some of the largest barriers to adolescent/young adult immunizations. A review of the vaccine literature in PubMed has not revealed previous examples of the use of empowerment/decision making development or the use of peer educators in immunization programs for adolescents and young adults. In Alachua County, the Control Flu Program has already demonstrated the success of the facilitated consent process and school-located immunization events<sup>12</sup> in achieving significantly higher rates of Flu

vaccination in adolescents/young adults. We will build on that existing work and existing collaborations between the university health service, the county schools and the county health department. We will utilize publically available information on vaccines from the CDCP, NFID, ACIP, Children's Hospital of Philadelphia Vaccine Education Center and the AAP. The collaborators have experience with collaboration for projects and research across the state (Alachua County DOH, Alachua County Schools, University of Florida departments of Pediatrics and Health Outcomes and Policy) and the Avnee Rawal Fund for Pediatric Health has a commitment to improving MenB immunization across the state. The survey we utilize and any material we develop re: decision making/empowerment of the youth or the peer education program will be shared publically at no cost to interested parties.

## **D.8 Detailed Workplan and Deliverables Schedule**

### **Narrative**

The research team, primary collaborators and staff will meet via videoconference at least monthly throughout the project. There will be weekly meetings via videoconference for the project Co-PIs, the project coordinator and "invited staff" based on the agenda for the week. There will be separate meetings weekly with one of the Co-PIs, the coordinator and the involved staff to oversee and coordinate the awareness, education, empowerment and accessibility events for the upcoming week.

The first 6 months of the project's two year timeline will be focused on organization and planning activities including: a) ClinicalTrials.gov study registration; b) IRB submission and approval; c) Focus groups with the 3 primary audience groups (students, parents and healthcare providers) to glean narrative data specific to Alachua County and meningococcal infection and use of meningococcal vaccines; d) pilot and finalize the education and empowerment curriculum and materials; e) train the "peer educators" for working with the youth and parents; f) begin the awareness component of the project for the county and for the specific target audiences (dovetail this with the Control Flu Program) ; g) collect additional baseline data on vaccinations for MenB and other vaccines for adolescents/young adults in Alachua County (prior to the education, empowerment and accessibility implementation); h) finalize the evaluation design and analysis plan.

We plan to recruit 1 control county with a commitment to collaborate on this project from the county's local health department, county school board and the local university or college. We will set up for data collection from that county relative to MenB vaccine administration within the target age groups within the county; prior to any awareness, education, empowerment and accessibility interventions. We will then organize their MenB vaccination program based on our model to begin in the second year of the project. We will provide the sponsor with an update on the education and empowerment curriculum, and the final evaluation design and analysis plan at the end of this 6 month period.

Beginning in the second six months, we will implement the schedule of education, empowerment and vaccine accessibility events, collect data on the pre- and post-education surveys, the post-immunization survey and vaccine administration to the different age groups and in the different immunization event venues (high schools, dorms, on and off university campus, etc.) in Alachua County. We will collect baseline data on MenB vaccination in the

“control county” and plan for implementation of awareness, education, empowerment and accessibility elements within that county, high schools and universities/colleges in the second year. We will prepare abstracts describing the intervention model and the preliminary data for submission to national professional conferences.

In the 2<sup>nd</sup> year (third sixth month period) we will analyze the first year data, surveys, vaccination numbers and any additional feedback we receive from the collaborators, community, targeted audiences and county. We will utilize that information to guide appropriate adjustments to our interventions and approach to the targeted audiences and provide feedback to all the collaborators and target audiences concerning their participation and the results of the project. We will guide and assist any “control county” working with us for implementation of the interventions in their own county and collection of data on the surveys and vaccination numbers after the interventions. We will present locally (in Alachua and Florida) on the model and the results of the first year of the project. We will prepare and submit follow-up abstracts on the complete analysis of the first year for national professional meetings and leading to the composition and submission of a full manuscript to a peer-reviewed journal.

In the final 6 months of the project, we will complete data collection on the immunization data in Alachua and any control county, analyze the data and results and complete the manuscript with the updated data. We will update the website with all the educational materials and links to the most utilized sites and information for adolescents, young adults and parents. We will complete the final description of process including description of collaboration efforts, organizational and logistical efforts, training of peer educators and best practices for our program. We will submit the completed manuscript for publication and a project report to the sponsoring agency. At the end of the second year we will be prepared to share our complete vaccine intervention model (with all the related materials, complete description of the model and the process for establishing such collaborations locally) to other counties in Florida and nationally.

Workplan Table / Deliverables Schedule:

**(Submit a “deliverable” to the sponsor for each starred activity\*)**



**First 6 months:**

- Registration with ClinicalTrials.gov\*
- IRB submission and approval through UF\*
- Pre-survey
- Begin Focus Groups with target audiences (students, parents, pediatricians)
- Pilot and finalize education and empowerment curriculum and materials\*
- Train the peer educators (submit curriculum and materials)\*
- Begin Awareness Campaign
- Collect additional baseline data on MenB immunization in Alachua County
- Schedule and plan education and immunization events for the 2<sup>nd</sup> 6 months (submit the schedule and description of events)\*
- Analyze focus group data and utilize for continued planning (submit analysis,

“lessons learned” and plan adjustments)\*  
Complete development of the website (Demonstrate its content and function to sponsor)\*  
Recruit a “control county” to work with (submit the additional collaborating groups, letters of collaboration and key participants)\*  
**Submit to the sponsor a “deliverable” for each starred activity\***



**Second 6 months:**  
Implement the schedule of education and vaccination events (submit numbers of participants for each event, surveys collected, vaccinations given to date)\*  
Collect post-intervention survey (awareness, education, empowerment)  
Collect post-immunization surveys  
Track and collect Florida SHOTS immunization data by zip code, age, date for Alachua and the “control county” (submit data for August 2016-May 2017)\*  
Disseminate all materials to the “control county” collaborators and guide them in the setup for the survey process and intervention implementation (Submit description of plan and process including involved collaborators)\*  
Prepare abstracts describing the intervention model and preliminary data (Submit abstracts to the sponsor)\*  
Analyze surveys



**Third 6 months:**  
Complete analysis of the first year data - surveys and vaccination data  
Review any feedback from collaborators, target audiences and community  
Submit first year report to the sponsoring agency\*  
Continue direct guidance of the control county in the survey process (before and after intervention) + intervention implementation  
Continue data collection for both counties  
Prepare abstract(s) with complete first year data, present locally and nationally (submit accepted abstracts to sponsor)\*  
Begin composition of a full-manuscript for a peer-reviewed journal  
Continue awareness, education, empowerment + immunization interventions



**Final 6 months:**  
Complete data collection for Alachua and “control county” (submit summary of data to sponsor)\*  
Analyze results and data  
Complete the full manuscript (submit prepared manuscript to sponsor)\*  
Update the website, education materials, links, apps (Review with sponsor)\*  
Complete a finalized description and guide for the intervention process, best practices, educational materials for dissemination (submit to sponsor)\*  
Submit final report to sponsoring agency\*  
Submit accepted / published manuscript\*

## E. References

1. Soeters HM, McNamara LA, Whaley M, Wang X, Alexander-Scott N, Kanadani KV, et al. Serogroup B meningococcal disease outbreak and carriage evaluation at a college—Rhode Island, 2015. *MMWR Morb Mortal Wkly Rep.* 2015;64(22):606–7.
2. MacNeil JR, Rubin L, Folaranmi T, Ortega-Sanchez IR, Patel M, Martin SW. Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices, 2015. *MMWR Morb Mortal Wkly Rep.* 2015;64(41):1171-1177.
3. Reagan-Steiner S, Yankey D, Jeyarajah J, Elam-Evans LD, Singleton JA, Curtis CR, et al. National, regional, state, and selected local area vaccination coverage among adolescents aged 13–17 Years — United States, 2014. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6429a3.htm>. Accessed 24 June 2016.
4. Hamborsky J, Kroger A, Wolfe CS. Centers for Disease Control and Prevention. *Epidemiology and prevention of vaccine-preventable diseases.* 13th ed. Washington D.C. Public Health Foundation; 2015.
5. McLeroy KR, Bibeau D, Steckler A, Glanz K. An ecological perspective on health promotion programs. *Health Educ Q.* 1988;15(4):351–77.
6. DiClemente RJ, Salazar LF, Crosby RA. A review of STD/HIV preventive interventions for adolescents: sustaining effects using an ecological approach. *J Pediatr Psychol.* 2007 Sep;32(8):888–906.
7. Burrus B, Leeks KD, Sipe TA, Dolina S, Soler R, Elder R, et al. Person-to-person interventions targeted to parents and other caregivers to improve adolescent health: a community guide systematic review. *Am J Prev Med.* 2012 Mar;42(3):316–26.
8. Albert D, Chein J, Steinberg L. The teenage brain: Peer influences on adolescent decision making. *Curr Dir Psychol Sci.* 2013 Apr 1;22(2):114–20.
9. Corbin J, Strauss A. *Basics of qualitative research: Techniques and procedures for developing grounded theory.* Sage publications; 2014.
10. Centers for Disease Control and Prevention. Adolescent and adult vaccine quiz. <http://www2.cdc.gov/nip/adultimmsched/>. Accessed 24 June 2016.
11. Tsai Y, Zhou F, Wortley P, Shefer A, Stokley S. Trends and characteristics of preventive care visits among commercially insured adolescents, 2003-2010. *J Pediatr.* 2014 Mar;164(3):625–30.

12. Tran CH, Sugimoto JD, Pulliam JRC, Ryan KA, Myers PD, Castleman JB, et al. School-located influenza vaccination reduces community risk for influenza and influenza-like illness emergency care visits. *PloS One*. 2014 Dec 9;9(12):e114479.
13. Livingston MD, Komro KA, Wagenaar AC. The effects of survey modality on adolescents' responses to alcohol use items. *Alcohol Clin Exp Res*. 2015 Apr;39(4):710–5.
14. Edwards PJ, Roberts I, Clarke MJ, DiGiuseppi C, Wentz R, Kwan I, et al. Methods to increase response to postal and electronic questionnaires. *Cochrane Libr*. 2009;
15. Faes C, Molenberghs G, Aerts M, Verbeke G, Kenward MG. The effective sample size and an alternative small-sample degrees-of-freedom method. *Am Stat*. 2009 Nov 1;63(4):389–99.
16. Yuan CT, Nembhard IM, Stern AF, Brush JE, Krumholz HM, Bradley EH. Blueprint for the dissemination of evidence-based practices in health care. *Issue Brief Commonw Fund*. 2010 May;86:1–16.