Nova Southeastern University
Health Professions Division
Grant Application

College: College of Dental Medicine

Department: Orthodontics

Background / TOC

The HPD Research Committee requires a complete research proposal or plan. Complete the application and submit to the Secretary for HPD Research – Ms. Chi Do (room 1522-A, x21784). The Chair of the HPD Research Committee will notify you by letter about the Committee's decision.

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Project Title (Type or Print):

Human Papilloma Virus Vaccine: facilitators and barriers affecting parents' willingness to vaccinate their children

Project Start Date: Upon approval Project End Date: July 16th, 2016

Debora Goldschmiedt Shapiro
Name of Principal Investigator (TYPE OR PRINT)

Postgraduate Orthodontic Resident
Title of Principal Investigator (TYPE OR PRINT)

ds2250@nova.edu
E-Mail Address (TYPE OR PRINT)

College of Dental Medicine, Department of Orthodontics
College and Department of Principal Investigator (TYPE OR PRINT)

$4575
Requested Funding Amount

Signature Page

NAME DATE POSITION

Print name

Signature Date Faculty Advisor (if applicable)

Print name

Signature Date Department Chair

Print name

Signature Date Dean's Designee for Research

Print name

Signature Date Dean

Print name

Signature Date Chairperson Research Committee

PRINCIPAL INVESTIGATOR ASSURANCE

I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I certify that individuals or NSU entities named herein are aware of their planned or potential involvement. I agree to accept responsibility for the scientific conduct of the project.

Debora Goldschmiedt Shapiro
Print name

Signature Date

Abstract

Brief Background and goal/research question

Human Papilloma Virus (HPV) is the most common sexually transmitted disease in the United States (U.S.) and causes about 5% of cancers worldwide, including oropharyngeal cancers. Although the incidence of smoking and alcohol related oropharyngeal cancer is decreasing, the incidence related to HPV infection is increasing. The increase in HPV related oropharyngeal cancers is especially surprising given the availability of a vaccine capable of preventing HPV infection and presumably, HPV related cancers. The goal of this study is to identify potential facilitators and barriers of parents' willingness to vaccinate their children for HPV.

Specific Aims

1. To describe the demographic characteristics, knowledge, attitudes, and prevalence regarding the HPV vaccination and willingness of parents of adolescent orthodontic patients to permit vaccination of their children.
2. To examine the association between parents' willingness to permit HPV vaccination of their children and parents' knowledge about HPV, and several covariates related to their perception of their child's risk of HPV infection, belief that peers would agree HPV vaccination is important, cost of the vaccination, and child's visit to a Primary Care Provider in the past 12 months.
3. To examine the association between the parents' perception of their child's risk to HPV infection and parental knowledge about HPV, belief their peers would agree HPV vaccination is important, and availability of the HPV vaccine at no cost.

Significance

HPV infection, although not curable, is easily preventable through proper vaccination. Despite the U.S. Advisory Committee on Immunization Practices recommendation to vaccinate all adolescents against HPV, only 39.7% of females and 21.6% of males have received complete HPV vaccination coverage. Our proposed study will examine the facilitators and barriers that may impact parents' decision to permit HPV vaccination of their children, and thereby provide critical information needed to support public health efforts to increase HPV vaccination rates among the adolescent population.

Innovation

Few studies have addressed this question regarding HPV vaccination. Therefore, the goal of the proposed study is to examine parental attitudes willingness to permit HPV vaccination of their children and inform interventions to increase the rate of HPV vaccination.

Research plan

Study participants will be recruited among parents with at least one child (age 10-17 years) who is an active patient of record in the NSU postgraduate orthodontic clinic. Survey administration will require 10-15 minutes. Data analysis includes univariate, bivariate, and multivariable analyses to describe sample characteristics and address the study specific aims.

Expected Results

We expect that an association exists between parents willingness to permit vaccination of their child and parental knowledge of HPV, perception of child's HPV risk, and other covariates examined.

Specific Aims

The purpose of this study is to examine orthodontic patient parents' willingness to permit Human Papilloma Virus vaccination of their children. Within this context the specific aims are as follows:

Specific Aim 1: To describe the demographic characteristics of adolescent patients and their parents attending a university based orthodontic clinic, the parents' knowledge regarding HPV, the prevalence of HPV vaccination among the adolescent patients, and to describe prevalence of parents' willingness to permit HPV vaccination of their children.

Specific Aim 2: To determine the association between parents' willingness to permit HPV vaccination of their children and parental self-rated knowledge about HPV, parental perception of their child's risk to HPV, parents' belief their peers would agree HPV vaccination is important, cost of the HPV vaccine, and whether their child has seen a Primary Care Provider (PCP) in the past 12 months.

> Hypothesis: Parents' willingness to permit HPV vaccination of their children will increase with increasing self-rated knowledge of HPV, perception their child is at risk of HPV infection, belief their peers will agree HPV vaccination is important, availability of the HPV vaccine at no cost, and that the child had seen a PCP in the past 12 months.

Specific Aim 3: To determine the association between the parents' perception of their child's risk to HPV infection and parental self-rated knowledge about HPV, parents' belief their peers would agree HPV vaccination is important, and availability of the HPV vaccine at no cost.

> Hypothesis: Parents are more likely to perceive their child at risk for HPV infection with increasing self-rated knowledge of HPV, belief their peers would agree HPV vaccination is important, and availability of the vaccine at no cost.

Significance

Human Papilloma Virus (HPV) is the most common sexually transmitted disease in the United States, and almost all sexually active men and women will acquire it at some point in their lifetime.[1] Transmission occurs by direct contact during sexual activity, including intercourse, oral, and anal sex, when cells from an infected individual shed and contact other epithelial cells of a susceptible host.[2] While most infections are asymptomatic, persistent HPV infection can cause anogenital warts, oral papilloma lesions, and progress to cervical and head and neck cancers.[2] There is no current treatment for HPV infection; however, infection is easily preventable through proper vaccination.[1] HPV vaccination consists of a 3-dose series, where the second dose is administered at a minimum of 1-2 months after the first dose, and the third dose is administered 6 months after the first dose.[3] The Advisory Committee on Immunization Practices (ACIP) recommends that vaccination be initiated at 11 or 12 years of age during routine physical appointments, however the vaccine is approved for males and females between the ages of 9 and 26 years.[4] Vaccination prior to HPV infection is critical for achieving vaccine efficacy, thus it is recommended to vaccinate preteens before they engage in sexual activities.[2,3]

The ideal age to vaccinate is prior to "sexual debut", which may occur as young as ages 11 and 12 years and denotes when the adolescent is at greatest risk of infection.[5] Finer and Philbin reported that less than 1% of 11 year olds, approximately 1% of 12 year old females, and 2% of 12-year males had engaged in intercourse.[5] Additionally, Finer and Philbin found that adolescents engaging in sex at a younger age, waited longer to begin using contraception such as condoms, which can reduce the risk of HPV transmission.[5] However, Finer and Philbin[5] did not include oral sex or other non-vaginal intercourse as indicators of sexual activity in their study, as such, the study may have underestimated the prevalence of sexual activity among the age group studied. The implication being that an even larger percentage of 11 and 12 year olds, than reported, are at risk of HPV infection. Pedersen C, et al.[6] compared the immunogenicity and safety of the *Cervarix* (HPV2) vaccine used by females 10-14 and 15-25 years of age. The serostatus of all participants at entry to the study was reported with the findings that 3% and 4% of females, aged 10-14 years, were HPV 16 or 18 seropositive, respectively.[6] Pederson, et al., not only reported that vaccination at ages 10-14 years was equally tolerated and safe, but also, that immunogenicity achieved was significantly higher in the younger age group (10-14 years old) vaccinated.

Two HPV vaccines, both with high efficacy in preventing HPV infection, are currently available in the U.S. *Gardasil* (HPV4) protects against HPV types 6, 11, 16 and 18, and is licensed for both females and males. *Cervarix* (HPV2) protects only against high-risk types 16 and 18 and is not recommended or licensed for males.[7,8] Neither vaccine is effective against existing HPV infections.[4] Evidence has shown that prior infection with one HPV type does not reduce vaccine efficacy against future exposure to additional HPV strains.[2] Therefore, the ACIP recommends all 11-12 year old females and males should be routinely vaccinated for HPV as a prophylactic effort to decrease incidences of HPV infection and related cancers.[9]

Our study will survey parents of adolescent patients in the NSU postgraduate orthodontic clinic. According to the CDC, children within the ages of 2 and 17 are much more likely to visit their dentist rather than their pediatrician within a 12 month period.[10] In 2010, 78.9% of children 2-17 years old visited a dentist (including specialists such as orthodontists), while 63.4% of children under the age of 18 visited a pediatrician.[10] Adolescents involved in active orthodontic

treatment generally visit their orthodontist on a monthly basis for a period of two years. The prolonged treatment period provides multiple opportunities for orthodontist / patient contact that may facilitate a strong doctor-patient relationship. This suggests that the orthodontic practice setting may be an overlooked venue that is well positioned to positively impact the low HPV vaccination uptake rate among the adolescent population through vaccination or educational intervention protocols. It is noteworthy that not all adolescents may have access to orthodontic care, however orthodontic care is accessible to lower socioeconomic status (SES) segments of the population, e.g., through Medicaid plans. The results of this study will not generalize beyond the target population, i.e., parents and patients attending a university based orthodontic clinic in south Florida, who may exhibit higher SES status than the general population. Nonetheless, this study provides a first look at the orthodontic practice as a unique venue targeted towards an important public health issue. An important aspect regarding generalizability of our study findings is that should our results demonstrate low uptake in HPV vaccination rates among our study population, that may have a higher SES / educational status than the general population, the findings will underscore the need to examine additional methods targeted towards impacting lower SES segments of the population that historically demonstrate disparities in access to oral and medical health care services.

In summary, our proposed study will highlight the need for increased awareness and education about HPV infection and prevention. The study will examine facilitators and barriers that may impact parents' decision to permit HPV vaccination of their children, and thereby provide critical information needed to support public health efforts to increase HPV vaccination rates among the adolescent population.

Innovation

An immunization and infective disease objective of Healthy People 2020 is to increase the vaccination coverage level of 3-doses of HPV vaccine, for males and females by 13-15 years of age, to 80% by the year 2020.[11] Unlike other commonly administered adolescent vaccinations, HPV vaccination rates remain extremely low.[12,13] In 2014, among adolescents aged 13 to 17 years, 87.6% and 79.3% received vaccinations for TDAP and Meningococcal, respectively, yet only 30.4% received complete HPV vaccination coverage.[13] The relatively low HPV vaccination rates are puzzling since the ACIP recommends that all 11 and 12 year olds receive one dose of HPV, TDAP, and Meningococcal vaccines together at a single visit.[7,8] It remains unclear why adolescents being vaccinated for TDAP and Meningococcal are not also receiving the HPV vaccine. Previous studies have assessed the attitudes and opinions of both female adolescents and young college-aged women, about the HPV vaccine and susceptibility to HPV infection,[14-17] but have not explained the observed disparity in HPV vaccination rates compared to TDAP and Meningococcal. Perhaps the vaccination rate disparity is explained by the current knowledge gap due to adolescents' lack of autonomy in making the vaccination decision and that college-aged women are beyond the age that the vaccine is optimally efficacious. Additionally, studies have examined whether cultural determinants, among specific ethnic minority groups, affected parental decisions regarding HPV vaccination of their children,[18-21] but few studies have addressed parents' attitudes towards the HPV vaccine or the HPV susceptibility of their children. In light of these observations, further understanding of the parental role as "gate-keeper" in permitting their children access to the HPV vaccination is necessary to inform action leading to substantial increases in the rate of vaccination coverage level of 3-doses of HPV vaccine. Therefore, the goal of the proposed study is to examine parental attitudes and willingness to permit HPV vaccination of their children.

Approach

Sample
Participants for this survey study will be recruited from parents with at least one child (age 10-17 years) who is an active patient of record in the NSU postgraduate orthodontic clinic at the time that the study begins. Inclusion criteria for parents' eligibility to participate in this study are:

(1) English speaking.
(2) Parents are capable of completing a survey instrument requiring 10-15 minutes of time.
(3) Legal custodians of children between the ages of 10 and 17 years.
(4) The child (children) is (are) current, active patients of record in the NSU postgraduate orthodontic clinic.

Parents not fulfilling all of the inclusion criteria outlined above will be excluded from study participation. Additionally, the parent of a child in the retention phase of treatment (i.e. retainer checks) will not be eligible to participate.

Measurements. Dependent Variables: For Specific Aim 1, prevalence of HPV vaccination will be measured by a survey item dichotomous response to whether the child had received the HPV vaccination. Prevalence of parents' willingness to permit HPV vaccination of their children will be measured by a survey item response based upon a 4-point Likert scale dichotomized to "willing" or "unwilling". For Specific Aim 2, the dependent variable will be the dichotomized "willingness" variable described for Specific Aim 1. The dependent variable for Specific Aim 3 will be parents' self-reported perception of their child's risk of HPV infection based upon a 4-point Likert scale response dichotomized to "at risk" or "not at risk".

Independent Variables: The primary independent variables of interest for Specific Aim 2 and Specific Aim 3 are categorical variables, assessed by Likert scale responses that queried parents' self-rated knowledge of HPV vaccination, belief that their peers would agree that HPV vaccination is important, and the cost of the vaccine. Additional independent variables for Specific Aim 2 include the dichotomized "risk" variable, a dependent variable described for Specific Aim 3, and a dichotomous response regarding whether the child had seen a primary care provider in the past 12-months.

Additional independent variables included in the univariate (descriptive) and bivariate analyses that will be evaluated for inclusion in multivariable models include demographic variables such as: age, gender, race/ethnicity, socioeconomic status, and other potential covariates.

Research Design
A letter introducing the study will be sent to more than 500 prospective participants to ensure a sample size of 300-400 participants, and a credible response rate. The letter will describe the study procedures and subject matter, and invite prospective participants to speak with the researcher or a research assistant at their child's next scheduled orthodontic appointment. At that time, the parent will be provided with additional information regarding the study, have the opportunity to ask questions, and asked if they would be willing to participate. Parents who decline participation or withdraw from the study will be informed that there are no penalties, and no impact regarding delivery of their child's orthodontic treatment or provision of service.

Prospective study participants, who provide verbal consent, will be escorted to a private room where the study procedures will be described fully and written informed consent will be obtained prior to administration of the survey. Parents will be informed that they may decline to participate or withdraw from the study at any time, without penalty and no impact regarding delivery of their child's orthodontic treatment or provision of service.

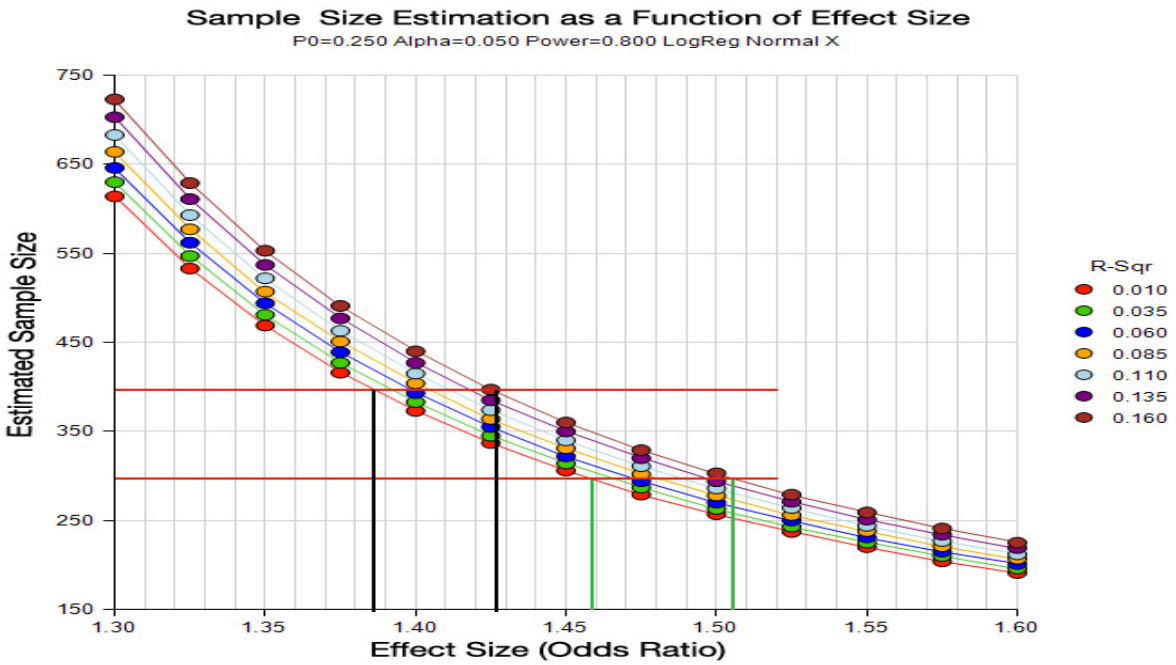
The survey is self-administered, however, the principal investigator or a research assistant will be present should the participant have any questions. Instructions will be provided in English, and the survey will be completed electronically on a tablet; the de-identified responses acquired will reside on a secured cloud-based survey instrument site (RedCap). The survey instrument consists of items that will request demographic data, and items developed from planned focus group interviews guided by the Integrated Behavior Model[22] of health behavior. These items are meant to examine the parental attitudes and the determinants of parents' willingness to permit HPV vaccination of their children. Item formats are either dichotomous (yes/no) responses or scaled 4-point Likert responses (strongly disagree to strongly agree). The survey will require 10-15 minutes and be completed in a single sitting. Participants who complete the survey instrument will receive a Target gift card ($5.00) in appreciation for their participation and compensation for their time. Incomplete survey instruments will be de-identified and discarded, and compensation will not be offered.

Statistical Analysis

The analytic plan includes univariate analysis for descriptive statistics (means, standard errors, frequencies, and proportions) of participant characteristics. Unadjusted bivariate analysis will examine the association of each independent variable with the primary dependent variables of interest using Chi-square and t-tests. Multivariable analyses (multivariable logistic regression) will be used to evaluate theory informed models that examine the determinants of parents' willingness to permit HPV vaccination of their children, and the predictors of parents' self-rated perception of their child's risk of HPV infection. Multivariable model building will commence with those covariates demonstrating a bivariate association with the main outcome variable at a level of $p \leq 0.1$, while demographic variables (age, gender, race/ethnicity, etc.) will be forced into the models following the method of Hosmer and Lemeshow.[23]

Power Analysis

Multiple logistic regression (MLR) analysis will be used to examine all binary outcomes. An 80% response rate of at least 500 prospective participants contacted for this study resulted in a sample size of 400 participants. Based on Cohen's "d" small effect size,[24] the MLR analyses are used to detect odd ratio from 1.33 to 1.36 with a power of 80%.



Response rate:
Based on the patient profiles and number of eligible participants we expect to meet our survey sample size of 400 actual participants.

Establishment of reliability and validity:
Reliability and construct validity will be assessed after survey administration. Content validity will be addressed during the focus group interview process.

Data Collection
Participants will be assigned a random ID number that will identify their responses to the survey instrument. The master list of participants and ID will be stored separately form the data collected on a password-protected secure server and only de-identified data will be analyzed in order to preserve participant confidentiality and anonymity. All study data will be destroyed by permanent deletion from the secured, password-protected servers, after completion of the study and the three-year minimum time required for protecting study documents.

Risks and Benefits
There are minimal risks involved in this study. Participants may view the survey questions as sensitive subject matter and feel uncomfortable completing the survey. However, results from the survey may highlight factors determining parent's decisions to permit HPV vaccination of their children. The study findings may be particularly impactful by informing interventions targeted to increase the rate of HPV vaccination among the adolescent population, a critical public health effort to reduce incidence of cervical and oropharyngeal cancers.

Bibliography and References Cited

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Vertebrate Animals

N/A

Select Agents

1. N/A

2.

3.

4.

Dr. Harold Laubach Date

Radiation Safety

N/A

Dr. Michelle Clark Date

Budget

Item	Describe	Amount
Supplies	Poster, to be used for presentations and conferences (SAO, APHA)	$75
Travel	Airfare and lodging for PI to present research	$1500
Equipment	Tablets loaned from the CDM Orthodontics Department	$0
Participant Incentives	Six hundred @ $5 Target gift cards to be given upon completion of the survey (purchased as needed and to allow the opportunity to increase incentive in order to increase study response rate).	$3000
		Total: $4575

Publication Plan

My plan is to present the study results at the Southern Association of Orthodontics annual meeting in October 2016. I anticipate submission of the research findings for publication in the American Journal of Orthodontics and Dentofacial Orthopedics (AJO-DO), or the Journal of the American Dental Association (JADA). Although JADA is not orthodontic specific, my research topic is critically important and applicable for all dentists. As healthcare providers, dentists can help increase HPV vaccination rates through educational intervention, i.e., informing parents of the risks of HPV and recommending the vaccine to patients and their families. Alternatively, given the novel nature of this study, an effective publication strategy must include giving consideration to submitting the research paper to a high impact public health journal (e.g., the American Journal of Public Health)

Biographical Sketch

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**	
NAME Debora Goldschmiedt Shapiro	POSITION TITLE Post Graduate Orthodontics Resident
eRA COMMONS USER NAME	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing. Include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MMYY	FIELD OF STUDY
Barnard College, Columbia University	BA	05/09	Biology
New York University College of Dentistry	DDS	05/13	Dentistry
New York Hospital Queens	GPR	06/14	General Dentistry

A. Personal Statement

Since I was a high-school student I have been involved in research as an assistant, collaborating as a team member, and leading my own projects. Currently, as a resident Orthodontics, a significant portion of my education is dedicated to reading and discussing literature involved in my field, both classic as well as current. My past experience in research and my current involvement in literature review has given me an appreciation for performing research and, more importantly, contributing to the scientific community. During these years I have also developed a passion for public health and increasing the public's education on oral health. I look forward to doing research that will contribute to public health awareness.

B. Positions and Honors

2013 Omicron Kappa Upsilon (OKU), The National Dental Honor Society

2013 Dr. Samuel Hess Award (outstanding scholarship throughout dental school)

2012-2013 Periodontics Honors Program

2010 Elsa Pleuger-Rahmsdorf Scholarship (merit scholarship)

2006 Barnard College *Howard Hughes Science Pipeline Project* grant

2005-2009 Deans' List recognition all four years at Barnard College

C. Selected Peer-reviewed Publications
None

D. Research Support
None

Resources and Environment

1. Consortium / Contractual Arrangements
   None

2. Consultants / Collaborators (Describe the relationship and attach letters of agreement with key consultants and collaborators. Please attach letters of commitment from named consultants and co-investigators.)
   None

3. Major Equipment (List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.)
   None

4. Laboratory Space
   None

5. Clinical Space
   None

6. Fixed Clinical Equipment
   None

7. Other Relevant Equipment
   None

Project Timeline

August 15 2014: Selected an area of interest for thesis.
November 30, 2014: Selected thesis mentor.
December 7, 2014: Began literature review.
February 30, 2015: Begin writing Grant Proposal.
March 16, 2015: Begin assembling Masters Committee members.
June 17, 2015: Begin writing IRB submission.
July 20, 2015: Finalize Masters Committee members.
August 5-12, 2015: Develop HIPAA compliant study protocols with institutional legal counsel.
August 24, 2015: Complete literature review.
September 18, 2015: Submit IRB approval form.
September 30, 2015: Submit Grant proposal.
October 1, 2015: Conduct focus group to guide the development of survey questions.
October 15, 2015: Select and filter sample of parents of active orthodontic patients in Axium; mail introduction letter to selected parents.
November 1, 2015: Begin conducting surveys and data collection
*November 2015 – May 2016: Continue conducting surveys until required sample size is reached.
June 1, 2016: Begin analyzing data.
July 15, 2016: Begin writing Masters Thesis.
August 15, 2016: Submit abstract and results to Southern Association of Orthodontics (SAO) for presentation at SAO meeting in October 2016.
September 15, 2016: Submit Masters Thesis draft to committee members for review.
October 30, 2016: Masters Thesis completed and submitted
November 21, 2016: Masters Thesis public defense

Leadership Plan

Debora Goldschmiedt Shapiro, D.D.S. is the principal investigator and will be responsible for survey development and administration for this study. She will also oversee survey administration by the selected research assistants. Richard Singer, D.M.D., M.S. the research supervisor and mentor, will advise on development of the survey items and format, monitor the research, and assist in the analysis and interpretation of the data. Lastly, all abstracts and articles prepared for conferences or publication by Debora Shapiro will be reviewed and approved by Richard Singer.