

Effects of the Influenza Vaccine on the Oral Cavity

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EFFECTS OF THE INFLUENZA VACCINE ON THE ORAL CAVITY

by

LAURA SAWIRES

A thesis submitted in partial fulfillment of the requirements
for the Honors in the Major in Health Sciences Pre-Clinical
in the College of Health and Public Affairs
and in the Burnett Honors College
at the University of Central Florida
Orlando, Florida

Spring Term, 2018

Thesis Chair: Danielle Webster, Ph.D.

ABSTRACT

According to existing literature, there is a suggested correlation between certain vaccinations and oral cavity symptoms. Studies have shown that the Diphtheria, Tetanus, Acellular Pertusis, as well as Polio Vaccinations have an association with presented symptoms of bleeding gums, sores, ulcers, white spots in the mouth or on lips, and unpleasant breath odor. Although these symptoms may not occur simultaneously or directly after administration of the immunization, there has been supported evidence of correlation. Given the relevance of an association between vaccinations and orally manifested side effects, an investigation on the presence of such association with the widely administered flu vaccine was conducted. Data for this work was collected from a population including undergraduate students studying at the University of Central Florida. A brief voluntary online survey requesting demographic information regarding administration of the vaccine as well as any experienced side effects was used. The study was cohort in nature as it tracked subjects with known exposure to the flu shot in the past six months to understand the outcome of interest. Results from the survey were used to determine that there is no correlation between orally manifested side effects and administration of the flu vaccine.

DEDICATION

“Rest assured and don’t think too much about any matter, leave it to God who’s in control” –
Pope Kyrillos VI

O give thanks to the Lord for He is good; His mercy endures forever.

To my parents, who sacrificed so much for me and support me every step of the way to fulfilling my dreams. Thank you for loving me and raising me to be who I am today.

To my sister, Mandy, who lightens up my world and has become my favorite person over the years. You make me laugh even when everything is terrible.

To my grandma, whose prayers are what got me this far in life. I love you so much teta, my beautiful queen.

To my best friend and sister, Christine, thank you for being my day one and for mentoring me through life. I couldn’t have done it without you.

To the rest of my family, cousins, and all my other friends, thank you for all your support and love throughout the years. Remember me in your prayers.

ACKNOWLEDGEMENTS

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I would also like to thank my other committee member, Dr. Brittney Wells, for her advice and support throughout the project. Her constant assistance and friendliness during the research process has made it a great experience.

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CHAPTER ONE: INTRODUCTION

As known from existing literature, there is a suggested correlation between certain vaccinations and symptoms manifested in the oral cavity. Studies have shown that the Diphtheria, Tetanus, Acellular Pertusis, as well as Polio Vaccinations have an association with presented symptoms of bleeding gums, sores, ulcers, white spots in the mouth or on lips, unpleasant breath odor, among others that are on the more serious end of the spectrum. Given the relevance of an association between vaccinations and orally manifested side effects, an investigation on the presence of such association with the widely administered flu vaccine should be conducted. There is no present research proving or otherwise refuting the existence of a correlation thus creating a gap in current knowledge.

The purpose of this research project is to provide understanding of the way in which vaccines negatively affect the oral cavity. The following research seeks to investigate the correlation between the flu vaccine and any side effects manifested in the oral cavity. The research question that is to be tested is “To what extent does the flu vaccine impact the oral cavity?” The purpose of this study is to characterize and assess the occurrence of symptoms commonly associated with periodontal disease and dental carries. The results of this research project will highlight additional information for future elimination of the side effects resulting from the administration of the flu vaccine.

CHAPTER TWO: LITERATURE REVIEW

In a world where preventive health care is favored as opposed to disease treatment, vaccination has become a key factor in the medical society. A vaccine is a biological preparation that provides active acquired immunity to a particular disease [2]. Vaccines typically contain an agent resembling the disease-causing organism made from weakened or killed forms of the microbe, its toxins, or surface proteins. The mechanism by which it works is through tricking the body into believing that it is experiencing a full-scale invasion by an infectious agent, thus stimulating the body's immune system to respond and destroy the microorganism by producing T-lymphocytes and antibodies [2]. This primary exposure leaves the body with memory immune cells- T-lymphocytes and B-lymphocytes that are to recognize and destroy antigens associated with the disease if ever in contact with it in the future.

History of Vaccination

The idea of acquired immunity as a result of preliminary exposure was first introduced in the sixteenth century by the Chinese who practiced variolation or inoculation; where material was taken from a person infected with smallpox and "given artificially" through rubbing into superficial scratches made in the skin, which prevented people from developing scarring from natural smallpox [1]. In the late 1700s came the "founder of vaccinology," Edward Jenner who created the world's first vaccine against smallpox using the protective effect of cowpox. This is where the term vaccine or vaccination was derived from "Variolae Vaccinae," which is Latin for smallpox of the cow [1]. Later in the nineteenth century was the birth of vaccines that are made in the laboratory. French scientist Louis Pasteur "found means of attenuating" live organisms

including cholera and anthrax creating a breakthrough in the Germ Theory of Diseases [1]. Progress continued into the production of vaccines that are used in modern day preventive medicine using several methods as live attenuation, killing of whole organisms, and purification of proteins of organisms or polysaccharides.

The Age of Preventive Healthcare

There are currently 25 diseases that can be prevented to a great extent by a vaccination. Those are: Adenovirus, Anthrax, Diphtheria, Hepatitis A, Hepatitis B, Haemophilus influenzae type b (Hib), Human Papillomavirus (HPV), Seasonal Influenza (flu), Japanese Encephalitis, Measles, Meningococcal, Mumps, Pertussis, Pneumococcal, Polio, Rabies, Rotavirus, Rubella, Shingles, Smallpox, Tetanus, Tuberculosis, Typhoid Fever, Varicella, and Yellow Fever [6]. Of these diseases, two have been completely eradicated by their preventable vaccines; polio and smallpox [3]. Many of them are on the verge of eradication, including measles and pertussis (whooping cough). Based on the US Centers for Disease Control and Prevention (CDC) recommended childhood vaccine schedule, a person will have received 69 doses of 16 vaccines by age 18.

The Influenza Vaccine

Influenza, commonly known as the flu, is a contagious respiratory illness that is caused by the influenza virus and infects the nose, throat, and sometimes the lungs. Seasonal influenza epidemics lasting from October to May cause serious and widespread illnesses each year. Disease resulting from the influenza virus affects all age groups but rates of infection are highest in high-risk groups, which are children under five and the elderly over 65 years [4]. The average

annual influenza-associated death rate from respiratory and circulatory causes between 1976 and 2007 ranged from 3000 to 49 000. The annual influenza vaccination has been proven to be the most effective strategy for the prevention of the seasonal influenza and its complications [9]. New strains of the vaccine are created with each annual flu season to accommodate for immunity developed by the virus and assure greatest protection from the disease. The most commonly reported side effects to the influenza vaccine have been flu-like symptoms such as fever, soreness, and runny nose [9].

Vaccines as a Double-Edged Sword

With the great benefits presented by vaccination and their ability to prevent severe diseases, still comes incidences of minor, and in some rare instances, serious side effects as a result of vaccine administration. That being said, many vaccine side effects can be asymptomatic or in some cases only present as generic cold like symptoms including headaches, fever, or an inflammation of some sort. However, many side effects are manifested in the oral cavity, which includes components of the mouth as the lips, mucosal lining (gums), tongue, and teeth. This is due to the fact that “immune-mediated diseases frequently affect oral mucosa,” often making the oral cavity “the first site of clinical manifestations” [15]. Moreover, many systemic conditions affect the mouth. The accessibility of the oral cavity for examination allows for early and convenient detection of disorders, such as organ damage or inflammation, that are potentially caused as a result of vaccine administration [10]. The severity of the manifestations can be reflective of the severity of the disease and can therefore be used “as a tool for determining disease progression” and effective treatment plans [10].

Vaccines and the Oral Cavity

According to existing literature, there is a suggested correlation between certain vaccinations and symptoms manifested in the oral cavity. Studies have shown that presented symptoms of bleeding gums, sores, ulcers, white spots in the mouth or on the lips, and unpleasant breath odor were manifested after administration of some vaccines including diphtheria, tetanus, acellular pertussis, and polio vaccinations. Although these symptoms may not occur simultaneously or directly after administration of the vaccination, there has been supported evidence of a correlation [9]. There have also been reports of adverse side effects manifested in the oral cavity associated with vaccine administration. From 1991 until 1998, it has been known of 18 cases of Lichen Planus in France and Italy [7]. Lichen planus is an inflammation of the skin and mucosal membranes including those inside the mouth. The incidences of occurrence have been reported to take place 7-120 days after vaccination against the Hepatitis B Virus (HBV) [7]. The vaccine may have simply “stimulated the immune system nonspecifically triggering lichen planus eruption” as occurs with other immune-related disorders [7]. Moreover, one case of a 41-year-old Hispanic male developing pemphigus vulgaris, an autoimmune blistering disorder of the skin and mucous membranes, was reported after the administration of the vaccination of the human papillomavirus [12]. Furthermore, a case of a 19-month-old child developing pityriasis rubra pilaris, an erythematous-squamous disease of diffuse plaques with pityriasisiform scales, has been reported two weeks following intramuscular diphtheria-tetanus-pertussis booster and oral poliovirus vaccination [13]. Another case finding is that of a 60-year-old male who presented with cutaneous verruca vulgaris lesions (warts) on the lips, tongues, and buccal mucosa after receiving the human papillomavirus vaccine [14]. Eight

other cases have been reported with similar warts and squamous cell papillomas, which are lesions caused by quadrivalent HPV vaccination [14].

CHAPTER THREE: METHODOLOGY

Study Design and Data Collection

A cohort descriptive correlational study design will be utilized. The targeted population from which the data for this study will be collected is undergraduate students studying at the University of Central Florida. This will take place through sampling a randomized group of students in the approximately 60,000 student campus. All subjects have to be 18 years of age or older to be eligible to participate in the study.

A brief voluntary online survey will be used to collect information in order to determine the presence of trends following the administration of the flu vaccine. An online survey will be created via the UCF Qualtrics account. The goal of the survey is to determine the presence of a correlation between the flu vaccine and any orally manifested side effects. The survey will consist of 14 questions including multiple choice as well as short response questions. The survey will begin with a preliminary question asking for the participants consent to take part in the following survey. Lack of consent will result in the termination of the survey and ineligibility of the study. It will then be followed by demographic questions to determine the participants age and gender. Academic information will also be collected to determine the participants' academic year in college and major. The following section will address receiving the flu vaccine and any experienced side effects, whether orally related or flu-like, as well as severity and duration of persistence of the symptoms, and if any medical attention was sought. The survey is divided into different sections and shows one question at a time. An answer of "NO" on any of the questions exits the participant out of the survey and thanks them for their participation.

The voluntary online survey will be distributed via online collaborative websites through posting of announcements on different UCF affiliated pages on Facebook as well as in the classes taught by the principal investigator on the Webcourses page of the course. This will ensure a randomized sample. The survey will be open for respondents to complete for six weeks from when it is released. Compensation to take part in the survey will not be provided. Participation for the duration of the survey, which is estimated to take a maximum of 15 minutes to complete, is merely voluntary and only according to the will of those in the targeted population. All the surveys submitted will be completed anonymously with no identifying data collected. The online survey presents no risk to the participants involved in completing it and subjects have the ability to withdraw at any time; however, only fully completed surveys will be used in the analysis process.

Data Analysis

Survey completion will be open to all students, however, only students who had received the flu shot in the past six months will be included in data analysis. The data will include information on the frequency of side effects resulting in proximity with administration of the flu vaccine in college students and the presence of a correlation from these findings. The principal investigators will be responsible for the retrieval of the data from the Qualtrics system at the conclusion of the survey period. The data retrieved will be analyzed to determine possible trends that point at the possibility of a correlation. It is estimated date for the investigators to complete this study and analyze the results is the end of February of 2018; however, the data will be stored under password protection until Spring of 2021. Participants will be provided contact

information of the principal investigators and will be free to contact them for any information regarding the study.

CHAPTER FOUR: RESULTS

Sample Demographics

As the survey was widely distributed through online collaborative websites as well as flyers around campus, containing a QR code with the link to the survey that can be scanned through the camera of any smart phone device, it was easily accessible by students of all years and majors; thus, allowing for a simple random sample that is representative of the population to be obtained. The online survey was active for six weeks in which 117 responses were received from a wide range of undergraduate students studying at the University of Central Florida. The study sample participants consisted of students ranging from 18 to 34 years of age with a high skew of female participants at 78.6% (n=92) and only 21.4% males (n=25). A huge majority of the participants reported to be White at 67.5% (n=79), followed by Hispanics and Latinos, African-Americans, and Asians. Roughly half of the participants represented science majors, which included Health Sciences Pre-Clinical, Biomedical Sciences and Biology, representing a combined majority of 47.8% (n=56). Other majors, such as Psychology, Finance, and Forensic Science, represented the remaining sample participants 52.2% (n=61). Additionally, a great amount of the sample represented upperclassmen including juniors, seniors and super-seniors at 74.3% (n=87); of which juniors comprised 60% (n=52). The Freshman class was the most underrepresented in the population with only six participants, which could likely be a result of selection bias as discussed in the methodological limitations section.

Sample Participants and Side Effects Resulting from the Flu Shot

Only 86 of the 117 (73.5%) reported ever receiving the flu shot in their lives, but only 37 of these participants received the flu shot in the past six months; figure 1. To understand the efficacy of the flu vaccine for the 2017-2018 flu season, only participants who received the flu shot in the past six months, which are 37 responses, will be used in the data analysis process as the baseline for comparison. Of those who received the flu shot in the past six months, only 27% (n=10) suffered from a side effect of any kind. Side effects were divided into two categories; one being flu-like symptoms and the other being orally-related side effects which are associated with the mouth. All 10 participants that reported suffering from side effects following receiving the flu shot, suffered from flu-like symptoms; however, only three of them suffered orally-related symptoms simultaneously; figure 2.

Figure 1: Percentage of Students that Received the Flu Shot within the Past Six Months

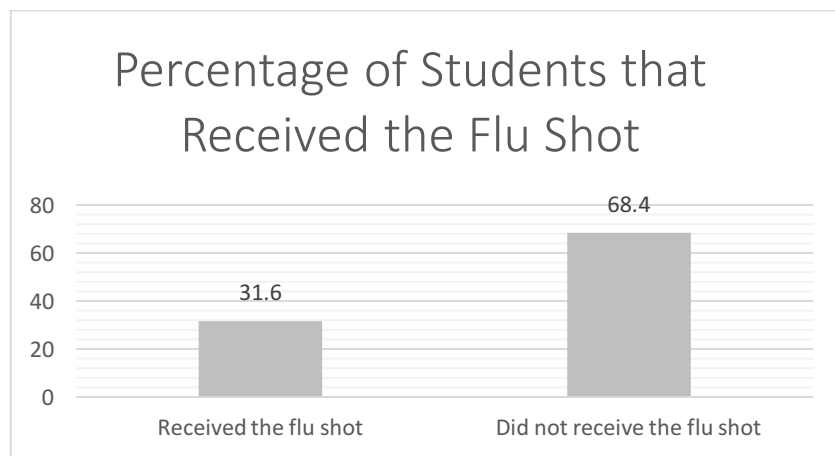
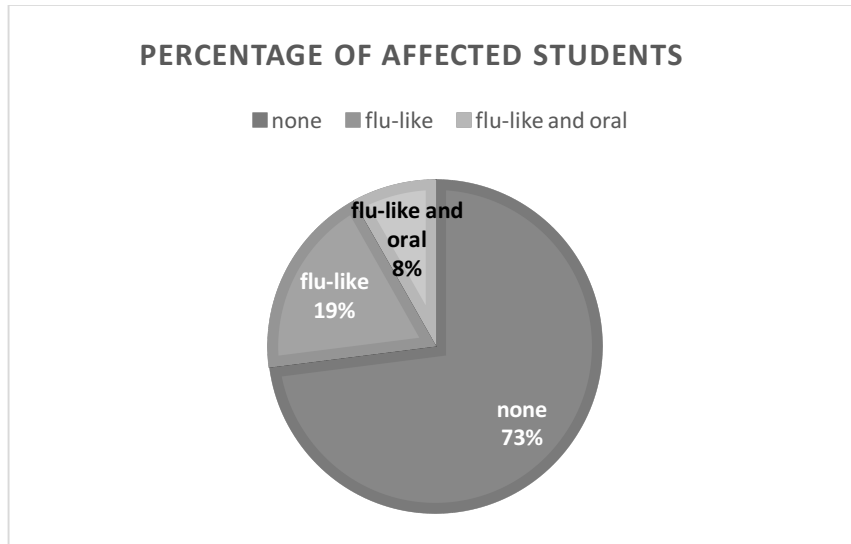


Figure 2: Percentage of Students Experiencing Side Effects

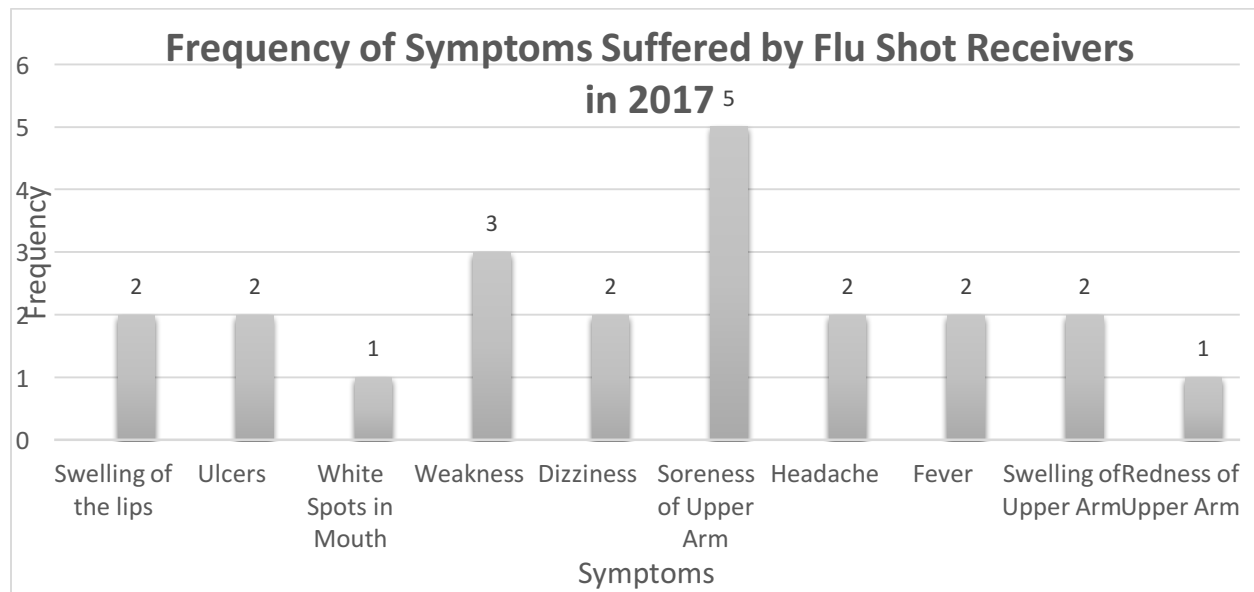


The details of the symptoms experienced by the sampled population was also reported; however, question regarding the specific side effects suffered by the participants were limited by the survey system to students who answered previous questions that classified them as sufferers of the flu vaccine. A list of common flu-like and orally-related symptoms that could occur as a result of having the influenza virus were listed for participants to choose the ones they experienced within three weeks of receiving the vaccine. Only three oral cavity manifested side effects were reported, which were swelling of the lips, ulcers, and the presence of white spots in the mouth. On the other hand, seven different flu-like side effects were reported; three dealt with pain of the upper arm, whether it being soreness, redness, or swelling, and the other four were headache, dizziness, weakness, and fever. Table 1 and figure 3 represent the breakdown and frequency of occurrence of each side effect as experienced by the participants in the sample population.

Table 1: Symptoms Experienced by Sample

Symptom	Symptom Type	Frequency	Percentage
Swelling of the lips	Orally-related	2	9%
Ulcers	Orally-related	2	9%
White spots in mouth	Orally-related	1	4.5%
Weakness	Flu-like	3	13.6%
Dizziness	Flu-like	2	9%
Soreness of upper arm	Flu-like	5	22.7%
Headache	Flu-like	2	9%
Fever	Flu-like	2	9%
Swelling of upper arm	Flu-like	2	9%
Redness of upper arm	Flu-like	1	4.5%

Figure 3: Frequency of Symptoms Suffered by Flu Shot Receivers in 2017



Symptom Characteristics

Moreover, participants were asked to report the particular characteristics associated with the side effects experienced. These duration that the symptoms lasted for ranged from a day to over a week with an average of three days experienced by 50% (n=5) of those who suffered side

effects. The severity of the symptoms was also expressed by the participants as pain levels ranging from mild to unbearable using a Likert scale where 1 represented mild, or light, pain and 5 represented severely unbearable pain. A pain of level 3 was average severe. According to the reported results, 40% (n=4) of participants suffered from a level 2 pain, which was equivalent to moderate pain. The remaining 60% was divided evenly over a level 1, 3, and 5 pain with 20% reported for each category. Participants were also asked to identify seeking medical attention as a result of the severity of the symptoms experienced. Medical attention was defined as visiting the individual's primary care physician, going into the emergency department, or a local walk-in clinic. Only 30% (n=3) of those who suffered from side effects needed medical attention for their symptoms and 66.6% (n=2) of them had reported a pain level of 5 showing severely unbearable pain; table 2.

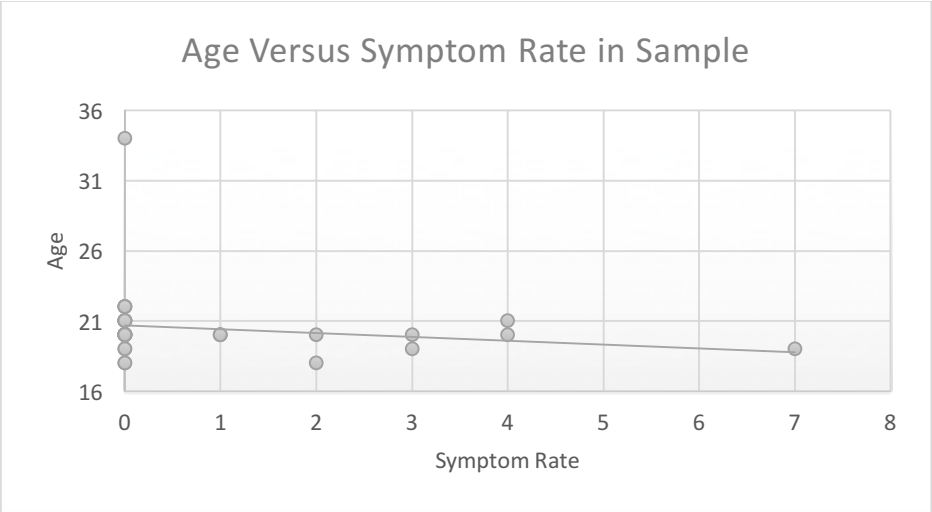
Table 2: Duration and Severity of Side Effects

Number of Orally-related symptoms	Number of flu-like symptoms	Duration of symptoms	Severity of Symptoms	Medical Attention Needed
1	3	3 days	2-moderate	No
1	1	Over a week	5-unberable	Yes
0	1	3 days	1-mild	No
0	4	5 days	3-severe	Yes
0	1	1 day	1-mild	No
0	1	3 days	2-moderate	No
0	4	3 days	2-moderate	no
0	2	1 day	3-severe	No
1	1	Over a week	5-unberable	Yes
0	2	3 days	2-moderate	No

In addition to studying the details of the side effects reported by participants in the sample, the relationship between demographics and symptom rate was also explored. To quantify the symptoms, 1 point was awarded for each flu-like symptom and 2 points were awarded for

each orally-related side effect reported for a maximum number of 7 points in the symptom rate. The age of the participants who received the flu shot within the past six months (n=37) was compared to the symptom rate reported. Participants who did not suffer from any side effects (n=27) were awarded zero points. A scatter plot was created, figure 4, to show the results and a line of best fit was inserted to determine the r-squared value and correlational value for the results. The R-squared value, or coefficient of determination, is a statistical measure of how close the data are to the regression line. For the line of best fit inserted into the scatter plot of age versus symptom rate, the R-squared value was 0.02971, which indicates that the model is a weak indication of the variability of the response data around the mean. The correlation coefficient, R-value, was calculated to be -0.3116, which shows a weak negative linear relationship and thus a weak correlation between age and symptom rate, where younger participants reported more symptoms. Gender was another factor that was also compared to the symptom rate. A two-sample Z-test was used to compare the symptom rate average of male and female participants, which was calculated to be 0.33 for males and 0.84 for females. Using a 5% significance level to determine if the proportions are the same, a Z-Score of 2.641 and p-value of 0.0083 were calculated. This indicates a calculate probability of 0.8% for the averages of symptom rates for males and females to happen randomly or by chance. A p-value that is less than 5%, as in this case, shows a statistically significant result and allows for the rejection of the null hypothesis stating that the proportions for males and females are the same, but rather that they signify the appearance of a correlation between gender and symptom rate, where females are significantly more affected than males.

Figure 4: Symptom Rate and Age in Sample



CHAPTER FIVE: DISCUSSION

Patterns of Vaccination

So far, this appears to be the first study to examine the effects of the flu vaccine on the oral cavity. Our research was aimed at exploring the presence of trends associated with symptoms experienced with receiving the flu shot for the 2017-2018 flu season. The target population of undergraduate students at a large college campus should serve as a baseline for generalization of the results due to the huge age range included in the sample from late teens to mid-thirties (18-34). It can be inferred from the survey responses that between July and December of 2017, which is the peak of the influenza infection season, only 31.6% of the student body had received an immune protection against this virus in the form of the flu shot; not taking into account other methods of virus protection such as the nasal flu mist vaccination. Even though the vaccine is highly recommended yearly for individuals over the age of 6 months and is offered at discounted prices and even for free at the university, many people refuse to be vaccinated due to a fear or misunderstanding concerning the flu vaccine. They believe that the cost outweighs the benefit in that the flu shot causes the individual to be sick with the virus. This is a misconception, however, as the flu-like symptoms that happen following receiving the vaccination are common side effects that take place as part of the body's normal immune response to the foreign inoculated influenza virus that had just entered. In most cases, the side effects occurring after receiving the vaccine are far less severe than the symptoms caused by actual flu illness [2].

Factors Affecting Symptom Rate

In looking at different factors associated with reporting side effects experienced after receiving the flu shot, it was determined that age and gender played a role in this process. Although a week correlational coefficient of $R=-0.3116$ was calculated, it can still be concluded that the younger range of the population reported suffering from far more symptoms than the older participants in the study. This could be due to the fact that teenagers are in the developing process of their immune system, while those who are in their twenties are at the peak of B and T cell production from the thymus and bone marrow leading to a better immune response [16]. Stress could also be a factor that affects the levels to which the symptoms are manifested and the significant toll they have on an individual.

Gender was also an element in the overall results of the survey. A significantly greater number of females participated in the survey than males which is expected since the university student body is comprised of 55.1% females and only 44.9% males. 37 participants stated that they had received the flu shot in the past six months; only six of them were males. This shows that females tend to be more vigilant with their health. Of the ten participants that reported suffering side effects, only one of them was male and his symptom rate score was 2. This is likely due to the fact that females are more likely to report symptoms than males and that they usually have lower tolerance for pain. Due to the fact that the severity of the symptoms experienced by the participants were asked to be self-reported according to a Likert scale, the subjective nature to pain tolerance could have led to more females selecting a level 5, unbearable pain, when describing the harshness of the side effects experienced. The three participants that

reported getting medical attention for their symptoms were also females. Females were also the ones to report finding a manifestation related to their oral cavity.

CHAPTER SIX: METHODOLOGICAL LIMITATIONS

The result of this study should be considered in the context of a number of limitations. Selection bias, sample size, subjectivity, and population representation are among the considerations that should be revised when replicating this study.

For this study, the sample size of 117 may have not been large enough to obtain useful data as only 37 of the survey responses were considered for the data analysis while the other 80 were disregarded as they had not received the flu shot in the past six months, which is the time period being examined by the researchers. The relatively small sample size could have been caused by limitations of having an online survey to collect information. Even though the survey was widely distributed through online collaborative websites as announcements on different UCF affiliated pages on Facebook as well as in the classes taught by the principal investigator on the Webcourses page of the course, not all students studying at the university had access to these online links. Efforts were also made to post flyers around campus, containing a QR code with the link to the survey that can be scanned through the camera of any smart phone device, however, not all students are aware of the ability to scan QR codes through a cellphone camera.

Selection bias was also apparent when considering the large number of juniors that responded to the survey, which comprised 44.4% of the total survey responses. Even though the survey was to be easily accessible by students of all years and majors, it seems that the majority of students that were part of the Facebook pages where the survey link was posted were juniors. This is mainly due to the fact that many students were recruited to take the survey from the researcher's classes and these classes have primarily upperclassmen causing the presence of a

selection bias in the sample and skewing the average age and grade level of students. Moreover, the effects of the flu shot on the oral cavity in non-college students including children and the elderly was not investigated in this study and might add significance to the results obtained.

The online survey also led to the presence of limitations in the results. Participants were asked to self-report symptoms suffered within three weeks of receiving the flu shot which they could have been vaccinated with up to six months earlier from when the survey was posted. This could have led to inaccuracy in the answers given in the survey as it is purely based on the memory of the participants. Another limitation could be the list of symptoms given in the survey questions for participants to select from. Although more than one answer choice can be selected for the questions asking about symptoms and the symptom list consists of most occurring side effects caused by the flu shot, the participant might have suffered more side effects than the ones listed. The subjectivity of the pain levels as reported by the Likert scale could have also added to the limitations of the results.

CHAPTER SEVEN: CONCLUSION

One of the major questions that this study hoped to answer was whether or not a relationship existed between receiving the flu shot and suffering from orally-related side effects. After qualitative analysis of the survey results, it appears that there are no statistically significant relationships amongst these variables. Rather the data shows that the vaccine effectiveness for the 2017-2018 flu season was high against influenza A and influenza B and that the benefits of being vaccinated against the virus outweigh the cost. Unlike some vaccinations, including diphtheria, tetanus, acellular pertussis, and polio vaccinations, the influenza vaccine proved to have no association with periodontal disease or dental carries. Only ulcers, white spots on the lips, and swelling of the lips were observed with correspondence to the oral cavity, which are common side effects associated with fighting infections.

The flu vaccine is for the most part manufactured from inactivated forms of the most prevailing strains of the virus or ones that are evolved from previous influenza seasons. The human body naturally reacts against any foreign invaders which explains the side effects experienced by individuals who choose to take the flu shot. The shot, however, does not protect against virus strains not covered by the vaccine or against flu-like symptomatic conditions caused by several other diseases including common allergies. The eradication of side effects from occurring completely is, up till this point, beyond medical and scientific as the human system is more intelligent. For this reason, people who have severe allergies or previously experienced unbearable pain from the flu shot vaccine are advised not to take it and refer to other preventive measures against the virus.

Although no substantial relationships were observed between receiving the flu shot and orally-related symptoms, other interesting trends were interpreted from the data. There appeared to be a correlation between gender and reporting of symptoms as it was significantly higher for females. The results also showed that 80% of the symptoms reported by survey participants dealt with pain in the upper arm encompassing swelling, redness, and soreness of the upper arm. This inflammatory response occurs at the injection site and is caused by the needle and the administered serum which is being fought against by the body's immune system. Future work may be expanded beyond this to allow the study of the effects of the flu vaccine on the oral cavity based on screening rather than an online survey. This would allow for more accurate data collection and validation.

**APPENDIX A:
IRB Approval Letter**



University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Determination of Exempt Human Research

From: **UCF Institutional Review Board #1
FWA00000351, IRB00001138**

To: **Danielle Melissa Webster and Co-PI Laura Sawires**

Date: **November 27, 2017**

Dear Researcher:

On 11/27/2017, the IRB reviewed the following activity as human participant research that is exempt from regulation:

Type of Review: Exempt Determination, Category 2
Project Title: The Effects of Vaccines on Dental Care
Investigator: Danielle Melissa Webster
IRB Number: SBE-17-13518
Funding Agency:
Grant Title:
Research ID: N/A

This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these changes affect the exempt status of the human research, please contact the IRB. When you have completed your research, please submit a Study Closure request in iRIS so that IRB records will be accurate.

In the conduct of this research, you are responsible to follow the requirements of the [Investigator Manual](#).

This letter is signed by:

A handwritten signature in cursive script that reads "Renea Carver".

Signature applied by Renea C Carver on 11/27/2017 01:52:08 PM EST

Designated Reviewer

APPENDIX B:
Consent

Consent

The Effects of Vaccine on Dental Care Informed Consent

Principal Investigator: Laura Sawires
Danielle Webster, Ph.D.

Co-Investigator(s): N/A

Sub-Investigator(s): N/A

Faculty Advisor: N/A

Department Chair: Suha Saleh, Ph.D., M.T.

Investigational Site(s): University of Central Florida

Introduction: Researchers at the University of Central Florida (UCF) study many topics. To do this we need the help of people who agree to take part in a research study. You are being invited to take part in a research study which will include about 150 people at UCF. You have been asked to take part in this research study because you are an undergraduate student at UCF. You must be 18 years of age or older to be included in the research study.

The person doing this research is Laura Sawires, an undergraduate Honors in the Major student conducting a Thesis, as well as Dr. Danielle Webster, a professor, both of affiliation in the Department of Health and Public Affairs; Health Sciences Pre-Clinical Track at UCF.

What you should know about a research study:

- *Someone will explain this research study to you.*
- *A research study is something you volunteer for.*
- *Whether or not you take part is up to you.*
- *You should take part in this study only because you want to.*
- *You can choose not to take part in the research study.*
- *You can agree to take part now and later change your mind.*
- *Whatever you decide it will not be held against you.*
- *Feel free to ask all the questions you want before you decide.*

Purpose of the research study: *The purpose of this study is to investigate the correlation between the flu vaccine and side effects manifested in the oral cavity by understanding the ways in which vaccines negatively affect the oral cavity. Given the relevance of an association between vaccinations such as the Hepatitis B, Polio, Tetanus, Acellular Pertussis, and Diphtheria Vaccines and orally manifested side effects, an investigation on the presence of such association with the widely administered flu vaccine will be conducted. There is no present research proving or otherwise refuting the existence of a correlation thus creating a gap in current knowledge that will be resolved through this research.*

- **What you will be asked to do in the study:** *Participants will be required to complete a brief online survey that should not take longer than 15 minutes. The survey will ask questions regarding participant demographics, education, and any effects experienced after the administration of the flu vaccine.*

Location: *The participants can complete the survey from any location using any device connected to the internet.*

Time required: *We expect that you will be in this research study for a maximum of 15 minutes, which is the duration of completing the online survey.*

Risks: *There are no reasonably foreseeable risks or discomforts involved in taking part in this study.*

Benefits:

The knowledge gained from the study will be important in understanding potential oral effects of the flu vaccine and will serve to benefit participants by making them more aware of side effects that are not widely broadcasted.

Compensation or payment:

There is no compensation or other payment to you for taking part in this study.

Anonymous research: This study is anonymous. That means that no one, not even members of the research team, will know that the information you gave came from you.

Study contact for questions about the study or to report a problem: If you have questions, concerns, or complaints, or think the research has hurt you, talk to Dr. Suha Saleh, Department Chair, Department of Health Professions at (407) 823-6761 or by email at suha.saleh@ucf.edu.

IRB contact about your rights in the study or to report a complaint: Research at the University of Central Florida involving human participants is carried out under the oversight of the Institutional Review Board (UCF IRB). This research has been reviewed and approved by the IRB. For information about the rights of people who take part in research, please contact: Institutional Review Board, University of Central Florida, Office of Research & Commercialization, 12201 Research Parkway, Suite 501, Orlando, FL 32826-3246 or by telephone at (407) 823-2901. You may also talk to them for any of the following:
Your questions, concerns, or complaints are not being answered by the research team. You cannot reach the research team. You want to talk to someone besides the research team.
You want to get information or provide input about this research.

I agree to give consent to take part in the following survey.

Yes

No

**APPENDIX C:
Survey Instrument**

Demographic Information

What is your age?

What is your gender?

Male

Female

What is your ethnicity?

White

Hispanic or Latino

American Indian or Alaska Native

Asian

Native Hawaiian or Pacific Islander

Black or African American

Educational Information

What year in school are you?

Freshman

Sophomore

Junior

Senior

Super Senior

What is your major?

Flu Vaccine Information

Have you ever received the flu shot?

Yes

No

Have you received the flu shot in the past six months?

Yes

No

Did you experience any side effects after receiving the flu shot?

Yes

No

Within three weeks of receiving the vaccine, have you suffered from any of the following orally related symptoms?

Swelling of the lips

Bleeding of the gums

Sores

Ulcers

White spots in mouth

White spots on lips

Unpleasant breath odor

I have not suffered from any of these side effects.

Within three weeks of receiving the vaccine, have you suffered from any of the following flu-like symptoms?

Swelling of upper arm

Soreness of upper arm

Redness of upper arm

Headache

Dizziness

Fever

Weakness

I have not suffered from any of these side effects.

On average, how long did these side effects persist?

Couple of hours

1 day

3 days

5 days

1 week

Over a week

Over a month

Rate the severity of the side effects experienced on the following scale?

1- mild

2-moderate

3-severe

4-very severe

5- unbearable (extremely severe)

Did you seek medical attention due to a side effect?

Yes

No

Powered by Qualtrics

**APPENDIX D:
QR Code Flyers**

Fellow Knights!!

Please scan this QR Code and take this quick 5 minute survey for research on the effects of the Flu Vaccine on the Oral Cavity.

Thank you in advance 😊



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