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Understanding the adoption process of an HPV vaccine school-entry requirement in Puerto Rico

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Understanding the adoption process of an HPV vaccine school-entry requirement in Puerto Rico

by

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy
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Dedication

To my daughter Ariana. Te amo, mami.
Acknowledgements

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Table of Contents

List of Tables ................................................................................................................................. iv

List of Figures ................................................................................................................................. v

Abstract .......................................................................................................................................... vi

Chapter 1: Introduction ................................................................................................................... 1
  Background .................................................................................................................................. 1
  Public Health Significance ...................................................................................................... 5
  Statement of Need .................................................................................................................. 7
  Key Terms .................................................................................................................................. 9

Chapter 2: Literature Review ........................................................................................................ 10
  The Human Papillomavirus .............................................................................................. 10
  The HPV Vaccine ............................................................................................................. 13
    HPV vaccine uptake and completion rates in the US. .................................................. 15
    Health implications of increasing HPV vaccination rates ........................................... 16
    Economic implications of increasing HPV vaccination rates ..................................... 19
    Factors that impact HPV vaccine rates .................................................................... 20
      Individual level. ........................................................................................................... 20
      Interpersonal level ................................................................................................. 25
      Community level ..................................................................................................... 26
      Organizational level .............................................................................................. 27
      Societal level .......................................................................................................... 27
  Vaccine Interventions ....................................................................................................... 29
    States’ police powers, vaccine mandates, and public health. ....................................... 31
    School-entry requirements ..................................................................................... 32
    HPV vaccine mandates ........................................................................................... 33
  Arguments in favor of and against the HPV vaccine school-entry requirement .......... 35
    Overall studies’ characteristics ............................................................................... 35
    Stakeholders/participants ......................................................................................... 36
  Reasons and Factors in Support of or Against an HPV vaccine school-entry requirement among Parents/Guardians, Physicians, and Policymakers ................................................. 37
    Parents/guardians ...................................................................................................... 37
    Physicians ................................................................................................................... 42
    Policymakers ............................................................................................................. 43
  The case of Puerto Rico ........................................................................................................ 43
    Background ................................................................................................................... 43
    Current immunization policy ....................................................................................... 43
List of Tables

Table 1: Information regarding available HPV vaccines ............................................................ 127

Table 2: Studies about stakeholders’ reasons and factors associated with HPV vaccine.  
school-entry requirement in the US: Studies’ characteristics (N=25) ................................. 128

Table 3: Studies about stakeholders’ reasons and factors associated with an HPV  
vaccine school-entry requirement in the US: Main findings (N=25) ................................. 133

Table 4: Additional exemplary quotes by theme ........................................................................ 139

Table 5: Timeline of policies and strategies leading to the HPV vaccine school-entry  
requirement in PR ..................................................................................................... 143

Table 6: Number of news articles published by year ............................................................ 144

Table 7: Overall distribution of newspaper articles by primary focus ................................. 144

Table 8: Articles published for each primary focus category by year ................................. 145

Table 9: Number of articles that mentioned the HPV vaccine school-entry  
requirement published by year and newspaper source .............................................. 145

Table 10: Type of argument included in the articles that mentioned the HPV  
vaccine school-entry requirement by year of publication ............................................ 146
List of Figures

Figure 1. Overview study design ................................................................................................... 57

Figure 2. Article selection process for content analysis (based on PRISMA guidelines by Moher, Liberati, Tetzlaff, & Altman, 2009) ............................................................................. 65

Figure 3. Average number of articles per month ......................................................................... 100

Figure 4. Average number of articles per month by the top eight primary focus categories ....................................................................................................................................... 101

Figure 5. Number of articles by argument category by year of publication .................................. 103

Figure 6. Application of MSA to study findings .......................................................................... 111
Abstract

Human Papillomavirus (HPV) is the most common sexually transmitted infection (STI) in the US. Infection with low-risk HPV (i.e., 6 and 11) can cause genital warts, and persistent infection with high-risk HPV types (i.e., HPV 16 and 18) can progress to cancer. Currently, there is an HPV vaccine that is recommended for boys and girls, aged 11 to 12. Healthy People 2020 established a national objective of 80% completion of HPV vaccination among children aged 13 to 15 years old. Although the HPV vaccine is proven to be a safe and effective primary prevention strategy, uptake and completion rates remain low in the US.

Vaccination mandates for school entrance are an effective strategy to improve vaccination coverage. In the US, HPV vaccine policies vary; some legislate in favor of educational campaigns, while others require health insurance to cover the HPV vaccine or require it for middle-school entry. Currently, only Virginia, Rhode Island, and Washington DC require the HPV vaccine for school entrance. In Puerto Rico (PR) the Department of Health recently approved the HPV vaccine school-entry requirement for children 11 to 12 years old, starting in fall 2018.

Despite HPV vaccination’s cancer-preventive properties and vaccine mandates’ effectiveness, HPV vaccine school-entry requirements have not been widely adopted in the US. Guided by the Multiple Streams Approach, the purpose of this study was to understand the adoption process of PR’s HPV vaccine school-entry requirement. Phase 1 consisted of a qualitative study in PR using in-depth interviews. Participants included stakeholders in the PR
HPV vaccine school-entry approval process (in favor/against). Purposive sampling was used to recruit stakeholders identified from online sources, by consulting local experts, and utilizing snowball sampling. Interviews were audio-recorded and transcribed. Data were analyzed using applied thematic analysis. Phase 2 consisted of a content analysis of PR’s newspapers from January 1st, 2015 to July 31st, 2018. Data were described quantitatively and qualitatively.

From 21 stakeholders that were interviewed, only one person expressed views against the HPV vaccine school-entry requirement. The stakeholders highlighted problems such as, the high incidence of HPV and HPV-related cancers in PR (e.g., cervical/oropharyngeal) that needed to be resolved. Social factors such as the case of Rhaiza López Plumeay, a young mother, who died of cervical cancer in 2015, and the VOCES HPV Advisory Panel Report served as focusing events that motivated the adoption process. Stakeholders also discussed other policy initiatives, such as changes to the current immunization law. The political turn-over in key government positions facilitated the adoption process. During the summer of 2017, a policy window opened, and the HPV vaccine school-entry requirement was adopted in the summer of 2018. The policy entrepreneurs worked on what was needed for the HPV vaccine school-entry requirement to be adopted through collaborations among different sectors.

A total of 286 news articles included the key terms “HPV” or “human papillomavirus” in Spanish. Thirty-four articles mentioned the HPV vaccine school-entry requirement. The highest number of publications that mentioned the HPV vaccine school-entry requirement in PR occurred in 2017, and during the first seven months of 2018. The arguments listed in the articles included concerns related to the side effects of the HPV vaccine, the sexual nature of the transmission of the virus, and that it should be the parents’ right to choose to vaccinate their children. Other areas such as the HPV clears by itself and that there is no consensus regarding
the HPV vaccine, were mentioned less frequently. Findings from this study can inform other states and public health practitioners interested in adopting HPV vaccine policy initiatives to improve HPV vaccination rates across the US and target the prevention of HPV-related cancers.
Chapter 1: Introduction

Background

The Human Papillomavirus (HPV) is the most common sexually transmitted infection (STI) in the United States (Centers for Disease Control and Prevention, 2015; Satterwhite et al., 2013), with around 18 million adolescents between the ages of 15 and 24 currently infected (Satterwhite et al., 2013). New cases of HPV are estimated to be around 14 million a year, half of which occur among this age group (Satterwhite et al., 2013). Common risk factors for HPV infection include a higher number of sexual partners (concurrently or sequentially), early sexual initiation, lacking or inconsistent condom use, young age, partner’s sexual behavior, immune system status, and biological susceptibility (Burchell, Winer, de Sanjose, & Franco, 2006; Centers for Disease Control Prevention, 2015; Markowitz et al., 2014; Ratanasiripong, 2012; Trottier & Franco, 2006). Infection with low-risk HPV types, HPV 6 and 11, causes anogenital warts (Garland et al., 2009), and persistent infection with high-risk types 16 and 18 can cause cancers such as cervical, vulvar, vaginal, penile, anal, and oropharyngeal (Forman et al., 2012; Markowitz et al., 2014; zur Hausen, 2002).

Currently, there is an HPV vaccine that is mainly targeted for boys and girls 11 to 12 years old (Centers for Disease and Control Prevention, 2016c), due to a better immune response before children become sexually active (Block et al., 2006). This segment of the population only requires two doses of the HPV vaccine (Centers for Disease and Control Prevention, 2016c). Catch-up vaccination is recommended for females between the ages of 13 and 26 years and for
males between the ages of 13 and 21 years, who will need three doses of the HPV vaccine (Markowitz et al., 2014; Petrosky et al., 2015). Furthermore, the nine-valent and the quadrivalent versions are also recommended up to age 26 years of age for men who have sex with men (Markowitz et al., 2014; Petrosky et al., 2015), transgender young adults and people with immunocompromised conditions (Centers for Disease and Control Prevention, 2016c).

During 2015, coverage with at least one dose of the HPV vaccine was 56.1%, and three doses were 34.9% among 13 to 17-year-old adolescents (Reagan-Steiner et al., 2016). Thus, uptake and completion rates of the HPV vaccine remain low in the US. Furthermore, there is state variation in the initiation and completion rates of the HPV vaccine among this age group. For example, Florida had a 62.5% initiation rate among females and 45.3% among males. Completion rates were 36.8% and 19.8%, for females and males respectively (Reagan-Steiner et al., 2016). Puerto Rico had overall initiation and completion rates estimated to be 75.8% and 52.8% respectively. Among females, the initiation rate was 80.8% and among males was 71.1%. Completion rates were 61.9% and 44.1%, for females and males respectively (Walker et al., 2017).

This low uptake and completion rates are due to a combination of multi-level factors. Factors such as young age, gender, low parental awareness of the HPV vaccine, parental concerns about their children’s sexual behavior, vaccine side effects and safety have been noted at the individual level (Berenson, 2015; Holman et al., 2014). At the interpersonal level factors such as lack of physician recommendation (Dorell, Yankey, Kennedy, & Stokley, 2013) and communication between mother and child (Gross, Laz, Rahman, & Berenson, 2015) have been found to impact HPV vaccine initiation and completion. Ethnicity is a factor at the community level, with Hispanic minorities usually having higher rates of HPV vaccine initiation (Henry,
Warner, Ding, & Kepka, 2015). At the organizational level, the HPV vaccine has received an endorsement from many important professional organizations such as the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, among others (Byington et al., 2016). Lastly at the societal level, issues such as the social perception of HPV as a female only issue (Daley et al., 2016), news media messages (Gollust, LoRusso, Nagler, & Fowler, 2016), and the variation of state-level policies regarding the HPV vaccine (Laugesen et al., 2014), also impact HPV vaccine uptake and completion.

Vaccines interventions have contributed to the improvement of the overall health of our society. Consequently, the reduction of vaccine-preventable diseases through vaccination is celebrated as one of the ten greatest public health achievements (Centers for Disease and Control Prevention, 1999; Centers for Disease Control and Prevention, 2011; Dube et al., 2013; Larson, Jarrett, Eckersberger, Smith, & Paterson, 2014). Vaccines were instrumental in the eradication of diseases such as polio and smallpox (Centers for Disease and Control Prevention, 1999; Dube et al., 2013), and have aided in lowering the incidence of pneumococcal infections and rotavirus hospitalizations in the US during the last decade (Centers for Disease Control and Prevention, 2011).

Vaccine interventions, mainly vaccination mandates, are an effective strategy to improve vaccination coverage. Based on the Community Preventive Services Task Force (GCPS, 2016) definitions, ‘school-entry requirements’ refer to laws that require vaccination and documentation as a condition to school attendance. The states create these laws; thus, there is variation across jurisdictions in the vaccinations included, the evidence required as documentation, the opt-out options (reasons parents can choose not to vaccinate their children), and how they are implemented (GCPS, 2016). ‘Vaccine mandates’ can be defined as a broad term that refers to
any law requiring vaccination. These can include school-entry requirements, or laws requiring hospital employees to be vaccinated (Cole & Swendiman, 2014). On the other hand, ‘school-based programs’ are defined as vaccination programs where immunization is delivered at the schools. These programs usually include education and promotion, tracking of vaccination status, and referral components (GCPS, 2016).

School-entry requirements are a highly effective strategy commonly used in the US to increase adolescent uptake of vaccines (Averhoff et al., 2004; Field & Caplan, 2008; Hinman, Orenstein, Williamson, & Darrington, 2002). Unfortunately, HPV vaccine policies have encountered a lot of resistance due to the intersection of vaccine safety and adolescent sexuality (Colgrove, Abiola, & Mello, 2010). Overall, arguments in favor and against of the HPV vaccine mandates have been previously debated. In 2006, when the HPV vaccine was approved by the FDA, arguments in support for HPV vaccine mandates was influenced by framing the issue under the umbrella of women’s health and children’s welfare (Colgrove, 2006). Additional arguments in favor of a school vaccine mandate note the vaccine cost-effectiveness, the appropriate age range for inoculation, the importance of preventing and reducing cervical cancer, and parental involvement in health decisions (Vamos, McDermott, & Daley, 2008). Arguments against the HPV vaccine mandates included concerns related to the lack of transmission of the virus through casual contact, interfering with parental autonomy, public distrust due to pharmaceutical lobbying during policy development, and the potential economic burden on the government, health departments, and private physicians (Gostin & DeAngelis, 2007; Javitt, Berkowitz, & Gostin, 2008; Mello, Abiola, & Colgrove, 2012).
Public Health Significance

In 1988, the Institute of Medicine (IOM) established in its seminal report ‘The Future of Public Health’ the core functions of public health as assessment, policy development, and assurance. These functions apply to all levels of the government (i.e., local, state, and federal), each level with its unique responsibilities (Institute of Medicine, 1988). The assessment core function includes the recommendation for public health agencies to “collect, assemble, analyze, and make available information on the health of the community, including statistics on health status, community health needs, and epidemiologic and other studies of health problems.” (Institute of Medicine, 1988, p. 7). Governmental and agencies cooperation was recommended to accomplish this function.

Policy development refers to “the development of comprehensive public health policies by promoting the use of the scientific knowledge base in decision-making about public health and by leading in developing public health policy” within the context of the democratic political process (Institute of Medicine, 1988, p. 8). Finally, assurance is a recommendation for public health agencies to guarantee their citizens the services that are needed “to achieve agreed upon goals are provided, either by encouraging actions by other entities (private or public sector), by requiring such action through regulation, or by providing services directly” (Institute of Medicine, 1988, p.8). Additionally, public health agencies should “involve key policymakers and the general public in determining a set of high-priority personal and communitywide health services that governments will guarantee” (Institute of Medicine, 1988, p. 8).

In 1994, the US Public Health Service operationalized the core functions; and the Ten Essential Public Health Services were created (Novick & Morrow, 2008). In the IOM’s 2003 follow-up report ‘The Future of the Public’s Health in the 21st Century’, the emphasis was on strengthening the public health infrastructures, and the importance of partnerships to enhance the
system (Novick & Morrow, 2008). Thus, six areas were identified to assure the conditions for population health. These include community, healthcare delivery system, employers and business, the media, academia, and government public health infrastructure (Institute of Medicine, 2003, as cited in Novick & Morrow, 2008).

In addition to the core functions and the essential services, public health is based on overarching tenets. These include an understanding that protecting the health of entire communities may sometimes be in conflict with the individuals’ autonomy, the idea that health depends on social, behavioral, and biological factors that affect all the population, and that prevention (i.e., primary, secondary and tertiary) is the desirable approach (Novick & Morrow, 2008; Schneider, 2016). Thus, the core functions, the ten essential services, and public health overarching tenets have contributed to the formation of the discipline and its current achievements.

The Centers for Disease Control and Prevention (2011) has identified ten areas in which public health has achieved significant accomplishments in lives and money saved during the first decade of the 21st century. These endeavors are in the areas of 1) vaccine-preventable diseases, 2) prevention and control of infectious diseases, 3) tobacco control, 4) maternal and infant health, 5) motor vehicle safety, 6) cardiovascular disease prevention, 7) occupational safety, 8) cancer prevention, 9) childhood lead poisoning prevention, and 10) public health preparedness and response (Centers for Disease Control and Prevention, 2011).

The present study falls under the policy development core function of public health by contributing to the overall science and creation of evidence. The study addresses issues related to the promotion of public health policy, the HPV vaccine school-entry requirement. The study’s research focus overlaps with two areas, vaccine-preventable diseases, and cancer prevention. The
research, practice, and policy implications that result from the study have been considered under this framework and will be discussed in Chapter 5.

**Statement of Need**

Healthy People 2020 established a national objective of 80% completion of the HPV vaccination among females and males aged 13 to 15 years old (U.S. Department of Health and Human Services & Office of Disease Prevention and Health Promotion, 2015). Despite research demonstrating the safety and effectiveness of the HPV vaccine as a primary prevention strategy (Petrosky et al., 2015; Stokley et al., 2014), HPV vaccination rates among adolescents remain far below the Healthy People 2020 goal.

HPV is the cause of most cervical, vulvar, vaginal, anal, and penile cancers, and is also associated with anogenital warts and recurrent respiratory papillomatosis (Markowitz et al., 2014). The HPV vaccine affords the opportunity to successfully prevent these types of cancers and HPV-related diseases (Markowitz et al., 2014; Petrosky et al., 2015). Moreover, the annual medical direct cost of the prevention and treatment of HPV-associated diseases in the US has been estimated to be around $8 billion (2010 US dollars) (Chesson et al., 2012). Thus, an overall reduction of the infection of HPV would significantly reduce the morbidity and mortality of these diseases and their associated economic costs.

In the US, provider recommendation and parental education have been widely used the strategies to promote HPV vaccination; thus, a call has been made to consider HPV vaccine school-entry requirements as part of the approaches to increase HPV vaccination rates (Daley, Thompson, & Zimet, 2019). Recommendations are based on the available evidence of the effectiveness and previous experience in the US with vaccination mandates for school entrance (Averhoff et al., 2004).
Currently, the policies related to the HPV vaccine vary in content; some legislate in favor of educational campaigns while others require health insurances to cover the HPV vaccine or require the HPV vaccine for middle school entrance (Abiola, Colgrove, & Mello, 2013; Colgrove et al., 2010; Laugesen et al., 2014). Virginia, Rhode Island, Washington DC (Barraza, Weidenaar, Campos-Outcalt, & Yang, 2016), and Puerto Rico (PR) are the only states/territories currently requiring the HPV vaccine for school-entry.

Despite cancer-preventive properties of HPV vaccination and the effectiveness of prior vaccine mandates, there is a need to understand why HPV vaccine school-entry requirements have not been widely adopted in the US. Thus, guided by the Multiple Streams Approach, the purpose of this study is to understand the macro level factors that influenced the adoption of the HPV vaccine school-entry requirement in PR. This purpose will be achieved via the following research questions:

1. How did the problems, politics, and policy streams intersect to inform the HPV vaccine school-entry requirement in Puerto Rico?
2. Who were the policy entrepreneurs involved in the adoption process and what were their roles?
3. What were the arguments in favor of and against the HPV vaccine school-entry requirement?
Key Terms

HPV – human papillomavirus

STI – sexually transmitted infection

US – United States

PR – Puerto Rico

MSA – Multiple Streams Approach/Theory/Framework

DOH – Puerto Rico’s Department of Health
Chapter 2: Literature Review

The Human Papillomavirus

The Human Papillomavirus (HPV) is the most common sexually transmitted infection (STI) in the United States (Centers for Disease Control and Prevention, 2015; Satterwhite et al., 2013). Around 79 million people aged 15 to 59 are currently infected with the HPV, 18 million of them between the ages of 15 and 24 (Satterwhite et al., 2013). New cases of HPV are estimated to be around 14 million a year, half of those among youth 15 to 24 years old (Satterwhite et al., 2013). Most of all sexually active individuals will contract the virus at least once during their lifetime. For instance, it was estimated that among heterosexual individuals with at least one sexual partner, 84.6% of women and 91.3% of men, will contract HPV by age 45 (Chesson, Dunne, Hariri, & Markowitz, 2014).

The HPV belongs to the *Papillomaviridae* family a group of non-enveloped DNA viruses that can cause tumors in the epithelium tissue (Morshed, Polz-Gruszka, Szymanski, & Polz-Dacewicz, 2014). In particular, HPV has an 8,000 base-pair long circular DNA wrapped in a protein shell composed of two molecules (L1 and L2) (Gattoc, Nair, & Ault, 2013; Munoz, Castellsague, de Gonzalez, & Gissmann, 2006). These two proteins (L1 and L2) and six early proteins (E1, E2, E4-E7) are necessary for the viral DNA replication within the infected cells (Morshed et al., 2014; Munoz et al., 2006). Currently, 170 types of HPV have been identified, 40 of which infect the genital tract (de Villiers, 2013).

An HPV infection is mostly asymptomatic and localized and can occur via various routes of transmission. HPV’s infections primarily occur via genital contact during sexual intercourse,
but other means of sexual contagion include oral-genital and anal-genital contact (Moscicki et al., 2012). Evidence also indicates other routes of transmission, such as skin-to-skin contact, vertical transmission from mother to infant during vaginal delivery, hands to genitals or genitals to hands, and/or by contaminated fomites – objects that could carry the virus (e.g., sonography probes, speculum) (Liu, Rashid, & Nyitray, 2015; Tay, 1995).

Common risk factors for HPV infection include higher number of sexual partners (concurrently or sequentially), early sexual initiation, lack or inconsistent condom use, young age, partner’s sexual behavior, immune status, and biological susceptibility (Burchell et al., 2006; Centers for Disease Control Prevention, 2015; Markowitz et al., 2014; Ratanasiripong, 2012; Trottier & Franco, 2006). Most HPV infections are transient and will clear within one to two years without clinical repercussions (Burchell et al., 2006; Trottier & Franco, 2006). Nevertheless, persistent infection can lead to diseases such as respiratory papillomatosis, genital warts, and some types of cancers (Centers for Disease Control Prevention, 2015; Jemal et al., 2013; Markowitz et al., 2014; Molano et al., 2003; Moscicki, 1998; zur Hausen, 2002). Among women, HPV infection can be tested during a routine Papanicolaou test; however, there are no HPV tests approved for men (Markowitz et al., 2014).

Low-risk HPV types 6 and 11 cause more than 90% of anogenital warts (Garland et al., 2009). It has been reported that anogenital warts or condylomata acuminata, can develop clinical symptoms as early as two to three months after infection with HPV (Garland et al., 2009; Winer et al., 2005). It is difficult to estimate the incidence of anogenital warts because in the US this is not required to be reported (Park, Introcaso, & Dunne, 2015). Based on data from the US National Health and Nutrition Examination survey from 1999 to 2004, among 18 to 56-year-old adults, 5.6% of reported having a prior genital warts diagnosis (Dinh, Sternberg, Dunne, &
Markowitz, 2008). Additionally, this study found that diagnosis of anogenital warts was higher among 25 to 34-year-old women and 35 to 44-year-old men, 10.4% and 6.0% respectively. Factors associated with having genital warts include sex, age, race/ethnicity, the number of lifetime sexual partners, and illegal drug use (Dinh et al., 2008).

Another less prevalent condition caused by HPV types 6 and 11 is recurrent respiratory papillomatosis (Lacey, Lowndes, & Shah, 2006; Markowitz et al., 2014). Infection with the HPV virus typically during childbirth, causes the growth of benign tumors in the respiratory tract (i.e., nose, mouth, larynx, lungs) (National Institute on Deafness and Other Communication Disorders, 2010). These tumors can be removed through surgery but often grow back causing respiratory obstruction (Lacey et al., 2006). Due to its rare occurrence, incidence and prevalence rates are difficult to evaluate, but some estimates indicate 80 to 1,500 incident cases and 700 to 3,000 prevalent cases among individuals younger than 18 years old in the US (Armstrong et al., 2000).

HPV-related cancers include cervical, vulvar, vaginal, penile, anal, and oropharyngeal (Forman et al., 2012; Markowitz et al., 2014; zur Hausen, 2002). From 2008 to 2012, approximately 30,700 HPV-associated cancers were diagnosed annually in the US (Viens et al., 2016). Specifically, 91% of cervical and anal cancers, 72% of oropharyngeal cancers, 63% of penile cancers, 75% of vaginal cancers, and 69% of vulvar cancers were attributable to HPV (Markowitz et al., 2014). Moreover, approximately 64% of these cancers are caused by HPV types 16 and 18 (Centers for Disease Control Prevention, 2015; Markowitz et al., 2014). This is because persistent biological infections with high-risk HPV types (i.e., HPV 16 and 18) are more likely to progress to cancer (Jemal et al., 2013; Markowitz et al., 2014; Schiffman, Castle, Jeronimo, Rodriguez, & Wacholder, 2007). Additionally, about 10% of the HPV-associated
cancers are attributed to HPV types 31, 33, 45, 52, and 58 (Centers for Disease Control and Prevention, 2015; Markowitz et al., 2014; Petrosky et al., 2015).

**The HPV Vaccine**

Currently, there are three approved HPV vaccines. The first two vaccines developed and later approved by the Food and Drug Administration (FDA) were the bivalent (Cervarix®) – only recommended for females – and the quadri-valent (Gardasil®) – recommended for both males and females. The Advisory Committee on Immunization Practices (ACIP) first recommended the HPV vaccine for *routine vaccination* for females in 2006 and males in 2011 (Markowitz et al., 2014). The third vaccine that was approved by the FDA in 2014 was the nine-valent version (Gardasil 9®). ACIP made it part of its recommended vaccines for both sexes in 2015 (Petrosky et al., 2015). Table 1 contains a detailed description of the HPV vaccines available.

The current ACIP recommendations indicate vaccinating children at 11 to 12 years of age, due to a better immune response before children become sexually active (Block et al., 2006). Additionally, the HPV vaccine is recommended for females between the ages of 13 and 26 years, and for males between the ages of 13 and 21 years, also as the known catch-up group, (Markowitz et al., 2014; Petrosky et al., 2015). Other populations to which the nine-valent and the quadri-valent versions of the HPV vaccine are also recommended include men who have sex with men (Markowitz et al., 2014; Petrosky et al., 2015), transgender individuals and people with immunocompromised conditions, all groups through age 26 (Centers for Disease and Control Prevention, 2016c).

Until recently, all approved vaccines required three intramuscular shots over a six-month period (scheduled at zero, two, and six months after the first shot) (Petrosky et al., 2015). The HPV vaccine series costs between $390 and $450, and additional fees may be charged by the
clinics and providers for administration costs (Association of Reproductive Health Professionals, n.d.). Research pointed to non-inferiority of two doses of the HPV vaccine (Dobson et al., 2013; Kreimer et al., 2015); thus in 2016, there was change to a two-dose/shots regime in the recommended number of dosages in the US. All 11 to 12 years old children should get two shots of the HPV vaccine six to 12 months apart. A third dose is required if the children received the two shots less than five months apart or if adolescents are older than 14 years or for 9 to 26-year-old individuals with immunocompromised conditions (Centers for Disease and Control Prevention, 2016c). Currently, the World Health Organization (WHO) recommends a two-dose schedule for females younger than 15, and a three-dose schedule for females older than 15, and immunocompromised or HIV-infected individuals (World Health Organization, 2014).

The vaccines are made of HPV L1 protein, which produces virus-like particles by using recombinant DNA technology; thus, making the vaccines not infectious (Markowitz et al., 2014). Common mild side effects associated with the HPV vaccine include pain and swelling at the injection site, headache, nausea, and muscle or joint pain (Centers for Disease and Control Prevention, 2015). Nonetheless, a recent review of nine years (up to the year 2015) of worldwide data from active and passive post-licensure safety surveillance of the 4valent HPV vaccine, found that only syncope (i.e., fainting) and possible skin infection were associated with vaccination. Furthermore, the review found that there was no higher incidence of serious adverse events, such as anaphylaxis, stroke, and autoimmune diseases, compared to background rates (Vichnin et al., 2015).
HPV vaccine uptake and completion rates in the US.

For 2016, it was estimated that only 56.0% of males between the ages of 13 and 17 years had received at least one dose of the HPV vaccine, in contrast to 65.1% of females in the same age group (Walker et al., 2017). For that same year, only 49.5% of females and 37.5% of males 13 to 17 years old had three doses of the HPV vaccine. Among both male and female adolescents, coverage with at least one dose of the HPV vaccine was 60.4%, and three doses coverage was 43.4% (Walker et al., 2017). These coverage rates are 28% points lower than at least one dose of the Tdap and 22% lower than at least one dose of the meningococcal vaccine (Walker et al., 2017). Lower rates are observed among the catch-up population. In 2012, the HPV vaccine uptake among females between the ages of 18 and 26 (considered catch-up group) was around 34.1% (Schmidt & Parsons, 2014). During the 2011 to 2012 period, the uptake rate among males 18 to 26 years old was 5.5% (Pierre-Victor, Mukherjee, Bahelah, & Madhivanan, 2014).

There is state variation in the initiation and completion rates of the HPV vaccine among adolescents 13 to 17 years old. During 2016, Rhode Island had the highest rate of initiation among females (90.1%) and males (87.8%). Mississippi had the lowest initiation rates for females (47.8%), while Indiana and Wyoming had the lowest initiation rates for males (36.9%). HPV vaccine three dose completion among females ranged from 30.8% in South Carolina to 73.0% in Rhode Island. Among males, completion rates ranged from 19.3% in Wyoming to 68.7% in Rhode Island. Overall initiation and completion rates in Puerto Rico were estimated to be 75.8% and 52.8% respectively. Among females, the initiation rate was 80.8% and among males was 71.1%. Completion rates were 61.9% and 44.1%, for females and males, respectively (Walker et al., 2017).
There are also racial/ethnic differences in HPV vaccination, as well as differences based on poverty level. In 2014, HPV vaccination initiation and completion were higher among Hispanic adolescents compared to non-Hispanic White adolescents (Reagan-Steiner et al., 2016). Non-Hispanic Black adolescents and American Indian/Alaska Native males had a higher HPV vaccine initiation rates compared to non-Hispanic Whites. Additionally, compared with adolescents living at or above the poverty level, HPV vaccination initiation was higher among adolescents living below the poverty level (Reagan-Steiner et al., 2016).

Healthy People 2020 established a national objective of 80% completion of the HPV vaccination among females and males aged 13 to 15 years old (Reagan-Steiner et al., 2016; U.S. Department of Health and Human Services & Office of Disease Prevention and Health Promotion, 2015). Despite research demonstrating the safety and effectiveness of the HPV vaccine as a primary prevention strategy (Petrosky et al., 2015; Stokley et al., 2014), the initiation and completion rates previously presented show HPV vaccination rates among adolescents remain far below the Healthy People 2020 goal.

**Health implications of increasing HPV vaccination rates.**

There are important *health* implications for increasing HPV vaccination. Research has reported findings regarding the reduction in the prevalence of HPV in the US population. A recent study found a 64% reduction in the prevalence of the HPV types covered by the 4valent vaccine among females between the ages of 14 and 19, within six years of the vaccine introduction in the US (Markowitz et al., 2016).

As discussed before, HPV is the cause of most cervical, vulvar, vaginal, anal, and penile cancers, and is also associated with anogenital warts and recurrent respiratory papillomatosis (Markowitz et al., 2014). Thus, an overall reduction of the infection of HPV would significantly
reduce the morbidity and mortality of these diseases. Moreover, HPV is also the cause of 72% of all oropharyngeal cancers; however, the HPV vaccine is not currently recommended for the prevention of this type of cancer because of lack of clinical trial data (Chaturvedi et al., 2011; Markowitz et al., 2014). Nonetheless, the vaccine includes HPV types 16 and 18, associated with 62% of the HPV-related oropharyngeal cancers (Gillison, Chaturvedi, & Lowy, 2008; Markowitz et al., 2014; Steinau et al., 2014). Therefore, increasing HPV vaccination rates could also have an impact on the reduction of oropharyngeal cancer rates.

It is important to note that, there are some disparities in the distribution of HPV-associated cancer incidence and mortality among race/ethnicities in the US (Jemal et al., 2013). For instance, data from 2008 to 2012 showed that cervical cancer rates were higher among Blacks compared to their White counterparts (9.2% and 7.1% respectively) (Viens et al., 2016). This same study found that cervical cancer rates were higher among Hispanics (9.7%) compared to non-Hispanics (7.1%) (Viens et al., 2016). Recent simulation models have been conducted to project changes in HPV-associated cancer burden. Findings suggest that HPV vaccination could not only decrease the morbidity and mortality of HPV-related cancers among all races/ethnicities, but it could also reduce the absolute degree of disparities (Burger et al., 2016). Nonetheless, some relative differences could worsen. For example, among males, the lifetime risk of dying of HPV-associated cancer lowered by 60%, but relative disparities increased when high uptake of the second generation of the HPV vaccine was assumed (Burger et al., 2016). Thus, the authors conclude that if the fundamental causes of disparities are not addressed (e.g., limited access to health care and cancer treatments) the relative disparities will likely continue and may even broaden (Burger et al., 2016).
Globally there is evidence in the reduction of HPV-related disease. A recent meta-analysis of female HPV vaccination programs in nine high-income countries (Australia, Canada, Denmark, England, Germany, New Zealand, Scotland, Sweden, and the US), was conducted to assess the population-level effects of these programs on the rates of genital warts (Drolet et al., 2015). Findings demonstrated significant reductions of HPV 16 and 18 infections, and of anogenital warts among 13 to 19-year-old girls when female vaccination coverage was at least 50% (Drolet et al., 2015). Among this age group, a significant reduction of HPV types 31, 33 and 45 was seen; thus, indicating some level of cross-protection. Among males under 20 years and women between 20 and 39 years old, a significant decrease of anogenital warts was also found indicating herd immunity effects (Drolet et al., 2015). In places with female vaccination coverage less than 50%, there were still significant decreases in HPV 16 and 18 infections and anogenital warts; however, no signs of cross-protection or herd immunity effects were found (Drolet et al., 2015).

Reductions in the rates of genital warts in the US has also been reported. For example, among female members of private health insurance 15 to 19 years old, the prevalence of genital warts significantly decreased during the years of 2007 to 2010 compared to 2003 to 2006, indicating some effect of the HPV vaccine after its introduction (Flagg, Schwartz, & Weinstock, 2013). Furthermore, Bauer, Wright, and Chow (2012) found a 35% and 19% significant reduction in genital warts diagnoses among females and males younger than 21 years, respectively, using a claims data from a California public family planning clinic. More recently, in a group of low-income and minority adolescents, rates of genital warts significantly decreased from pre- to post-vaccination periods from 3.5% to 1.5% in females and from 3.6% to 2.9% in males (Perkins, Legler, & Hanchate, 2015).
Economic implications of increasing HPV vaccination rates.

Besides the health implications, there are economic consequences of improving HPV vaccination. The annual medical direct cost of the prevention and treatment of HPV-associated diseases in the US has been estimated to be around $8 billion (2010 US dollars) (Chesson et al., 2012). Routine cervical cancer screening and follow-up accounted for about $6.6 billion, cervical and oropharyngeal cancers cost were around $1 billion, anogenital warts accounted for $288 million, and recurrent respiratory papillomatosis accounted for 171 million dollars (Chesson et al., 2012). Furthermore, women bear about two-thirds of the annual costs of HPV-associated diseases (Chesson et al., 2012). Therefore, increasing the HPV vaccination rates could save billions of dollars to the US health care system, and could result in a decrease in the burden of HPV-related diseases among women. Additionally, routine HPV vaccination of 12-year-old females, “in the context of current screening and assuming lifelong vaccine-induced immunity, had an incremental cost-effectiveness ratio of $43,600 per QALY gained, as compared with screening alone” (Kim & Goldie, 2008, p. 825).

In the US, recent data showed a 64% and a 34% decrease in the prevalence of HPV 6, 11, 16, and 18 after the HPV vaccine introduction among 14 to 19-year-olds and 20 to 24 years old females, respectively (Markowitz et al., 2016). Thus, in addition to the reduction of the prevalence of anogenital warts (i.e., HPV 6 and 11) by the uptake of the HPV vaccine, this could also mean the savings of around 167.4 million dollars; which was the estimated direct costs associated with genital warts among 15 to 24 year old young adults (Chesson, Blandford, Gift, Tao, & Irwin, 2004).
Factors that impact HPV vaccine rates.

Many barriers and facilitators influence HPV vaccine acceptance among stakeholders, which affect HPV vaccination rates in the US.¹ In this section, common barriers and facilitators to HPV vaccine uptake and completion will be presented following the levels of the Socio-Ecological Model (SEM). The SEM is a framework commonly used in public health to identify, organize, and analyze factors that can impact/influence a public health issue or/in a population. This framework consists of the following levels of influence: intrapersonal, interpersonal, organizational, community, and societal (Coreil, 2010). Because of this multilevel perspective, the SEM is useful for understanding health problems, identifying needs or areas for public health intervention, and for developing interventions.

Individual level.

Factors such as age, sex, beliefs, attitudes, and knowledge are usually considered at the individual level. In the case of the HPV vaccine, the adolescent’s sex is a factor that influences vaccination rates. A study using data from the National Immunization Survey-Teen 2013 (NIS-Teen 2013), showed that girls were more likely to be vaccinated and had completed the three doses compared to boys between the ages of 13 and 17 years (Lindley et al., 2016). This is also the case among the college student population. A recent study noted that, although the difference between males and females decreased in comparison to rates of fall 2009 to 2011, HPV

¹ There are two systematic reviews that summarize barriers to HPV vaccination among adolescents aged 11 to 17 living in the US. Holman et al. (2014) included studies from 2009 to 2012. Berenson (2015) followed-up Holman’s review by looking at studies from 2013 to 2015. Therefore, some of the factors presented in the following sections are based on the studies included in these reviews.
vaccination rates in years 2012 and 2013 were still higher among females than males college students (Thompson et al., 2016).

Age is another factor that influences HPV vaccination. In most studies identified by Holman et al. (2014), younger age was a reason for not vaccinating or for delaying vaccination (Baldwin, Bruce, & Tiro, 2013; Bastani et al., 2011a; Control & Prevention, 2012; Dorell, Yankey, Santibanez, & Markowitz, 2011; Gilkey, Moss, McRee, & Brewer, 2012; Hoffman et al., 2012; Laz, Rahman, & Berenson, 2012; Reynolds & O'connell, 2012). However, among males, this age difference was not observed in either HPV vaccine initiation or completion (Control & Prevention, 2012; Curtis et al., 2013).

Parents, including caregivers, also report individual-level barriers to HPV vaccination. Holman et al. (2014) and Berenson (2015) noted in their reviews of studies that parents report the need for more information about the HPV vaccine. Additionally, in a recent study, parents of children 11 to 17 years old who decide to delay the HPV vaccine, have also reported the need for more information about the vaccine (Gilkey, Calo, Marciniak, & Brewer, 2017). Parents have also mentioned the cost of the HPV vaccine as a barrier to uptake in most studies summarized by Holman et al. (2014). Moreover, Berenson (2015) highlighted the cost of the HPV vaccine is a barrier to adolescent vaccination. This perception of the cost of the HPV vaccine is a barrier to HPV vaccination among parents even when they could get the vaccine through the Vaccines for Children program (Vadaparampil, Staras, et al., 2013).

As reported by Holman et al. (2014) and Berenson (2015), research has found that some parents also think that the HPV vaccine will cause their children to initiate sexual activity and/or engage in risky sexual behavior. For instance, in a qualitative study with Puerto Rican mothers one of the themes related to HPV vaccination uptake was the idea that the vaccine would indicate
to their daughters that it would be fine to engage in sexual activity (Fernandez et al., 2014). This phenomenon is known as sexual risk compensation or sexual disinhibition (Zimet, Rosberger, Fisher, Perez, & Stupiansky, 2013). Nonetheless, two systematic reviews have concluded that there is no evidence for these concerns (Kasting, Shapiro, Rosberger, Kahn, & Zimet, 2016; Madhivanan et al., 2016). Furthermore, among college students no association between inconsistent condom use and HPV vaccination was found (Vazquez-Otero et al., 2016), further providing evidence that the HPV vaccine does not promote risky sexual behaviors.

Holman et al. 2014 noted that studies’ findings of parental worries related to side effects and safety, and concerns about the newness of the vaccine did not clearly indicate if HPV vaccine uptake was affected (Laz et al., 2012; Litton, Desmond, Gilliland, Huh, & Franklin, 2011; Sanders-Thompson, Arnold, & Notaro, 2011). Berenson (2015) also identified studies in which parents expressed concerns about the possibility of long-term health effects associated with the vaccine as a reason for not vaccinating their children (Blackman et al., 2013; Dorell et al., 2014). For example, in a sample of African American and Bahamian parents, most agreed needing more assurance on the HPV vaccine safety (Blackman et al. 2013). Concerns about adverse events were also found to be among the most common factors against HPV vaccination among parents from Georgia (Gargano et al., 2013).

Parental religiosity or religious beliefs influence HPV vaccination uptake is a contested factor. Holman et al. (2014) found two studies in which religious affiliation was associated with disapproval in getting the vaccine (Pierre-Joseph et al., 2012; Thomas, Strickland, DiClemente, Higgins, & Haber, 2012), whereas in two other studies there was no association to HPV vaccine acceptance (Litton et al., 2011; Sanders-Thompson et al., 2011). For example, Litton et al., (2011), conducted a survey among female caregivers of 10 and 14-year-old girls, and found that
religious attendance as well as factors such as perceived susceptibility and severity of the infection were not associated with intention to vaccinate their children. On the other hand, among African American parents of young children, religious affiliation was correlated with planning and getting the HPV vaccine (Thompson et al., 2011).

Furthermore, Berenson (2015) found studies that reported that among parents there is a lack of awareness and knowledge of the HPV likelihood of infection, of the risks or understanding that transmission of the virus can be prevented with the vaccine; resulting in some parents choosing not to vaccinate their children. For example, in a recent qualitative study guided by the HBM, most of the participants of a sample of African American parents perceived that their adolescent daughters were not susceptible to the virus. These parents believed their daughters were not sexually active (Galbraith-Gyan et al., 2019). Similarly, Berenson (2015) reported on studies that found that among adolescents there is lack of knowledge about the virus, cervical cancer, and the HPV vaccine.

Overall these barriers and concerns contribute to HPV vaccine hesitancy among parents/caregivers (Patel & Berenson, 2013). Additionally, health care providers may not recommend the HPV vaccine if they perceive parental vaccine hesitancy (Allison et al., 2016). Vaccine hesitancy (VH) has emerged as a concept to describe the phenomena of individuals deciding to delay or refuse vaccination. VH was defined by the SAGE Working Group as “delay in acceptance or refusal of vaccination despite the availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place and vaccines. It is influenced by factors such as complacency, convenience, and confidence” (MacDonald, 2015, p. 3). This definition integrates the concepts ‘complacency’, ‘convenience’ and ‘confidence’ all part of the “3 C’s” model previously developed by the WHO EURO Vaccine Communications
Working Group in 2011 (MacDonald, 2015). The first C, ‘complacency,’ occurs when there is a perception of low risk of vaccine-preventable diseases and people think vaccines are not needed (MacDonald, 2015, p. 2). The second C, ‘convenience’ covers the accessibility and affordability factors related to vaccination services (MacDonald, 2015, p. 2). Finally, ‘confidence,’ refers to the trust people have in vaccine safety, in the health care system and health care providers, and in the policymakers who create the mandates related to which vaccines are required (MacDonald, 2015, p. 2).

Another critical characteristic of VH is that it is considered along a continuum with individuals who accept and those who refuse vaccines at the extremes, and the ‘vaccine-hesitant individuals’ standing as a heterogeneous group in the middle (Benin, Wisler-Scher, Colson, Shapiro, & Holmboe, 2006; Dube et al., 2013; Kestenbaum & Feemster, 2015; Larson et al., 2014; MacDonald, 2015). Vaccine-hesitant individuals are heterogeneous because their indecision varies depending on the type of vaccine; they might refuse some, accept some and/or delay others (Dube et al., 2013; Larson et al., 2014).

Despite these barriers, there are facilitators to HPV vaccine acceptance and initiation among parents. In Holman et al. (2014) review of the literature, some facilitators included in the summarized studies were parents’ interest in protecting their children before the initiation of sexual activities, perceived risk of diseases associated to HPV, and parental preventive-care seeking behaviors. Among adolescents, the promotion of health, prevention of STIs, and cancer prevention were mentioned as common reasons for accepting the HPV vaccine among high school, college, and graduate health students, respectively (Suryadevara et al., 2016).

Among health care providers Holman et al. (2014) identified studies in their review that found individual-level barriers. Some of these studies noted barriers such as low knowledge
about the relationship of HPV with genital warts (Perkins & Clark, 2012a; Saraiya, Rosser, & Cooper, 2012), providers offering too much or too little information about the vaccine to parents (Goff, Mazor, Gagne, Corey, & Blake, 2011; Hughes, Jones, Feemster, & Fiks, 2011), assessing their patients based on perceived risk factors (Goff et al., 2011; Hughes et al., 2011; Perkins & Clark, 2012a), and concerns about parental attitudes towards vaccination (Perkins & Clark, 2012a, 2012b; Quinn, Murphy, Malo, Christie, & Vadaparampil, 2012).

Additional factors noted by Holman et al. (2014) among this group of stakeholders included concerns about the cost of the vaccine and issues with insurance coverage and reimbursement (Luque, Raychowdhury, & Weaver, 2012; Quinn et al., 2012). Berenson (2015) also reported findings from studies on the cost associated with the storage of the HPV vaccine, and inadequate reimbursement mentioned as barriers to HPV vaccination by physicians (Allison et al., 2013; Luque, Tarasenko, Dixon, Vogel, & Tedders, 2014; Malo et al., 2013; Vadaparampil, Murphy, Rodriguez, Malo, & Quinn, 2013).

Interpersonal level.

At the interpersonal level, factors such as family, peer, and partner and other relationships are common influences. Relationships with health care providers are essential. Physician recommendation is the most significant predictor of HPV vaccination among women (Rosenthal et al., 2011), as well as among adolescents (Dorell et al., 2013; Dorell et al., 2011). However, a recent systematic review of the literature by Gilkey and colleagues (2016), found that providers still confront barriers to recommendation such as feeling uncomfortable when talking about sex, perceiving parental hesitancy to get the vaccine, or believing their patients are at low risk of contracting HPV. Additionally, the authors found that if patients were young, male or from a racial/ethnic minority, providers would be less likely to recommend the HPV vaccine (Gilkey &
McRee, 2016). For example, data from the NIS-Teen 2013, showed that parents of boys 13 to 17 years old were less likely to report provider recommendation compared to parents of girls in that age group (Lindley et al., 2016). Lack of physician recommendation has also been cited as a reason for not receiving the HPV vaccine in a study including high school, college, and graduate health students (Suryadevara et al., 2016), and among parents as reported in the literature reviews by Holman et al. (2014) and Berenson (2015).

Another factor that can be listed at this level is the communication between mother and child. In a survey with mothers of children 9 to 17 years old, communication about STI’s, and contraception and condom use were positively associated with HPV vaccine initiation (Gross et al., 2015). This is an important factor because mothers are usually the ones deciding to vaccinate their children against HPV (Berenson, Laz, Hirth, McGrath, & Rahman, 2014; Gross et al., 2015).

Community level.

Some factors considered at the community level are geographical and/or cultural influence. The concept of community can include geographical locations, as well as cultural/ethnic groups. For instance, among low-income immigrant ethnic minority women concerns about locating a place for vaccinating their daughters was a barrier to HPV vaccination (Bastani et al., 2011b). Parents from Latino communities have mentioned the lack of provider recommendation as the main barrier to HPV vaccination for their sons and daughters (Aragones, Genoff, Gonzalez, Shuk, & Gany, 2015; Warner et al., 2015). In terms of geographical factors, a study looking at community-level factors associated with HPV vaccine uptake among female adolescents found that communities composed of mostly Hispanics and urban residence were associated with higher vaccine initiation (Henry et al., 2015). Among boys, having public health
insurance, lower income, education, and being Hispanic are factors associated with HPV vaccination (Kepka, Ding, Hawkins, Warner, & Boucher, 2016).

**Organizational level.**

The organization level includes experiences with the health care system, schools, and/or the workplace. For instance, Holman et al. (2014) found that across studies preventive care appointments, frequent contact with the medical system, and have received other vaccines were all associated with receiving at least one dose of the HPV vaccine. Additionally, Berenson (2015) identified the need to access the health care system at three different occasions as a barrier for HPV vaccination.

Professional associations can also play a role in promoting the HPV vaccine. The HPV vaccine has received endorsement and support from multiple influential organizations such as the ACIP, the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the WHO (Byington et al., 2016; World Health Organization, 2014). Nonetheless, research indicates that vaccine recommendations alone, by institutions such as ACIP, do not increase immunization rates (Askelson et al., 2010; Rosenthal, Kottenhahn, Biro, & Succop, 1995).

**Societal level.**

At this level, factors such as federal and state policies and programs, social norms, and the media can influence HPV vaccination rates. For example, Holman et al. 2014 found a study indicating a positive association between HPV vaccine intention with the belief it agreed with social norms regarding the vaccination of children (Reynolds & O'Connell, 2012). This study used the Health Belief Model and the Theory of Reasoned Action to predict intention to HPV vaccination in a sample of parents/legal guardians of girls 9 to 18 years old (Reynolds &
O’Connell, 2012). Additionally, a more recent study looking at social norm’s beliefs among parents of boys also found that parents who thought other parents were also vaccinating their children were more likely to have the intention to vaccinate their sons compared to those who did not agree to vaccinating (Schuler & Coyne-Beasley, 2016).

Another common social perception is that the HPV is a female issue; this notion, known as the “feminization of HPV”, is largely the result of the intersection between sexism and the vaccine’s scientific evolution (i.e., the known science) (Daley et al., 2016). Furthermore, on a review of studies about the US news media coverage of the HPV vaccine since 2006, Gollust and colleagues (2016) found two common themes: “a rising focus on political controversy and a consistent emphasis on the vaccine as for girls, even beyond the point when the vaccine was recommended for boys” (p. 1). These messages influence stakeholders such as parents, providers, and policymakers. Additionally, network and word cluster analyses of online presentation of HPV information suggest that compared to boys, HPV vaccine information for women and girls is usually presented in sexual terms (Ruiz & Barnett, 2015).

At the federal level, the Vaccines for Children program provides the HPV vaccine – and other required and recommended vaccines – at no cost to providers for use among uninsured or underinsured, Medicaid-eligible, and to American Indian/Alaska Native children up to 18 years old (Smith, Hinman, & Pickering, 2014). The Patient Protection and Affordable Care Act of 2010 also requires insurances to cover vaccines recommended by the ACIP with no cost to the beneficiary (Markowitz et al., 2014). Using data from the National Health Interview Survey, a recent study estimated that 1.1 million and 854,000 women between the ages of 19 and 25 initiated and completed the HPV vaccine, respectively, based on this ACA provision (Lipton & Decker, 2015).
At the state level, the introduced legislation related to the HPV vaccine is varied in content. Some states, such as Colorado, New Jersey, North Carolina, have legislated in favor of awareness campaigns, while other states (e.g., Illinois, Maine, Nevada, and New Mexico) require health insurances to cover the HPV vaccine (Laugesen et al., 2014). The National Conference of State Legislatures reports that at least 25 states and territories have passed some type of legislation regarding the HPV vaccine. From those, only the states of Virginia and Rhode Island, and Washington DC require the HPV vaccine for school entrance (National Conference of State Legislatures, 2016). Details of the HPV vaccine school-entry policies are described in the School-entry requirements section (p. 38).

**Vaccine Interventions**

Vaccines interventions have contributed to the improvement of the overall health of our society. Consequently, the reduction of vaccine-preventable diseases through vaccination is celebrated as one of the ten greatest public health achievements (Centers for Disease and Control Prevention, 1999; Centers for Disease Control and Prevention, 2011; Dube et al., 2013; Larson et al., 2014). Vaccines were instrumental in the eradication of diseases such as polio and smallpox (Centers for Disease and Control Prevention, 1999; Dube et al., 2013), and have aided in lowering the incidence of pneumococcal infections and rotavirus hospitalizations in the US during the last decade (Centers for Disease Control and Prevention, 2011).

The Community Preventive Services Task Force (CPSTF, 2016) has identified and organized vaccine interventions into three major categories: 1) enhancing access to vaccination services, 2) increasing community demand for vaccines, and 3) provider- or system-based interventions. Reducing out-of-pocket costs, and vaccine programs in schools and organized childcare centers, are examples of recommended vaccine interventions under the first category (CPSTF, 2016). Examples under the second category include client reminder and recall systems,
and vaccination requirements for childcare, school, and college attendance (CPSTF, 2016).

Under the third category, recommended interventions include immunization information systems and provider reminders (CPSTF, 2016).

It is important to note that school-based programs, school-entry requirements, and vaccine mandates are different concepts. To differentiate between school-based programs and school-entry requirements, the definitions provided by the CPSTF (2016) will be used and are presented below.

School-based programs are defined as:

“Vaccination programs in schools or organized child care centers are multicomponent interventions delivered on-site to improve immunization rates in children and adolescents. These programs include two or more of the following components: 1) Immunization education and promotion, 2) Assessment and tracking of vaccination status, 3) Referral of under-immunized school or child care center attendees to vaccination providers, 4) Provision of vaccinations. […] Vaccination programs are often collaborations between the school or child care center and local health departments, private healthcare providers, or community healthcare services.” (CPSTF, 2016)

“Potential barriers to implementation of vaccination programs in schools might include difficulties coordinating between different programs, need for staff training, disruption of school routines, and concerns regarding confidentiality” (Briss et al., 2000, p. 112).

School-entry requirements are defined as:

“Vaccination requirements are laws or policies requiring vaccinations or other documentation of immunity as a condition of child care, school, and college attendance. Their purpose is to reduce the incidence of vaccine-preventable disease and associated morbidity and mortality by increasing vaccination rates. Laws are created by states, with the specific vaccines required established by the legislature and embodied in statutes or adopted as administrative rules by health or education departments. Institutions such as colleges and private schools may establish additional vaccination policies for attendance or residence. Vaccination requirements vary across jurisdictions by comprehensiveness, acceptable documentation of immunity, access to exemptions (especially nonmedical exemptions), and the type and consistency of enforcement.” (CPSTF, 2016)

“Potential barriers to implementation of vaccination requirements for child care, school, and college attendance include administrative burden, difficulty coordinating various programs, and difficulty passing legislation” (Briss et al., 2000, p. 104).
The last concept, *vaccine mandates* can be defined as a broad term that refers to any law requiring vaccination. These can include school-entry requirements, or laws requiring hospital employees to be vaccinated (Cole & Swendiman, 2014). In a recent systematic review looking at the economics of vaccine interventions from 1980 to 2012, it was reported that school-based interventions are considered cost-effective. Population-wide laws had the most reach, but in the case of school-entry laws, there was no adequate cost and cost-effectiveness data. Additionally, the authors noted that, from an economic perspective, HPV vaccine strategies were among the least studied (Jacob et al., 2016).

**States’ police powers, vaccine mandates, and public health.**

The 10th amendment of the US Constitution prescribes that the powers that are not part of the federal government nor prohibited by the Constitution are reserved to the states, these are known as the police powers (Cole & Swendiman, 2014; Gostin, 2008). Due to the police powers, the states have the authority to enact laws for the protection of the health and general welfare of their citizens (Cole & Swendiman, 2014; Gostin, 2008). Thus, each state in the US has its power to decide vaccination policies. From a public health perspective, policy powers “include all laws and regulations directly or indirectly intended to reduce morbidity and premature mortality in the population” (Gostin, 2008, p. 135). Examples of these regulations include isolation, quarantine, and vaccination laws (Gostin, 2008).

The theory of herd immunity has historically been used as a justification to enact vaccine mandates in the US. This theory poses that a chain of infection is interrupted when large numbers of individuals in the population are immune to the disease (Javitt et al., 2008). The US Supreme Court established a legal precedent in the case of *Jacobsen v. Massachusetts* (1905.197U.S.11) when it decided to uphold a smallpox vaccine mandate in favor of herd
immunity over the principle of autonomy (Colgrove & Bayer, 2005; Field & Caplan, 2008). With this decision, the US Supreme Court acknowledged the state of Massachusetts’ police powers to create reasonable regulations for the protection of the public’s health (Cole & Swendiman, 2014). Additionally, public health practitioners tend to favor vaccine mandates based on a utilitarian perspective, where society’s well-being overrides individual autonomy (Field & Caplan, 2008). A result of making vaccinations a requirement via vaccine mandates, access increases for underserved populations; thus, justice is another principle considered by Field & Caplan (2008) in the ethical framework. Furthermore, other perspectives also justify the need to enact laws requiring vaccination. Brennan (2016) argues that mandatory vaccination under a libertarian political framework is achievable because people advocating against vaccines are imposing unfair harm on others.

School-entry requirements.

Vaccination mandates for school entrance are a highly effective strategy commonly used in the US to increase adolescent uptake of vaccines (Averhoff et al., 2004; Field & Caplan, 2008; Hinman et al., 2002). Additionally, vaccine mandates for school entry are recommended by the CPSTF (2016) to increase vaccination uptake among children and adolescents. Moreover, these types of mandates have been found to be effective in reducing racial/ethnic disparities in vaccine uptake; such as in the case of requiring the hepatitis B vaccine for 5th grade in Illinois (Morita, Ramirez, & Trick, 2008). Currently, all of the US states and Washington DC have some kind of school-entry laws that require documentation of immunization (Cole & Swendiman, 2014). However, most of these policies provide opt-out options or exemptions based on medical reasons, religious objections or philosophical concerns (Bradford & Mandich, 2015; Field & Caplan, 2008).
According to Bugenske, Stokley, Kennedy, and Dorell (2012), while education-only requirements do not increase meningococcal conjugate and HPV vaccine coverage; middle-school requirements are associated with higher coverage of vaccines such as tetanus/diphtheria (Td) or tetanus/diphtheria/pertussis (TdaP). Thus, one way to increase HPV vaccination rates would be to make the vaccine mandatory for school entrance. For instance, mandating the polio vaccine has proven effective in the eradication of the virus in the US (Osazuwa-Peters, 2013). However, in the case of the HPV vaccine policies, controversy has surrounded the matter due to “the intersection of two highly charged policy areas: immunization safety and adolescent sexuality” (Colgrove et al., 2010, p. 785).

**HPV vaccine mandates.**

As mentioned before, legislation related to the HPV vaccine vary. Some states have created legislation in favor of educational campaigns, while others require health insurance to cover the HPV vaccine, or require the HPV vaccine for middle-school entrance (Abiola et al., 2013; Colgrove et al., 2010; Laugesen et al., 2014). Currently, only Virginia, Rhode Island, and Washington, DC require the HPV vaccine for school-entry. As of September 2017, eight states (Georgia, Hawaii, Illinois, Minnesota, New Mexico, New York, Texas, and Rhode Island) have proposed different bills related to HPV vaccination for the 2017-2018 sessions. From those, only two from New York proposed for the HPV vaccine to be required for all children born after January 1, 1996/8 (National Conference of State Legislatures, 2017).

One of the first efforts to require the HPV vaccine occurred in 2007, when the Texas Governor at the time, Rick Perry, issued an executive order to require the vaccine for sixth-grade girls (Colgrove et al., 2010). A strong backlash followed when donations from Merck to his campaign were made public (Mello et al., 2012). The order was overridden by the Legislature,
which thought the governor was ‘overreaching’ his constitutional powers (Abiola et al., 2013; Colgrove et al., 2010).

In the US, Virginia’s mandate was the first one to be enacted in 2007 and was put into effect on 2009 (Pitts & Tufts, 2013). Virginia’s school entry law requires the first dose for females entering sixth grade. However, it is up to parental/guardian discretion to elect not to get the vaccine, since broad opt-out options are available (Virginia Department of Health, 2014). Consequently, such policy has not improved HPV vaccine uptake rates in Virginia five years after its enactment (Cuff et al., 2016). The Washington DC mandate that was initially passed in 2007 and implemented in 2009 applied only to girls. Later in 2014, it was amended to include boys (Barraza et al., 2016). It currently requires the three-dose completion for all students entering sixth to twelve grade and allows for all the types of opt-out options (i.e., medical reasons, religious objections or philosophical concerns) (Government of the District of Columbia Department of Health, 2015). Rhode Island’s school-entry HPV vaccine mandate (passed in July 2015 – through public regulation by Rhode Island Department of Health) only allows exceptions based on medical or religious reasons and requires boys and girls to be vaccinated (State of Rhode Island Department of Health, 2015; Washburn et al., 2016).

In June 2017, the PR’s Department of Health (DOH) announced the HPV vaccine was going to be required for children 11-to-12 years old starting on the 2018-2019 academic year. The Secretary of Health indicated in a press release that the HPV vaccine series should be initiated at 11 years old along with the Tdap and the meningococcal vaccine. On June 2018, the official announcement of the DOH was published indicating that the HPV vaccine was going to be required for children 11-to-12 years old starting in fall 2018.
Arguments in favor of and against the HPV vaccine school-entry requirement.

Support from different types of stakeholders and the public’s involvement is necessary for policy creation and adoption (Walt et al., 2008). Thus, exploring and understanding stakeholders’ reasons and identifying factors in support of or against the HPV vaccine school-entry requirement is important for these policy processes to be successful. Based on a systematic search of the literature (last updated on September 12, 2017), 25 studies were identified as research involving any stakeholder reasons and factors in support or against the HPV vaccine school-entry requirement (Tables 2 and 3). The purpose of the following sections is to present a summary of the current state of the literature.

Overall studies’ characteristics.

Although 25 studies were identified, three pairs of studies used the same dataset/participants (Table 2). Publication years ranged from 2007 to 2016. A total of eight studies used qualitative methods, 13 studies used quantitative methods, two used mixed methods, and two studies used an experimental design (Table 2).

Data collection years ranged from 2005 to January 2015 (two studies did not report this information) (Table 2). Only four studies reported collecting their data after October 2011 when the HPV vaccine was recommended for routine vaccination for boys by ACIP (Centers for Disease Control Prevention, 2011). Nan and Madden (2014) did not report year for data collection, but it was estimated to be during 2012). Furthermore, from these studies, just three asked if the HPV vaccine school-requirement should be created for boys and girls (Califano, Calo, Weinberger, Gilkey, & Brewer, 2016; Calo, Gilkey, Shah, Moss, & Brewer, 2016; Vercruysse et al., 2016). Two studies (although using the same database/participants) were about an existing mandate (the Virginia school-entry requirement) (Pitts & Tufts, 2013; St John, Pitts,
& Tufts, 2010), and one study addressed perceptions of school-entry compared to school-based programs among parents of girls and physicians (Vercruysse et al., 2016).

In terms of theoretical frameworks used; nine studies did not mention any theory, and six studies used a theoretical approach to guide their study (Table 2). The theories used included Theory of Planned Behavior, the Awareness-to-adherence Model and the Diffusion Model (Kahn et al., 2009), the Cultural Cognition/Risk Theory (Kahan, Braman, Cohen, Gastil, & Slovic, 2010), Journalistic Framing (St John et al., 2010), Multiple Streams Theory (Abiola et al., 2013), the Health Belief Model (HBM) (Perkins et al., 2013), and the Cultural Theory of Risk with Message Framing Theory (Nan & Madden, 2014). One study did not mention a theory, but it was based on the same database/participants from the Abiola et al., 2013 study; thus, it was probably guided by Multiple Streams Theory (Colgrove et al., 2010).

Finally, seven studies used theories for data collection purposes (e.g., items/scales), such as the Health Belief Model (HBM) (Pierre-Joseph, Belizaire, et al., 2014; Pierre-Joseph, Clark, et al., 2014), and Transtheoretical model (Vercruysse et al., 2016). For their data analysis, Tissot et al. (2007) used framework analysis, Perkins, Pierre-Joseph, Marquez, Iloka, and Clark (2010) used Grounded Theory and content analysis, and Pitts and Tufts (2013) used thematic analytic procedures. Sanderson et al. (2009) integrated their findings to the HBM in the discussion section.

**Stakeholders/participants.**

In terms of the stakeholders involved in these studies; about half of the studies (n = 12) included parents/guardians. From those, seven studies were with parents of girls only, four were with parents of boys and girls, and one study included parents of only boys (Table 2). Three studies involved physicians; one included pediatricians (Tissot et al., 2007), another one was
with primary care physicians (Kahn et al., 2009), and one study included both, pediatricians and family physicians (Califano et al., 2016).

Three studies included multiple types of stakeholders. Abiola et al. (2013) and Colgrove et al. (2010) (same dataset/participants) had mostly policymakers, but also included representatives from the industry, medical professional organizations, and advocacy groups. Vercruysse et al. (2016) recruited both parents of 11 to 17-year-old girls and health care providers.

Finally, seven studies included other types of stakeholders such as, emergency department patients (Millen, Ginde, Anderson, Fang, & Camargo, 2009), a national sample of American adults (mean age 47, study did not indicate if the participants were parents) (Kahan et al., 2010), minority men 18 to 22 years old (Pierre-Joseph, Belizaire, et al., 2014), minority women 18 to 22 years old (Pierre-Joseph, Clark, et al., 2014), 18 to 22 years old college students (Smith, Wilson, Pulczinski, & Ory, 2014), undergraduate students (18 to 29 years old) (Nan & Madden, 2014), and 18 to 26 year old female college students (Wilson, Smith, Rosen, Pulczinski, & Ory, 2016).

Reasons and Factors in Support of or Against an HPV vaccine school-entry requirement among Parents/Guardians, Physicians, and Policymakers.

Parents/guardians. (see Table 3)

Reasons and factors in support of an HPV vaccine school-entry requirement. There are some characteristics of the parents that make them more likely to support the HPV vaccine school-entry requirement. These include if the mother - in this case, Latina - has been diagnosed HPV+ (Sanderson et al., 2009), had a Pap test during the previous year (Yeganeh, Curtis, & Kuo, 2010), and parents having a low socioeconomic status and a history of HPV-related disease
Another factor associated with support is the reported ethnicity of the parent. Ethnic minorities, including immigrants, compared to Caucasians (Perkins et al., 2010), Latinos compared to another ethnicity (Yeganeh et al., 2010), and Hispanics responding to a survey in Spanish compared to African Americans and Hispanics answering in English were more likely to support the HPV vaccine school-entry requirement (Robitz et al., 2011).

When parents discussed reasons to support the HPV vaccine school-entry requirement, characteristics specific to the HPV vaccine were mentioned. An overall positive attitude towards the benefits of the vaccine (St John et al., 2010), its function in the prevention of cervical cancer (Perkins et al., 2010) and STIs (Vercruysse et al., 2016) were some of the reasons mentioned. Moreover, factors associated with support included thinking that the vaccine works well (Robitz et al., 2011), the benefits of the vaccine (Carlos et al., 2011), vaccine safety (Yeganeh et al., 2010), being interested in the vaccine (Ferris et al., 2010), knowledge about the reduction of the risk and effectiveness of the vaccine against cervical cancer (Ferris et al., 2010; Smith et al., 2011), and genital warts (Ferris et al., 2010). Furthermore, the perceived severity of the virus was also a reason to support the HPV vaccine school-entry requirement among parents of adolescent boys (Perkins et al., 2013).

There were also factors related to the child that parents associated with the support of an HPV vaccine school-entry requirement. For instance, parents of children between the ages of 12 and 14 compared to parents of younger (9-11) and older children (15-17) were more likely to support it (Ferris et al., 2010). Similarly, Smith et al. (2011) found parents were more likely to agree if they thought there were more benefits of providing the vaccine at a younger age. Other factors associated with supporting the requirement was if their daughters were already vaccinated (Yeganeh et al., 2010) or if the parents intended to get the HPV vaccine for their daughters.
Some factors were about their children’s’ sexual behavior. Parents thinking that their children are susceptible to contract the HPV (Ferris et al., 2010) were more likely to support the requirement. Similarly, parents considering protecting sexually active adolescents expressed their support (Perkins et al., 2010).

Another reason mentioned among parents that support the HPV vaccine school-entry requirement was the idea that it is a public health intervention that would be beneficial for all (Perkins et al., 2010; Perkins et al., 2013; Vercruysse et al., 2016). Moreover, one study found that irrespective of parents supporting or not the mandate; they all thought it should be required for both, boys and girls (Perkins et al., 2013). In the Smith et al. (2011) study, parents who thought all children should get the vaccine were also more likely to support the requirement.

Lastly, there were factors related to the characteristics of the HPV vaccine school-entry requirement. Back in 2008, parents thought the opt-out option of the Virginia HPV vaccine school-entry requirement was a ‘ploy’ to get parents to agree to it (St John et al., 2010), and once the vaccine is normalized the government would remove the option to opt-out. However, subsequent studies have found that parental agreement increases when opt-out options are provided in the requirement. For example, agreement to the HPV vaccine school-entry requirement increased from 59% to 92% (Robitz et al., 2011), from 47% to 84%, and from 21% to 57% (Calo et al., 2016) when opt-out options were included as part of the mandate. Moreover, in a recent study by Calo et al., 2016, factors associated with supporting an HPV vaccine school-entry requirement were evaluated by looking at the HPV vaccine school-entry requirement with and without the opt-out option. Without the opt-out option, Hispanic parents compared to non-Hispanic Whites were more likely to support the HPV vaccine school-entry requirement; as well as parents who thought the HPV vaccine was as important as other vaccines and was effective at
preventing cervical cancer. Similarly, parents who thought it would be difficult to find a clinic or provider to get the vaccine were more likely to support the HPV vaccine school-entry requirement without any opt-out option provided (Calo et al., 2016). When the opt-out option was considered, parents who thought that the HPV vaccine is effective at preventing cervical cancer, and is as or more important than other vaccines, were more likely to support the requirement (Calo et al., 2016).

Reasons and factors against the HPV vaccine school-entry requirement. The infringement on parental rights and autonomy was the most common reason cited and associated with being against the HPV vaccine school-entry requirement (Ferris et al., 2010; Horn, Howard, Waller, & Ferris, 2010; Pitts & Tufts, 2013). Moreover, they expressed it is the parents’ rights or personal choice to decide to vaccinate their children, thus; a mandate would be a limitation to parental autonomy (Perkins et al., 2013; Pitts & Tufts, 2013; Smith et al., 2011; St John et al., 2010; Vercruysse et al., 2016).

There were characteristics of the parents or parental factors associated with not supporting an HPV vaccine school-entry requirement presented in the literature. These factors included ethnicity, such as African American (Robitz et al., 2011), and Caucasian (Perkins et al., 2010), their beliefs that the vaccine will not work, and not having vaccinated or not having the intention to vaccinate their daughters (Robitz et al., 2011). Lastly, parents residing in the Midwest states compared to the Northeast states were less likely to support the HPV vaccine school-entry requirement when on opt-out option was provided (Calo et al., 2016).

There were also reasons related to the HPV vaccine and the HPV. Parents who thought that the vaccine was new and who had safety concerns about it and its side effects were more likely to be against the HPV vaccine school-entry requirement (Carlos et al., 2011; Horn et al.,
2010; Perkins et al., 2010; Robitz et al., 2011; Smith et al., 2011). The newness of the vaccine was also mentioned as a reason not to support the HPV vaccine school-entry requirement, even though the data for this study were collected during 2012 to 2013, almost a decade after the HPV vaccine approval by the FDA (Vercruysse et al., 2016). Also, parents discussed that there is not enough research on the vaccine and that its long-term efficacy it’s not known (Pitts & Tufts, 2013). The mode of HPV transmission was also discussed as a reason to be against the HPV vaccine school-entry requirement among parents. Some noted the lack of casual transmission (Perkins et al., 2013; Vercruysse et al., 2016), while others emphasized the sexual transmission of the virus (Pitts & Tufts, 2013).

Related to sexual activity/behavior of their children, parents who thought that their daughters would initiate sexual activity were less likely to support the HPV vaccine school-entry requirement (Smith et al., 2011). Additionally, parents also discussed that adolescents were not sexually active; thus, there was no need for the requirement (Vercruysse et al., 2016). Additionally, mothers who thought their daughters were too young for vaccination were less likely to support the HPV vaccine requirement for school entrance (Carlos et al., 2011).

Parents who thought that drug companies or ‘pharma’ were behind the push for the HPV vaccine school-entry requirement were less likely to support it (Calo et al., 2016; Smith et al., 2011). This was also a concern among parents when discussing their thoughts about the existing mandate in Virginia (Pitts & Tufts, 2013). These parents also mentioned a lack of information about the mandate and the safety and efficacy of the vaccine as concerns for them (Pitts & Tufts, 2013; St John et al., 2010), which were also commented among parents of boys (Perkins et al., 2013).
Physicians. (see Table 3)

Among physicians reasons mentioned in support of the HPV school-entry requirement included the effectiveness of this strategy to increase immunization and its public health impact (Kahn et al., 2007; Tissot et al., 2007; Vercruysse et al., 2016). Similar to parents, agreement to an HPV school-entry requirement increased when opt-out provisions were provided (Califano et al., 2016). In this study 74% of physicians supported an HPV vaccine school-entry requirement with or without opt-out options; but when opt-out options were not specified only 47% agreed. Moreover, being in practice longer than 20 years, providing a good quality HPV vaccine recommendation (which was a self-reported measure the authors based on the following characteristics: as being gender and age appropriate, consistent, urgent and with a strong endorsement), and considering the HPV vaccine as important as Tdap and meningococcal vaccines were physicians’ characteristics associated with support when no opt-out options were included (Califano et al., 2016).

The most common reason mentioned against the HPV vaccine school-entry requirement among physicians was the lack of HPV transmission through casual contact (Kahn et al., 2009; Tissot et al., 2007; Vercruysse et al., 2016). Physicians also expressed concerns about the long-term efficacy and safety (Kahn et al., 2009; Tissot et al., 2007) and newness of the HPV vaccine (Vercruysse et al., 2016). Other reasons such as limitations to parental autonomy (Kahn et al., 2009), costs, and challenges of the implementation (Vercruysse et al., 2016), worries that some patients not covered by Medicaid or VFC may not be able to get vaccine, society’s poor understanding of HPV and the vaccine, and the limited clinicians’ experience with the HPV vaccine (Kahn et al., 2009) were also discussed.
Policymakers.

Colgrove, Abiola, and Mello (2010) found policymakers have indicated factors such as newness of the vaccine, the sexually transmitted nature of the HPV, cost of the vaccine, governmental coercion, and the policy process as reasons against the adoption of school mandates. Policy entrepreneurship was reported as in important factor in support of this type of vaccine mandates (Colgrove et al., 2010).

The case of Puerto Rico

Background.

For July 2016, the US Census Bureau estimated a population of 3,411,307 in the Commonwealth of Puerto Rico. Moreover, 20.4% of the estimated population was under 18 years of age, and 52.4% of the population was estimated to be female (United States Census Bureau, n.d.). PR is among the states/territories with the highest rates of estimated HPV-associated cancer (including anal, cervical, oropharyngeal, and rectal cancers), with a rate of 13.10 cases per 100,000 people who develop cancer (Centers for Disease and Control Prevention, 2016a). Furthermore, PR has the highest rate of HPV-associated cervical cancer in the nation with rates of 11.70 cases per 100,000 women; followed by West Virginia with a rate of 9.9 per 100,000 women (Viens et al., 2016). Overall initiation and completion rates in Puerto Rico were estimated to be 75.8% and 52.8% respectively. Among females, the initiation rate was 80.8% and among males was 71.1%. Completion rates were 61.9% and 44.1%, for females and males respectively (Walker et al., 2017).

Current immunization policy.

PR’s current immunization law is Act 25 of 1983, which repealed Act 235 from 1974. Act 25 of 1983 was enacted to cover mandatory immunization for private and public schools at all levels, day care centers and social treatment centers ("Ley de Inmunizacion," 1983). As part
of the instructions of the law, students need to provide the completed DOH’s certificate of immunization at the beginning of the academic year, to be accepted at school. It is the duty of the school’s director and staff to ask for this certificate and notify the parents/caregivers if any of the required vaccinations is missing and where to get them (“Ley de Inmunizacion,” 1983). The opt-out option mechanisms provided by this law include either a sworn declaration indicating religious reasons or a certification indicating medical reasons. School administrators must also prepare a report to the DOH indicating the number of students accepted, those accepted provisionally, and those who submitted any type of exception (“Ley de Inmunizacion,” 1983). The immunization record should be revised every 60 days until all immunizations have been completed. Those who do not comply after the determined timeframe will be excluded from school (“Ley de Inmunizacion,” 1983).

By the law guidelines, the Secretary of Health must announce the required vaccinations every year three months before the beginning of classes (“Ley de Inmunizacion,” 1983). The only vaccines listed in the law are the ones against polio, diphtheria, tetanus, measles, and mumps (“Ley de Inmunizacion,” 1983). Additionally, under Act 25 of 1983, PR’s government authorized the Secretary of Health to decide which vaccines will be required for school entrance. Under this regulatory authority, the Secretary of Health officially announced in the summer of 2018 that the HPV vaccine was going to be required for children 11-to-12 years old starting in the fall of 2018.

**Summary**

Persistent infections with Human Papillomavirus (HPV), the most common STI in the US, can lead to genital warts and cancers such as cervical, vaginal, penile, anal, and oropharyngeal. The HPV vaccine provides the opportunity to prevent cancer; yet, vaccination rates in the US remain low. Vaccine mandates such as school-entry requirements are
recommended evidence-based population strategies use to increase vaccination. In the case of the HPV vaccine, only Virginia, Rhode Island, Washington DC, and more recently Puerto Rico, have adopted an HPV vaccine for school entrance. PR adopted the HPV vaccine school-entry requirement in the summer of 2018 providing a timely scenario to explore the limited use of this type of policy. Thus, the purpose of this study is to understand the macro-level factors that influenced the adoption of the HPV vaccine school-entry requirement in PR.
Chapter 3: Theoretical Framework

Introduction

Theories are useful in research to explain and predict phenomena, such as human behaviors. According to Glanz, Rimer, and Viswanath (2008), a theory is “a set of interrelated concepts, definitions, and propositions that present a systematic view of events or situations by specifying relations among variables, in order to explain and predict the events or situations” (p.26). Theories can help investigators frame their research questions, the study design, the process for data analysis, and the writing/reporting of their findings. Also, theories are useful in the development and evaluation of public health interventions (Glanz et al., 2008). The purpose of this study is to understand the macro level factors that influenced the adoption of the HPV vaccine school-entry requirement in PR. Multiple Streams Approach/Framework (MSA) considers macro-level factors, as well as the process by which a policy is adopted. In the literature, Multiple Streams has been labeled as a theory, a framework and as an approach. The following sections describe the theoretical framework used for this study.

Theoretical Framework: Multiple Streams Theory

Overview of the Theoretical Framework.

In 1984 John W. Kingdon published his seminal work *Agendas, Alternatives, and Public Policies* in which he led the underpinnings for MSA (Kingdon, 1995; Zahariadis, 2007, 2014). His primary goal was to understand “why some subjects become prominent on the policy agenda, and others do not, and why some alternatives for choice are seriously considered while other are neglected” (Kingdon, 1995, p. 3). Kingdon was curious about the agenda-setting
process in the US, rather than about the implementation of policies. Therefore, MSA explains how the coupling of the three streams – problems, politics, and policy – by the policy entrepreneurs during policy windows increases the chance of policy adoption (Kingdon, 1995; Zahariadis, 2007, 2014).

MSA considers choice as a collective output of the system in which policymaking occurs under ambiguity (Zahariadis, 2014). More recently, Zahariadis has defined MSA as “a lens or framework […] that explains how policies are made by the government under conditions of ambiguity” (Zahariadis, 2014, p. 25). Additionally, he argues that manipulation is an important aspect of the dynamics of the policy process since it is a way to deal with ambiguity (Zahariadis, 2003, 2014). Ambiguity is manipulated by the policy entrepreneurs to serve different aims in the policy process (Zahariadis, 2014).

Zahariadis (2014) describes the following assumptions in which MSA is based. First; “Individual attention or processing is serial, systematic attention or processing is parallel” (p. 28). MSA operates under the assumption that, in political systems, many issues can be seen at the same time – parallel processing – and that MSA includes the broader social aspects and the individual level, thus; goes from the macro to the micro level. Second; “Policymakers operate under significant time constraints” (p. 29), which refers to the lack of time policymakers have to attend the different problems and potential solutions. Third, “The streams flowing through the system are independent” (p. 29), which describes how the three streams – problems, policy, and politics – run separate and in parallel one to another. These assumptions of MSA are useful in the understanding of how the system works, and for setting the context for the policy decision making process.
Key Structural Elements of MSA.

The problem stream, policy stream, politics stream, policy window, and the policy entrepreneurs are the five key structural elements part of the MSA (Zahariadis, 2007, 2014). For a diagram that shows the relationship of these key elements see Zahariadis, 2007.

The problem stream is composed of the concerns and conditions that people, such as policymakers and citizens, believe need to be resolved. For example, increasing HPV vaccine uptake and completion or reducing cervical cancer disparities. Policymakers become aware of these concerns through the following factors: indicators or the data that describe the problem (e.g., HPV vaccine uptake data from the National Immunization Survey-Teen), the focusing events – which are events that call attention to the problems these are usually pointed out by the media or the policy entrepreneurs (e.g., Merck “One Less” campaign), feedback from previous experiences that worked or did not work, and the load or the amount of problems the policymaker needs to attend to (Zahariadis, 2007, 2014).

The policy stream includes the “primeval soup” of ideas or all the options for solutions coming from the experts. It is important to note that not all ideas will receive consideration by the policymakers (Kingdon, 1995; Zahariadis, 2014). Thus, MSA posits that there are criteria that guide and are part of the policymakers’ selection process (Zahariadis, 2007, 2014). These criteria include; technical feasibility, value acceptability, and level of integration. If a solution seems challenging to implement, does not align with the values of the policymaker, or seems too costly, it has a lesser chance of approval (Zahariadis, 2007, 2014).

The politics stream refers to the broader political context and is composed of three features: “the national mood, pressure-group campaigns, and the administrative or legislative turnover” (Zahariadis, 2007, p. 73). The way groups of people think, the changes in members,
positions and political parties in power, and the influence some groups have over policymakers, all impact the chance that an idea is set on the agenda (Zahariadis, 2007, 2014). Moreover, when the national mood and changes in the government combine, these have powerful effects on the agenda (Zahariadis, 2014).

The *policy windows* are particular moments in time when the three streams align, intersect or couple. These moments tend to be short in duration, and MSA assumes that the policy windows open one at a time (Zahariadis, 2007, 2014). As Kingdon (1995) defines it, a policy window “is an opportunity for advocates of proposals to push their pet solutions, or to push attention to their special problems” (p. 165). These windows are critical because they provide context to the policy-making process. For example, this alignment (policy window) occurred in 2009 when the state of Virginia was able to pass the first HPV vaccine school-entry requirement in the US (Pitts & Tufts, 2013).

Finally, the *policy entrepreneurs* are the people or institutions who work on the coupling or joining the three streams together when the policy window opens (Kingdon, 1995). This group includes individuals and organizations, such as think tanks. They are, as Zahariadis (2007, 2014) describes, the manipulators of the policymakers, and those with the strategies, time, and resources to invest in their problem of interest.

MSA includes three processes in order for these elements to combine and produce a choice. These processes are 1) attention, 2) search, and 3) selection (Zahariadis, 2014). **Attention**, the first of these processes, tends to be limited or scarce among policymakers. MSA posits that this is resolved by “institutional structure, the type of policy window that opens, and the symbols used to attract attention” (p. 36). The **search** process of solutions in governments is constant and influenced by the policy communities. Both public and private sectors can generate
ideas, and depending on the integration of these communities, different approaches will be conceived (Zahariadis, 2014). Lastly, the selection process is directed by the policy entrepreneurs using their skills and manipulation tactics. These strategies include framing or how the options are presented; affect priming or using emotions to drive social processes; salami tactics (slicing solutions into distinct phases presented to the policymakers who perceive them in this way as less risky); and the use of symbols which provide messages and evoke emotions (Zahariadis, 2014).

**Critiques.**

Several critiques have been raised regarding MSA. One critique questions if the conclusions of MSA are either empirical or assumption driven. To this, Zahariadis (2014) explains, that although MSA is based on the garbage can model in which decisions are the result of unplanned energy fluctuations, and in MSA the policy entrepreneurs couple the streams on purpose. These fluctuations are based on, what MSA assumes is the ambiguity of the decision-making process by the policymakers. Zahariadis (2016) notes this “does not reject but rather supplements rational choice” (p. 4)

Furthermore, a meta-review concluded that, even though MSA has been very prolific, has been used in many studies to analyze public policy, and has also been used in a variety of political contexts; most studies only use the five main or core elements but lack consistency in using all the subcomponents of the theory (Jones et al., 2016). This presents a problem since all the components were proposed to work together when the theory was developed (Jones et al., 2016; Kingdon, 1995). Others point to MSA’s easy usability or low ‘barrier to entry’, due to its flexibility and apparent lack of need for a thorough codebook or hypotheses testing; and call for further empirical theoretical development (Cairney & Jones, 2016).
Other research applications of MSA.

MSA has been used as an approach to evaluate different areas of health policy. This approach has been commonly used in tobacco policy research. For instance, a systematic review of qualitative studies looked at the application of frameworks used in tobacco policy studies and found that most of the studies used MSA (Arabloo, Tourani, & Ravaghi, 2018). One study included in the systematic review, used MSA to assess the enactment of a smoke-free law in Kentucky despite strong opposition from the hospitality industry. Findings noted the importance of collaborations between health care providers and a legal group with knowledge in tobacco control (Greathouse, Hahn, Okoli, Warnick, & Riker, 2005). MSA also guided another study that used interviews and archival documents to evaluate a non-smoker protection act brought to the agenda by the Governor of Tennessee (Mamudu et al., 2014). The authors noted the convergence of the streams occurred, but the contextual factors did not support the policy change; thus, resulting in the use of a weaker bill (Mamudu et al., 2014).

Blackman (2005) utilized MSA to describe the literature regarding tobacco control policy process in the state of California and highlights a couple of limitations of the theory. These limitations relate to the power differential between the stakeholders (i.e., the tobacco industry and public health advocates), and the lack of focus on implementation (Blackman, 2005). In a case study included in the systemic review, MSA was used to understand the factors of tobacco control in Turkey and included data from interviews, documents, and surveys (Hoe, Rodriguez, Uzumcuoglu, & Hyder, 2016). Based on the findings, these researchers added the global stream to include the influence that had global prioritization of the issue of tobacco control (Hoe et al., 2016). Lastly, in a recent case study, MSA was also used to appraise the adoption of Bill C-32 banning flavored tobacco products in Canada (Lencucha, Ruckert, Labonte, & Drope, 2018).
Other studies have used MSA to guide the analysis of interview data on health care administration practices in Canada (Smith et al., 2015), to explore, via interviews with policymakers and researchers, the agenda-setting process of HIV/AIDS control in Iran (Khodayari-Zarnaq, Ravaghi, Mohammad Mosaddeghrad, Sedaghat, & Mohraz, 2016), and to look at non-communicable diseases policy development in Barbados and identify policy entrepreneurs (Unwin, Samuels, Hassell, Brownson, & Guell, 2016). Also, a recent study by Kumar, Gleeson, and Barraclough (2018), used MSA to analyze interviews with consumer advocates, and food industry and government employees on the development of nutrition labeling standards in Australia.

**Current related research.**

Research using MSA includes a literature review of the issues of redefining HPV-related anal neoplasia as a problem of all sexually active individuals and not only an issue of people living with HIV (Walhart, 2013). In this review, policy solutions to increase anal cancer screening are examined via a theoretical application of MSA (Walhart, 2013). The author uses the elements of problem, policy and political streams, policy window, and policy options in her application of MSA. There are also two publications using qualitative methods, one explored the factors that influenced states’ action regarding the HPV vaccine mandates (Colgrove et al., 2010), and another one explored the HPV vaccine policy formation process in the US (Abiola et al., 2013). These studies used the same dataset consisting of 73 key informant interviews collected from six states (i.e., California, Indiana, New Hampshire, New York, Texas, and Virginia). These interviews were conducted following an interview guide based on the elements of MSA. Abiola et al. (2013), provides a comprehensive description and discussion of MSA in its application to understanding the political dimensions of HPV vaccine policy formation in
those six states. The authors found the importance of effective policy entrepreneurs in the influencing of the policy process. For Colgrove et al. (2010) it is important to note that there is no mention of MSA in their publication, but the study is included here because the data used were collected using MSA as the guiding framework.

Lastly, a recent study by Shapiro, Guichon, Prue, Perez, and Rosberger (2017) utilized MSA to explore the reasons why some Canadian jurisdictions decided to fund the HPV vaccine school-based program for boys by reviewing the literature. The authors conclude that MSA was useful to identify factors that influenced the decision under each of the streams, particularly how cost-effectiveness and stakeholder advocacy guided the policy-making process (Shapiro et al., 2017).

Summary

This chapter presented the theoretical framework used for this study selected based on the purpose of this study, which is to understand the macro-level factors that influenced the adoption of the HPV vaccine school-entry requirement in PR. The key elements of Multiple Streams Theory were discussed, as well as critiques, other research applications of MSA, and current research related to the topic at hand.
Chapter 4: Methods

Introduction

The methodology used to conduct this study is presented in this chapter. The purpose and research questions guiding this study are provided to guide the reader. Also, an overall description of the setting is presented to contextualize the study. An overview of the study design is followed by the details of the methodology used for each Phase. The chapter ends with a description of the strategies used to maximize data trustworthiness.

Purpose and Research Questions.

Guided by the Multiple Streams Theory, the purpose of this study is to understand the macro level factors that influenced the adoption of the HPV vaccine school-entry requirement in PR during the summer of 2018. This was achieved via the following research questions:

1. How did the problems, politics, and policy streams intersect to inform the HPV vaccine school-entry requirement in Puerto Rico?
2. Who were the policy entrepreneurs involved in the adoption process and what were their roles?
3. What were the arguments in favor of and against the HPV vaccine school-entry requirement?

Research Setting: Puerto Rico

Puerto Rico is an island on the Caribbean with an estimated population of around 3,411,307 million residents (United States Census Bureau, n.d.). In 2015, the Puerto Rican median house income was $18,626 with 58% of children living in poverty (Krogstad, Starr, & Sandstrom, 2017), and the unemployment rate was estimated to be at 13% (Government
In a 2014 Pew Research Center survey describing religion in Latin America found that 56% of Puerto Ricans identified as Catholic, 33% as Protestant, 8% as unaffiliated, and 2% as other. Spanish is the main language spoken on the island.

A Spanish colony since 1493, PR became a US territory in 1898, after Spain lost the Spanish-American war and conceded the island. In 1900, the Foraker Act established a civil government, after two years of military rule (Trías Monge, 1997). The Jones Act awarded Puerto Ricans US citizenship in 1917 (Trías Monge, 1997). The Commonwealth of PR was established in 1952 when the US government approved the island’s constitution, and a three-branch government (i.e., executive, legislative and judiciary) was created (Government Development Bank for Puerto Rico, n.d.).

Every four years, local elections take place, and Puerto Ricans elect their Governor and the members of the Legislative Assembly (Senate and House of Representatives). Puerto Ricans living on the island have representation in the US Congress via a Resident Commissioner, but cannot vote for members on the Congress or the President (Government Development Bank for Puerto Rico, n.d.). The current Governor, elected in 2017, is from the PNP party (Partido Nuevo Progresista). This political party advocates for statehood status for the island.

As a territory of the US, PR has a Medicaid Program that receives funds from the federal government since January 1st, 1966 under the Social Security Act (Departamento de Salud, n.d.-b). This program is managed directly by the PR’s DOH and provides healthcare services access to the medically indigent population. The Administration of Health Insurances of Puerto Rico or ASES (Administración de Seguros de Salud de Puerto Rico – in Spanish) plays the role of administrating the PR’s government health plan or “Plan de Salud Vital del Gobierno” which is
responsible for providing coverage for physical and mental health services through networks of preferred providers (Administracion de Servicios de Salud [ASES], n.d.).

In terms of preventative health services, a division in the DOH administer the immunization funds available from the VFC to vaccinate low-income population from 0 thru 18 years old (Departamento de Salud, n.d.-a). Also, the ‘Centros de Salud Primaria 330’ provide immunization services to uninsured or underinsured groups. Funds for these primary care clinics come from the Bureau of Primary Health Care part of HRSA (VOCES, 2015). In the private sector, there are health insurance carriers available on the market. For immunization coverage, there are available vaccination centers in private hospitals that accept private health insurances with the corresponding copayments. Also, but less common, there are some providers, such as pediatricians, who provide these services (VOCES, 2015).

Aftermath of hurricane Maria.

This section is described here to provide contextual information about the period during which this study took place. On September 20th, 2017 Maria hit PR as a category four hurricane with winds of 155 mph spreading all over the island and rain producing catastrophic flooding (National Weather Service, 2017). Due to this atmospheric event, the island lost power/electricity causing significant damages to the healthcare system, including the private and the public sectors.

Overview of study design

This study employed an exploratory sequential mixed-methods research design (Clark & Creswell, 2011). The study consisted of two phases (Figure 1). First, a qualitative phase consisting of in-depth interviews, followed by a content analysis of newspaper articles. This second phase of the study was conceptualized to address the need for information on the arguments against the HPV vaccine school-entry requirement.
Phase 1: In-depth Interviews

Recruitment.

Participants were recruited using a non-random sampling strategy or purposive recruitment which is appropriate for qualitative studies (Hennink, Hutter, & Bailey, 2011). Purposive sampling techniques were used to recruit stakeholders identified from online sources with publicly available contact information (e.g., PR’s Department of Health website), by

Phase 2: Content Analysis

Phase 1 consisted of in-depth interviews. Participants included stakeholders in the PR’s HPV vaccine school-entry approval process. Purposive sampling was used to recruit stakeholders identified from online sources, by consulting local experts, and utilizing snowball sampling. Interviews were audio-recorded and transcribed. Data were analyzed using applied thematic analysis (Guest, MacQueen, & Namey, 2012a). Phase 2 consisted of a content analysis guided by Bernard and Ryan (2010) steps and Neuendorf (2016) recommendations, that looked at articles published about the HPV vaccine school-entry requirement in two PR’s newspapers from January 1st, 2015 to July 31st, 2018. Data were described quantitatively and qualitatively. More details describing each of these phases are provided below. All study materials and procedures were approved by the University of South Florida Institutional Review Board (Appendix A).

Phase 1: In-depth Interviews

Recruitment.

Participants were recruited using a non-random sampling strategy or purposive recruitment which is appropriate for qualitative studies (Hennink, Hutter, & Bailey, 2011). Purposive sampling techniques were used to recruit stakeholders identified from online sources with publicly available contact information (e.g., PR’s Department of Health website), by
consulting local experts, and utilizing the snowballing technique (Hennink et al., 2011). If participants were identified through an online source, they were contacted via email using the information available online. Email recruitment scripts provided information about the study. Key informants shared study information with potential participants and provided them with the researcher’s information (i.e., phone and email) if they were interested in further details about the study.

**Inclusion Criteria.**

Inclusion criteria included being 21 years old and older and involved in the PR’s HPV vaccine school-entry adoption process (in favor or against), such as staff from the department of health, physicians and organizations that played a role in the policy process. Participants categories included members from non-profit organizations, leaders from professional medical organizations, government employees, professors, researchers, and physicians, among others (See Phase 1: Interviews, Sample Description in the Results section). Exclusion criterion included being younger than 21 years old.

**Data collection.**

All interested participants meeting the inclusion criteria were scheduled for an in-depth interview. In-depth interviews were conducted either by phone or in-person depending on the participant’s preference and were audio-recorded.

**Sample size.**

In qualitative research, there is no mathematical formula to determine the sample size. Guest, Bunce, and Johnson (2006) call to “operationalize the concept as the point in data collection and analysis when new information produces little or no change to the codebook” (p. 65). In other words, when the “information you collect begins to repeat itself” (Hennick et al.
For in-depth interviews, Guest et al. (2006) have suggested that data saturation can be achieved with 12 interviews. Thus, interviews were conducted until saturation was reached, measured by following guidelines provided by Guest et al., 2006 and the when during the snowballing process participants recommended stakeholders who had already been interviewed or were scheduled for an interview. A total of 21 interviews were conducted. Twenty participants described themselves as in favor of, and one was against the HPV vaccine school-entry requirement. From the 21 interviews, eight were conducted in person, and 13 were conducted over the phone. Interviews lasted an average of 45 minutes (ranging in minutes from 20:30 to 72:30) and were completed between May and August 2018.

**Instrumentation.**

The interview guide consisted of open-ended questions adapted from an instrument used by Abiola et al. (2013). This guide was composed of open-ended questions to evoke conversations with the participants (Hennink et al., 2011). The format followed Hennick et al., 2011 recommendations. Thus, a funnel design with an introduction, opening, introductory, transition, key, and closing questions was considered in the adaption of the interview guide. The main topic areas of the interview guide included background information about the participant, previous work (e.g., strategies or policies) related to the HPV vaccine, motivation, barriers and facilitators for the adoption, and arguments in favor of and against the adoption of the HPV vaccine school-entry requirement.

This interview guide was translated into Spanish by the researcher and shared with two local experts for feedback. Additionally, the interview guide was pilot tested with two key informants, and suggested changes were made. The suggested changes mainly consisted in the variation of some words to reflect everyday language, and the flow/order of the questions. A
journal was kept to collect notes and thoughts during and after the interview was conducted. Probing was another technique used to gather information during discussions (Hennick et al., 2011).

**Data analysis.**

Data were analyzed using applied thematic analysis (Guest et al., 2012a) and techniques recommended by Hennink et al. (2011). The following analytic steps were followed and are expanded below: the creation of a codebook, training of a second coder, assessment of intercoder agreement, application of data reduction and summarization techniques, and the selection of exemplary quotes. All the data were analyzed in Spanish.

First, the audio-recorded material for all interviews was transcribed. A codebook with *a priori* codes, based on the interview guide was prepared. Additionally, the researcher was cognizant of emerging themes that arose from the data; thus, inductive codes were included in the codebook as suggested by Hennink et al. (2011). The codebook included the name and short name of the code, a description of the code, and an example of a quote from the data as recommended by Hennink et al. (2011). The notes taken during the interviews (noted in the journal) helped during the codebook development process by providing the ID number of the participant who provided a good quote or was eloquent in their narration when answering the questions.

A second coder who is proficient (reading and speaking) in Spanish was trained using the codebook. Before all the data were coded, the researcher and the second coder independently coded one interview. Then they met to clarify issues about the codebook, and discuss the coding of the interview to achieve agreement (Morrison-Beedy, Côté-Arsenault, & Feinstein, 2001). After the meeting, the researcher made the agreed changes to the codebook and listed the set of
coding rules that were also agreed with the second coder. The journal also helped to keep track of the agreements and discussions that occurred during the training process.

All interview data were imported to MaxQDA (VERBI Software, 2017). After the training process discussed above, the second coder and the primary investigator independently and consecutively coded three interviews (n = 3). An inter-coder agreement score of Kappa equal to 0.80 or more is a standard recommended to establish the reliability of the coded data (Guest, MacQueen, & Namey, 2012b). Using MaxQDA a Kappa score was calculated using those three interviews. After meeting and clarification of the coding, a final Kappa score of 0.89 was achieved. The remainder of the interview data were coded by the researcher (n = 18). During the process of coding, the researcher created memos that were later used for the creation of the data summaries.

During the data reduction phase, qualitative matrixes were created by code. This step enabled the researcher to use a cross-case comparison technique to identify patterns by comparing a code across all interviews (Hennink et al., 2011). Additionally, categorization of the data was done to create summaries. These summaries or themes were linked back to the theoretical framework, by conceptualizing the data at an abstract level (Hennink et al., 2011). Exemplary quotes were chosen by the researcher to represent the themes. In Chapter 5: Results, the themes are presented following the key elements of MSA.

Protection of Human Subjects.

As part of the steps set in place to ensure the protection of human subjects, this study was submitted to the University of South Florida Institutional Review Board (USF IRB) for review and approval. All recruitment materials (i.e., emails) were prepared following the USF IRB guidelines.
All participants in Phase 1 were asked to sign an informed consent form (Appendix B) approved by the USF IRB and were given adequate time to read and ask questions about the study. A copy of the consent form was provided to each participant, which contained the contact information for the USF IRB and the researcher. Participants who took part in the phone interviews were asked to provide verbal consent. The researcher explained the purpose of the study to all participants. Participants were informed that they could stop participation at their discretion. Interviews were audio recorded after obtaining informed consent from the participants. Participants received a $20 gift card in appreciation for their time. Participants who preferred to complete the interview over the phone received the gift cards via email.

All data collected were stored on a password-protected computer. Data were only shared with members of the research team (doctoral candidate, Committee Members, and second coder). Data analyses were conducted with de-identified data. Lastly, exemplary quotes taken from the participant's interview data were de-identified for the dissemination activities (i.e., posters, dissertation, and oral presentations).

**Phase 2: Content Analysis of PR’s newspaper articles**

During Phase 1 of this study only one person who identified as been against the HPV vaccine school-entry requirement was interviewed. Thus, this second phase of the study was conceptualized to address the need to include more information on the arguments against the HPV vaccine school-entry requirement. Overall, the methodology of this phase was guided by the seven steps of content analysis as summarized and recommended by Bernard and Ryan (2010, p. 289) and listed here:

1. Formulate research question or a hypothesis, based on existing theory or prior research.
2. Select a set of texts to test the question or hypothesis.
3. Create a set of codes (variables, themes) based on the research questions or hypothesis.
4. Pretest the variables on a few of the selected texts. Fix any problems that turn up with regards to the codes and the coding so that the coders become consistent with the coding.
5. Apply the codes to the rest of the texts. Keep checking for coder reliability.
6. Create a case-by-variable matrix from the texts and codes.
7. Analyze the matrix using whatever level of analysis is appropriate.” (Bernard and Ryan, 2010, p. 289)

Additionally, guidelines from Neuendorf (2016) on the design of descriptive quantitative content analysis as well as previously published content analysis guided the development of Phase 2. Guidelines by Neuendorf (2016) used in this study included the addition of a second coder, the recommendation for coder training, and the calculation of Kappa for the assessment of inter-rater reliability. Previously published content analyses related to the HPV vaccine (Dodd, Marlow, Forster, & Waller, 2016; Penţa & Băban, 2014; Quintero Johnson, Sionean, & Scott, 2011) and the HPV vaccine school-entry requirement newspapers’ coverage (Casciotti et al., 2014), were used to guide the selection and development of potential variables to abstract.

Protocol.

A protocol delineating the steps for this phase was developed. This document was shared with members of the committee for their feedback. The information included in the protocol that guided the content analysis is described below.

Newspapers and unit of analysis.

Two of the most circulated Puerto Rican newspapers and their respective websites were reviewed (El Nuevo Día, n.d.; elVocero.com, 2013). These are *El Nuevo Día* and *El Vocero*. Both newspapers are available online. Each article was considered the unit of analysis.

Key terms.

The words ‘VPH’ and ‘virus del papilloma humano’ (Spanish), (‘HPV’ and ‘Human Papillomavirus’), were the key terms used to search the articles on each of the newspapers search engine.
Inclusion and Exclusion criteria.

Articles published from January 1st, 2015 to July 31st, 2018 were included. The year 2015 was chosen as the starting date because on May 2015 the VOCES HPV Panel Report was published by VOCES (PR’s vaccine coalition). This report summarizes HPV and HPV-related cancers epidemiological data, HPV vaccination uptake and completion rates, and population sexual behaviors all in the context of PR. It also included the HPV vaccine school-entry requirement as one of the strategies to help achieve the Healthy People 2020 goal (80% of males and females with the recommended doses of the HPV vaccine). Additionally, the report was mentioned by the stakeholders who participated in the interviews as an important document that guided the process of adoption of the HPV vaccine school-entry requirement. The unrelated advertisement was excluded from the content analysis. The process of selection is described in Figure 2.

Instrumentation.

A set of variables was created based on the previous studies listed, and from the findings of Phase 1. A data collection sheet (i.e., a codebook) was prepared and tested with a sample of 10% of the articles by two coders. This step allowed for latent themes, if any, to be captured, and for revisions to the data collection sheet. The final version of the data collection sheet was transformed into a case-by-variable matrix in Excel. Each article was listed in the first column by their identification number. The other variables were listed in a column each.
Figure 2. Article selection process for content analysis (based on PRISMA guidelines by Moher, Liberati, Tetzlaff, & Altman, 2009)
Data collection.

Scanning steps.

The researcher searched for the keywords on each of the newspapers’ online database search engines. The titles of articles were reviewed to eliminate articles that were not relevant or could be excluded based on the date. Repeated articles were also excluded. The remaining articles were accessed in full and were reviewed using the inclusion and exclusion criteria described above (Figure 2).

Data abstraction.

Data were abstracted from the articles and entered into the case-by-variable matrix. The researcher and a second coder independently coded a random sample of 10% of the articles and an inter-coder agreement was calculated. Kappa of ≥ 0.80 was used as a reference to establish reliability (Bernard & Ryan, 2010). Coding of the rest of the articles was completed by the researcher on the main variables that summarized the articles. As additional assurance of reliability, intra-coder reliability or stability reliability (Neuendorf, 2016) was assessed when the researcher reached the coding of the first 100 articles. A randomly selected sample of 10% of the articles was coded a second time by the researcher and intra-coder Kappa was calculated. SPSS version 24 was used to calculate Kappa scores.

Data analysis.

Data were summarized using descriptive statistics (i.e., frequencies and percentages) in Excel and SPSS version 25. The articles were also analyzed qualitatively to identify the arguments against the HPV vaccine school-entry requirement. This analysis was also conducted following techniques of applied thematic analysis (Guest et al., 2012a), such as coding, categorization, summarization, and the selection of exemplary quotes. These steps were
conducted using Excel and a word document, due to the small simple size of the articles analyzed qualitatively.

**Trustworthiness**

The concept of trustworthiness was introduced in the 1980s in order to address the criteria needed to evaluate the quality of qualitative research (Morse, 2015; Ulin, Robinson, & Tolley, 2005). These criteria or standards include *credibility, transferability, dependability,* and *confirmability* (Guba, 1981; Lincoln & Guba, 1985), and are equivalent to what in quantitative research is called internal validity, external validity, reliability, and objectivity (Guba, 1981; Morse, 2015). Not without criticism, these criteria have been used with little change over time (Morse, 2015). The following descriptions of trustworthiness apply to both phases of the study.

*Credibility* (i.e., validity), refers to “the confidence in the truth of the findings, including an accurate understanding of the context” (Ulin et al., 2005, p. 25). To maximize credibility for the findings of this study, the researcher engaged in prolonged engagement with the data, had debriefing meetings with the co-major advisors, and triangulated the findings from the phases when writing the Results and Discussion Chapters (more details in the Triangulation section), as recommended by Guba (1981). Moreover, interviews were conducted until saturation was reached, measured by following guidelines provided by Guest et al., 2006 and the moment during the snowballing process when participants recommended stakeholders who had already been interviewed or were scheduled for an interview. Additionally, the findings are based on the narrative data, as exemplified by the included quotes, to show credibility (Ulin et al., 2005).

*Transferability* (external validity, generalizability), refers to the ability to be able to apply findings to other contexts, however, in qualitative research “data are conceptually, not statistically, representative of people in a specific context” (Ulin et al., 2005, p. 27). To be able
to achieve this, it was important to select a sample representative of the experiences crucial for answering the research questions noted for the study (Ulin et al., 2005). As recommended by Guba (1981), purposive sampling was utilized for both phases of this study. Additionally, the use of a theoretical framework and an interview guide adapted from a previous study, help with the transferability when comparing and contrasting the findings to other contexts.

**Dependability** (reliability), refers to “whether the results are dependable, whether the research process is consistent and carried out with careful attention to the rules and conventions of qualitative methodology” (Ulin et al., 2005, p. 26). For this study, a journal that includes all the decisions made regarding data collection and analysis during the investigation was kept as a way to address dependability by creating an audit trail (Guba, 1981). Having a second coder for both of the phases to discuss coding also helped with this criterion (Morrison-Beedy et al., 2001). Additionally, for Phase 1 inter-coder agreement, i.e., Kappa statistic, and for Phase 2 inter-coder and intra-coder agreement were calculated and considered. These steps contributed to creating a methodically sound study that can be replicated, even though its findings will be context specific due to the nature of qualitative research (Ulin et al., 2005).

**Confirmability** (objectivity) means that the researcher makes an effort to separate her personal values from those of the participants (Ulin et al., 2005, p. 26). For the current study, the researcher kept a journal in which she wrote her thoughts, assumptions, and biases during the data collection and analysis steps of both phases of the study (see Reflexivity section) (Guba, 1981). Additionally, during the data analysis process memos were written to track any thoughts that might bias the interpretation and/or the findings, and were considered during the data summarization (Guest et al., 2012a). The limitations of the study are also recognized as suggested by Shenton (2004) (see Chapter 6: Discussion).
Reflexivity.

As the researcher of this study, my perspectives may have influenced the data collection and analysis processes (Hennink et al., 2011). Reflexivity requires the researcher to keep track of his/her thoughts, biases and assumptions along the research process to be able to identify situations in which those could influence the data collection and analysis (Ulin et al., 2005). Thus, in my reflection described below, I tried to put forward my background, position, and biases, as a way to acknowledge their potential effect during the overall research process of this study.

I am from Puerto Rico. I was born and raised in San Juan, the capital of Puerto Rico. Both of my parents are physicians. Although in mainland US, I am categorized as “Latina/Hispanic,” in the sociocultural context of PR I am a white woman from a highly educated family. Before entering the world of public health research, I studied law and became an attorney. I worked in PR as an attorney in a non-profit corporation that provided legal aid for underserved populations. This job exposed me to the detrimental effects of social inequality, poverty, addiction, violence, and abuse daily. As a mother, witnessing other mothers lose custody of their children was almost unbearable. I could not prevent myself from empathizing. The difficult situations experienced by my clients under extremely aggravating circumstances produced a profound feeling of sadness and a sense of powerlessness. I was able to momentarily aid my clients, but I knew that once they got out of the door, they would again face the same social circumstances that in the first place got them in trouble. This made me realize that social problems require a change at the collective level, and not at the individual level. Larger societal changes take place through policy change.
During and after my MPH program, I had the opportunity of working with cancer survivors. Interviewing cancer survivors and talking about personal experiences was saddening and draining. Following that, I did research with various USF faculty on oropharyngeal cancer prevention, Hispanic cancer survivors, and barriers to HPV vaccine uptake in Hispanic populations. After identifying and understanding some of the barriers for cancer prevention at the individual and societal levels, my interest continued to be on policy. I was interested in documenting, analyzing, and understanding the process of adoption of the HPV vaccine school-entry requirement. This was taking place in Puerto Rico and was perfect timing for my dissertation research.

As a native Puerto Rican with well-developed interpersonal-professional skills, it was easy to navigate the institutional culture in Puerto Rico. I have a good understanding of unwritten rules, social expectations, and subtleties during social interactions that can only be learned by living many years as a Puerto Rican in the island. This allowed me to gain access to informants and promote openness during interviews, by being assertive.

This project involved studying a population of Puerto Ricans, not as the other, but as a member of it; with the capacity to “zoom out” and observe as an outsider. This has provided me with multiple angles and varied ranges of magnification for analysis. My perspectives have one foot on the emic side and one foot on the etic side. On the emic side, I share some of the experiences, views, and identities of the Puerto Rican participants. On the etic side, I bring the outsider’s perspective of a researcher who has been academically trained in the mainland US. Making sense of what lies behind the events that led to the process of adoption, requires an understanding of the historical and cultural particularities of Puerto Rico. This is where being Puerto Rican is an asset.
**Triangulation**

By using different sources of data and methods, or triangulation, a better understanding of phenomena can be achieved (Carter, Bryant-Lukosius, DiCenso, Blythe, & Neville, 2014; Patton, 1999). In qualitative research, triangulation can also be used to “test validity through the convergence of the information from different sources” (Carter et al., 2014, p. 545). Four types of triangulation have been described: 1) method, 2) investigator, 3) theory, and 4) data source triangulation (Denzin, 1978; Patton, 1999). This study used method and data source triangulation to better understand the process of adoption of the HPV vaccine school-entry requirement. The details of the data triangulation for this study are provided in Chapter 5: Results.

**Summary**

This chapter presented the design of the current study as well as the detailed information about the methodology conducted for both phases. Phase 1 consisted of a qualitative study in PR using in-depth interviews. Participants included stakeholders in the PR HPV vaccine school-entry approval process (in favor/against). Purposive sampling was used to recruit stakeholders identified from online sources, by consulting local experts, and utilizing snowball sampling. Interviews were audio-recorded and transcribed. Data were analyzed using applied thematic analysis. Phase 2 consisted of a content analysis of PR’s newspapers from 2015 to July 2018 to further explore the arguments against the HPV vaccine school-entry requirement. Data were summarized and described quantitatively and qualitatively. The findings from both phases are presented in the next chapter.
Chapter 5: Results

Introduction

The following chapter presents the findings from this study. For each phase, an overall description of the sample is provided, followed by a summary of the results. For Phase 1 of the study, findings are framed following the key elements of the theoretical framework. Phase 2 results are presented following the stages of the content analysis. A final section includes triangulation of the results obtained from each phase.

Phase 1: Interviews

Sample Description.

A total of 21 stakeholders were interviewed. These participants spoke about their current or past experience with the adoption process of the HPV vaccine school-entry requirement. In the sample, there was only one person who expressed views against the HPV vaccine school-entry requirement. For the purpose of an overall description participants were categorized into five groups: 1) “Non-profit” included leaders and members of non-profit organizations or from a public corporation (n = 5), 2) “Professional Organization” included leaders of professional medical organizations (n = 3), 3) members of the “Government” (e.g., DOH employees and policymakers) (n = 5), 4) “Researchers” included members of the academia such as professors and researchers (n = 4), and 5) “Other” category (i.e., physicians, attorney, pharma representative) (n = 3). Note that participants could fit under two of the previous categories based on their different roles. For this sample description, participants were grouped under the category they identified their role was during the interview. For example, two OBGYN physicians
expressed their thoughts from their experiences as researchers, thus, were grouped under the Researchers group.

**Themes.**

Based on the interview data, and presented guided by the MSA elements, the following themes were found to be salient in the process of adoption of the HPV vaccine school-entry requirement in PR. The stakeholders highlighted *indicators* such as the high incidence of HPV and HPV-related cancers in PR (e.g., cervical/oropharyngeal) indicators of *problems* to be resolved. Also, social factors such as the case of Rhaiza López Plumey, a young mother, who died of cervical cancer in 2015, and the VOCES HPV Advisory Panel Report served as *focusing events* during the process. Stakeholders discussed other *policy* initiatives, such as changes to the current immunization law as concurrently being worked on.

Additionally, the *political* turn-over in key government positions influenced the adoption process. During the summer of 2017, a *policy window* opened, and the HPV vaccine school-entry requirement was adopted in the summer of 2018. All the work needed for the HPV vaccine school-entry requirement to be adopted was conducted through collaborations among different sectors composed of the *policy entrepreneurs*. Below is a summary of each of the themes including exemplary quotes to illustrate the findings. Additional exemplary quotes are listed in Table 4.

**Problem Stream.**

Stakeholders talked about problems or factors they perceived served as catalysts to the process of adoption of the HPV vaccine school-entry requirement. These conditions can be organized into two categories, either health-related (indicators) or social conditions (focusing events).
Indicators.

Among the health-related problems, one of the most frequently mentioned condition by the participants was the high HPV-related cancers incidence and prevalence in the island’s population. Particularly, stakeholders mentioned the current high rates of cervical cancer and the increasing rates of oropharyngeal cancer. Another health-related problem that served to initiate the process of adoption was the concern of how common HPV is in PR, as evidenced by studies conducted in the island. For example, stakeholders from a medical professional organization and from the government noted about HPV and cervical cancer;

“Bueno, yo creo que el hecho de que los cánceres cervicales hayan estado aumentando dramáticamente y se presentaron de hecho en la conferencia de prensa que se hizo las estadísticas del aumento en cáncer de cervicales y de que no hemos podido bajar el cáncer de boca y de las áreas asociadas, no porque no estemos bajando la incidencia de fumar sino porque nos está aumentando los asociados a VPH.” —003

“Well, I think that the fact that cervical cancers have been increasing dramatically, and as a matter of fact the statistics of the increase in cervical cancer were shown in the press conference that was done, and that we have not been able to decrease oral cancer and related areas, not because we are not decreasing smoking incidence, but because we have an increase of HPV related [cancers]”—3, Professional Organization

“Con VPH por la consecuencia tan terrible que es el desarrollo de cáncer y por las tasas elevadas de prevalencia de la infección, no del cáncer sino de la infección, sobre todo en las mujeres jóvenes de Puerto Rico, ciertos grupos entienden que esto se debe hacer.”—007

“With HPV, due to the terrible consequences of developing cancer and the high incidence of infection rates, not cancer but the infection, especially in young women in Puerto Rico, some groups understand that this needs to be done.”—007, Government

Participants noted that PR already had a relatively high HPV vaccine uptake (first dose). However, participants mentioned the need to increase HPV vaccine completion rates. This need to increase HPV vaccination completion rates was another health-related problem that needed to be solved. The following quotes from a researcher and a member of a medical professional organization convey these notions;
Focusing events.

Among the social conditions affecting the adoption of the HPV school entry requirement policy, stakeholders mentioned two main factors 1) VOCES HPV Advisory Panel Report (Report), and 2) the case of Rhaiza López Plumey, a young Puerto Rican mother, who died of cervical cancer in 2015.

VOCES HPV Advisory Panel Report (Report): Participants highlighted the importance of the Report made possible by VOCES and publicly available in 2015. VOCES took the initiative to make this report by creating a panel of experts. This report documented the need for increasing HPV vaccination on the island due to the high prevalence of HPV and HPV-related cancers and provided recommendations for action. One of the main recommendations suggested by the Report’s panel was to make the HPV vaccine a requirement for school entrance.
The following quote illustrates how stakeholders described the Report;

“No es algo que se logró de hoy para mañana, o que fue un capricho, sino esto fue un plan de trabajo establecido que yo te puedo compartir el documento, este es un documento de casi 70 y pico de páginas. De hecho, lo puedes encontrar en el Internet, puedes poner "Informe del panel asesor", de hecho, se llama "Informe y recomendaciones del Panel Asesor de VPH al Departamento de Salud.” –002

“It [HPV vaccine school-entry requirement] is not something that was accomplished overnight, or that it was a whim, instead this was an established work plan for which I can share with you the document, this is an almost 70-something page document. In fact, you can find it on the Internet, you can enter “Informe del panel asesor” [Advising Panel’s Report], in fact, it is called “Informe y recomendaciones del Panel Asesor de VPH al Departamento de Salud” [HPV Advising Panel’s report and recommendations for the Department of Health].” –002, Non-profit

Among other recommendations, the Report noted the need for comprehensive HPV-related education not only for the parents but also for providers, religious leaders, and the press.

The following quote from a stakeholder part of the government shows how education was an important area for improvement;

“Una de las cosas que se ha identificado es que, en ese momento, tanto la comunidad, como hasta los mismos profesionales de la salud, no habían recibido suficiente educación sobre la vacuna, indicaciones, sus efectos, el propósito, efectos secundarios, que la gente, particularmente la comunidad, pero también había desconocimiento en las profesionales de la salud.” –015

“One of the things that was identified was that, at that moment, the community, and even the healthcare professionals, had not received adequate education regarding the vaccine, indications, its effects, purpose, side effects, that the people, in particular, the community, but there was also a lack of knowledge in the healthcare professionals.” –015, Government
Here is a quote from a member of the ‘Other’ category that illustrates how the Report promoted the HPV vaccine school-entry requirement as a recommendation from the expert panel;

“There was a unanimous consensus of all participants, that in Puerto Rico the use of the vaccine should be promoted and that, eventually, if we wanted to lower our virus incidence rates, we should also promote that it be one of the requirements for school admission [...]” – 005, Other

The case of Rhaiza López Plumey: Another social condition mentioned was the case of Rhaiza López Plumey. Stakeholders described the case of Rhaiza as the story of a young Puerto Rican mother of three boys who died of cervical cancer in 2015. Rhaiza took part in an interview that narrated her cancer journey/story and made a call to all women to get screened for cervical cancer. This interview was part of a video that was posted and shared on social media. From the participants’ perspectives, Rhaiza’s story, and later her death, impacted the PR population and seemed to have brought awareness to the issue of cervical cancer. The following quotes illustrate Rhaiza’s case as a significant factor in the adoption;

“Una de las cosas que surtió un efecto, que fue como bien emotivo fue un video que preparó Rhaiza Vélez Plumey, una joven madre de 32 años que murió a consecuencia de un cáncer de cérvix, donde ella hacía un llamado a las mujeres a hacerse los exámenes de rutina, de prevención de cáncer de cérvix y un llamado a vacunar a los jóvenes para evitar el cáncer de cérvix.” — 015

“One of the things that had an effect, that was like very moving was a video prepared by Rhaiza Vélez Plumey, a 32-year-old young mother that died as consequence of cervical cancer, in which she made a plea to women to get their routine tests of cervical cancer prevention and a plea to get vaccinated to young people to avoid cervical cancer.” – 015, Government

“A nosotros nos ayudó mucho también, por último, la historia de Rhaiza. La historia de Rhaiza para mí fue un turning point total [...]” — 002

“Rhaíza’s story helped us a lot too. For me, Rhaíza’s story was a complete turning point [...]” –002, Non-profit
Feedback.

Stakeholders described the work that was accomplished before the HPV vaccine school-entry requirement could be adopted in 2018. These efforts to increase HPV vaccination rates date back to the years when the vaccine was first recommended by ACIP. The PR’s DOH listed the HPV vaccine as a recommend vaccination for girls and women, and then for boys and men following the ACIP guidelines and approvals for each group. For example, this quote illustrates DOH’s actions to stay on par with ACIP guidelines changes on age recommendations for girls;

"Aquella vez, para el año 2006, el ACIP decía, "Vamos a vacunar a las niñas a los 11 años, ese es el mejor momento" te dan toda la data científica y se estableció esa política pública. después entendimos, un año más tarde, entendimos que no había que limitarlo solamente a los 11 años, sino que aquella que no se hubiese vacunado a los 11 y ahora tuviera 13 o 15 podía beneficiarse porque calificaba para el programa, así que emitimos (DOH) la recomendación.” –007

"That time, for 2006, the ACIP was saying, “We are going to vaccinate girls at age 11, that is the best moment” they give you all the scientific data and it was established as a public policy. Afterwards we understood, a year later, we understood that it should not be only limited to 11-year-olds, but that for those [talking about girls] that had not been vaccinated at 11 and now had 13 or 15 could benefit because [she/they] still qualified for the program, hence we (DOH) issued the recommendation.” –007, Government

Following the changes in the ACIP guidelines related to the inclusion of boys, the DOH also recommended the HPV vaccine for boys. As illustrated by this quote, a pediatrician noted;

"Sí, la vacuna del VPH una vez salió se integró como parte de las recomendaciones del Departamento de Salud y se dieron charlas [...] luego salió que se aprobó para los niños y cuando se aprobó hubo una campaña para que se vacunara a los varones también.” –001

"Yes, once the HPV vaccine came out it was integrated as part of the Department of Health’s recommendations and talks were given [...] after, it came out that it was approved for boys and when it was approved there was a campaign for the vaccination of boys too.” –001, Other

Having limited access to the HPV vaccine in terms of availability and cost was also commonly mentioned as a barrier to the adoption. The HPV vaccine is expensive, and the stakeholders considered that it needed to be covered by the health insurances. Therefore,
previous work described also included the support of policies that made it mandatory for private insurance companies to cover the HPV vaccine for girls (2010) and then for boys (2012). As indicated by the stakeholders, Vaccines for Children and Salud Vital (insurance provided by the PR’s government) cover the vaccines for the public sector. Thus, access to the public and the private sectors was ensured. As noted by the following participants;

“Antes de eso, también apoyamos lo que fue la primera legislación, que tenía que ver con lograr que todos los planes médicos que hay en Puerto Rico ofrecieran la vacuna de manera gratuita, que la tuvieran en su cubierta para las niñas primero, y después en la política pública se incluyó varones. Nosotros tuvimos la oportunidad de revisar esos proyectos de ley, y apoyar que se dieran.” – 014

“In Puerto Rico la legislatura de los años 2009 y posteriormente en el 2014 se legisló para que todos los seguros-- O sea, además de las-- Del código de seguros que te mencioné y la ley federal, hay unas leyes locales específicas sobre el VPH sobre de que las aseguradoras deben cubrir el costo de la vacuna.” – 007

Also, stakeholders noted the importance of different strategies to increase education and awareness about cervical cancer (2016) and the HPV vaccine. As it is illustrated in the following quote, a member of a non-profit organization provided an example of a bill to increase HPV-related cancer awareness;

“The other proposed bill that was worked on, was to create an HPV-related cancers awareness month, and to create a cervical cancer awareness month which is the highest percentage of related cancers that we are seeing, so a proposed bill was created in PR...
que se creó un proyecto de ley en Puerto Rico que fue aprobado en el 2016 donde se declara enero como el mes del cáncer cervical y todos los cáncer ginecológicos asociados a VPH y eso está por ley y se creó lo que es el mes TEAL que significa, es un acrónimo que dice Take Early Action and Live, así que empezamos esta campaña, llevamos tres años haciéndola donde los hombres y mujeres se ponen un accesorio TEAL y se educa sobre cuáles son los cánceres asociados a VPH.” – 002

Table 5 shows a timeline of the specific policies and strategies that were mentioned by the participants and identified by the researcher.

Stakeholders noted these previous efforts that happened before the HPV vaccine school-entry requirement, seemed to have helped increase HPV vaccine rates in PR. The following quote illustrates this remark by a member of the government;

“En los últimos años, a pesar de que todavía no era efectivo el que fuera mandatorio la vacuna, sí la campaña promoviendo la vacuna, educando a la gente y a todos los profesionales lograron aumentar significativamente el nivel de vacunación contra VPH en PR.” – 015

In fact, stakeholders indicated that the CDC awarded recognition to the PR’s DOH in the summer of 2018 due to high adolescent overall and HPV specific vaccination rates. For example, a member from a non-profit organization noted;

“So you can have an idea, Puerto Rico in 2016 won the territory in all of the nation with the highest rates of HPV vaccination. It has won this award consecutively for two years at the Department of Health level, and we really if you look inside of that national from the Federal Government, well we already have the first dosage at 80%, for the
The DOH Secretary announced during the summer of 2017 that the HPV vaccine school-entry requirement was going to start during the 2018 academic year. The purpose of this announcement was to have an entire year for additional education and promotion of the HPV vaccine, and for parents to begin the HPV vaccine series for their children. This notion is illustrated by the following quote by a member of the government;

“En ese año el Departamento de Salud y otros grupos han hecho campañas de educación, de divulgación, se han hecho actividades educativas para enfermeras, para médicos, para personal escolar, inclusive hasta para periodistas, comunicaciones en periódicos y otros medios, para educar al pueblo sobre este mandato.” –015

“During that year the DOH and other groups have done educational campaigns, promotion, educational activities for nurses, for physicians, for school personnel, even for journalists, and other media, to educate the country about the requirement” –015, Government

*Policy Stream.*

After the 2017 DOH’s announcement during the summer, other policies started to be considered by policymakers. Some stakeholders mentioned the House of Representatives (HR) Bill 537 and HR Resolution 537, HR Bill 1303, and HR Bill 1576 (Table 4).

Stakeholders described the purpose of the HR Bill 537 to investigate the safety and efficacy of the HPV vaccine as a reaction by policymakers after anti-vaccination groups raised concerns. Public hearings were conducted in early 2018, and HR Resolution 537 was published in June 2018. The investigation concluded that the DOH’s determination to include the HPV
vaccine to the school required vaccine schedule aligns with the medical community position, as it is illustrated in the following quote;

“Un proyecto de ley [Proyecto 537] donde supuestamente la cámara de representantes, la Comisión de Salud de la Câmara de Representantes investiga cuán segura es la vacuna de HPV. [...] Pero por lo menos se vio. Se vio y se habló ahí, todo mundo tuvo tiempo de exponer cuán segura era la vacuna, fueron todos los expertos, etcétera.” –009

“A bill [referring to HR 537] where supposedly the chamber of representatives, the HR representatives’ Health committee, researches how safe the HPV vaccine is. [...] But at least it was looked upon. It was looked upon and talked about there; everybody had time to state how safe the vaccine was, all the experts were there [attended] etcetera.” –009, Non-profit

Some stakeholders also talked about HR Bill 1303 as a project that was petitioned by VOCES and supported by the DOH. This bill had the goal of changing the current immunization law (Act 25 of 1983). The bill included making the use of the PR Immunization Registry (PRIR) as mandatory and continue to require health insurance companies to pay for vaccinations.

The following quote by a member of a medical professional organization describes some of the changes proposed to the current immunization law by Bill 1303;

“The change that has been done right now is including in the law, is that here in Puerto Rico we have the Puerto Rico Immunization Registry [PRIR], it is being included there, so that everything, any provider and school that takes in children, have the necessity and obligation to enter all the data into the system [...] The other change was to make the health insurers to raise awareness regarding prevention, for them to cover the vaccines and all the vaccines, that are not only on the scheduled vaccines but the ones that a requirements, to be covered [paid for].” –013, Professional Organization
During the summer of 2018, again as a reaction to the HPV vaccine school-entry requirement announcement by the DOH Secretary, the anti-vaccination groups promoted the presentation of Bill 1576. A few participants mentioned Bill 1576 which proposed an amendment to Law 25 of 1983. The amendment consisted in the addition of the philosophical vaccination exception that would allow parents to not vaccinate their children due to their beliefs. The amendment proposed on Bill 1576 was described by a Researcher as follows;

“La 1576 [Proyecto] todavía no ha entrado a floor no ha sido discutida, pero para mí el elemento más importante que tiene esa ley, es que se abre otra oportunidad para que el padre puede decir que no quiere vacunar a su hijo por conciencia, por conceptos filosóficos.” –019

“The 1576 [Bill] has not yet been brought to floor, it has not been discussed, but for me the most important element that this law has, is that it opens another opportunity for the parent to say that he/she does not want to vaccinate his/her child due to beliefs, due to philosophical beliefs.”—019, Researcher

**Technical feasibility.**

The fact that the current PR immunization law authorizes the DOH Secretary, not the Legislature, to decide the addition of the HPV vaccine to the list required vaccinations for school entrance was also mentioned by the stakeholders as a facilitator. As the following participant described;

“For example, in the 50 states of the United States the ones that decide if a vaccine becomes mandatory or not, are the legislators and senators, not in Puerto Rico. Law 25 in Puerto Rico, which is the Immunization law that if you want, I can share it with you too, established the secretary of health is the one that has the responsibility to look out for public health in terms of preventable diseases. Law 25 gives that authority to the secretary. Obviously, the secretary has to do everything with evidence, not because it is his/her caprice to include the vaccine, you understand. That is historically the way it has
Additionally, stakeholders considered that announcing the requirement during the summer of 2017 eased the adoption process of the HPV vaccine school-entry requirement. The stakeholders described that the DOH Secretary made this announcement a year early in order to provide education and orientation for parents before making it officially mandatory for 2018.

The following quotes illustrate this decision;

“El año pasado para mayo del 2017 ya el secretario de salud anunció que durante el año escolar 2018-2019 la vacuna del VPH comenzaba como un requisito en ese grupo de edad de 11 y 12 años. Eso es un paso muy sabio de parte del departamento de salud que dio a la población un año completo para educarse en el tema, para buscar información con sus proveedores de salud, fuese médico, farmacéutico, enfermeras, centro de vacunación. Y tienes un año completo de esa preparación y esa educación.” –005

“Last year around May 2017, the secretary of health had already announced that for the 2018-2019 school year the HPV vaccine will be a requirement for that group [between] ages 11 and 12. That is a very wise step from the department of health that gave the population a whole year for them to educate themselves, to seek information from their health providers, be it medical, pharmaceutical, nurses, vaccination centers. And you have a whole year of that preparation and that education.” –005, Other

“The secretary signed the announcement that he does every year promoting the public health policy giving a year so that there was an education, dissemination process, this was signed the 17, so that instead of being official in the 17, it would be official during the school year that starts in August 2018.” –015, Government

Another aspect that participants mentioned made the HPV vaccine school-entry requirement feasible, was that it targeted 11 and 12-year-old adolescents. This was an important factor for the stakeholders due to two reasons 1) the economic savings of only having to provide
two doses, and 2) the better immune response to the HPV vaccine at these ages. These two reasons are illustrated in the following quotes;

“The current chosen age requirement for school entry by the Department of Health is 11, 12 years of age. We know that the CDC extends it until 26 years, but it has been proven scientifically that the younger the person is the higher the response or the better the adherence to his/her immunological system that person will have.”—005

“The current chosen age requirement for school entry by the Department of Health is 11, 12 years of age. We know that the CDC extends it until 26 years, but it has been proven scientifically that the younger the person is the higher the response or the better the adherence to his/her immunological system that person will have.”—005, Other

“En este caso lo que va a decir la orden administrativa es el corte, se le llama el corte, de 11 a 12, y cada año se va a ir añadiendo un grupo adicional. Pues nosotros vamos asegurando que esas niñas y esos niños reciban solamente dos dosis, lo que va a representar una economía inmediata en dosis de vacuna, porque si esperas a los 14, entonces le tocan tres.”—002

“In this case what the administrative order is going to say is the cohort, it is called the cohort, from 11 to 12, and an additional group will be added each year. Well, we are going to ensure that those girls and boys receive just the two dosages, which will represent an immediate economization in vaccine doses, because if you wait till 14, then [he/she] will need three.”—002, Non-profit

Value acceptability.

The HPV vaccine school-entry requirement also aligned with the stakeholders’ idea of providing protection and overall public health wellness to the population of the island. From their perspective the creation of this requirement would address HPV-related cancer health disparities in the population. A researcher noted;

“Sigue siendo un problema de salud pública, porque si tú miras históricamente tú miras la data, el cáncer cervical y muchos de los cánceres asociados al virus del VPH tienden a ocurrir en las pacientes que son socioeconómicamente nivel más bajo.”—017

“It is still a public health issue because if you look historically if you look at the data, cervical cancer and many of the HPV-related cancers tend to occur on low socioeconomic level patients.”—017, Researcher
Moreover, stakeholders described the HPV-related cancer prevalence as a public health issue that needed to be solved. For example, as illustrated with the quotes below;

“Así que dentro de los primeros 10 cánceres, vamos a poner tanto en hombres como en mujeres, cánceres asociados a VPH son las primeras razones de muerte. Por ende, esto es un asunto de salud pública que hay que atender.” —002

“So in the first 10 cancers, including in men as in women, HPV-related cancers are the first [number one] causes of death. Hence, this is a public health matter that needs to be addressed.”—002, Non-profit

In addition to the public health implications of this requirement, some stakeholders mentioned it was important for them to make sure the HPV vaccine continues to be covered by the health insurances, and that its cost is reimbursed to medical providers. As conveyed by a member of a professional organization;

“The public health issue is important, that the vaccine becomes a requirement, how will it be covered, we are dealing with this issue in the coverage project, and that type of things, and the intention of the insurers to lower what they pay for the HPV vaccine, because the people getting vaccinated will increase, which what Triple S and MCS did was an atrocity. We are basically trying to resolve the economic issue, but the public health issue is the most important, and then now we are dealing with the other [thing].” –003, Professional Organization

Stakeholders also mentioned the economic savings in the long-term due to the prevention of HPV-related cancers, as another important factor that was considered for the adoption of the HPV vaccine school-entry requirement. For instance, a member of a non-profit organization talked about the data showing the monetary savings;
“Demostramos con un estudio que hizo el Centro Comprensivo de Cáncer, de que si Puerto Rico para el 2020 logra vacunar el 80% de las niñas y el 67% de los niños, vamos a ahorrar casi $88 millones en diagnósticos y tratamientos posteriores en cáncer cervical. Así que se le presentó al Departamento de Salud una data contundente, una data basada en evidencia, una data acumulativa, unas estadísticas.”—002, Non-profit

Level of integration.

Stakeholders agreed that the adoption process of the HPV vaccine school-entry requirement was successful because different sectors, such as the government, academia and non-profit organizations, collaborated to create a consistent message and had a defined purpose. This aspect is illustrated by the following quote;

“Nootros teníamos un objetivo claro y ahora mismo es reducir los cánceres asociados al VPH a través de inmunización aumentando un 80% la taza de inmunización en los adolescentes para la vacuna de VPH, ese es nuestro objetivo y nuestro norte, y todo lo que trabajamos, lo trabajamos en esa dirección. Si tú le preguntas a cualquiera que está partnership te va decir que ese es su objetivo.” —008, Other

Politics Stream.

Pressure-group campaigns.

When the HPV vaccine school-entry requirement was announced by the Secretary of Health on the summer of 2017, the anti-vaccination groups reacted and created resistance. From the stakeholders’ perspective, the composition of these groups varied based on their views, but all shared concerns towards the HPV vaccine and making it mandatory. These views included

“We had a clear objective and right now that is to reduce HPV related cancers through an 80% rate increase of immunization among adolescents for the HPV vaccine, this is our objective, our north, and everything we work on, we work in that direction. If you ask anyone who is partnership they will tell you that this is their objective.”—008, Other
worries related to the safety and side effects of the vaccine, not wanting to do something against their will, religious concerns, and lifestyle choices. The following quotes present these arguments;

“Ellos hablan de la seguridad mayormente, problemas de seguridad, los cuentos de que tuvo de que si en España murieron yo no sé qué cuántas niñas que han quedado, que han tenido problemas neuromusculares, que han quedado paralítico, etcétera, y la evidencia científica no prueba eso, no es lo que nos dice los estudio que se han hecho.”—009

“They mainly spoke about safety problems [of the vaccine], stories that in Spain girls died, others have neuromuscular problems, or are paralyzed, etc., and the scientific evidence does not support this, this is not what the studies say [about the vaccine].”—009, Non-profit

“The hecho de hacerlo obligatorio ha creado que aquel que no quería vacunarse le estás reforzando de que alguna razón, que le están haciendo algo en contra de su voluntad y se aferra más en no oír las explicaciones.”—001

“The fact of making it mandatory resulted in, for those that did not want to get vaccinated, you are reinforcing that for some reason, you are doing something against his/her will and they will not pay attention to the explanation.”–001, Other

“Porque la iglesia aquí en Puerto Rico es bastante poderosa, y en los estados que la vacunación es mandatoria, esos son los grupos que más se han opuesto, porque va un poco de acuerdo a la filosofía de las iglesias, que ellos lo que promueven es la abstinencia, y nosotros lo que estamos promoviendo es una vacunación.—002

“Because here in Puerto Rico the Church is quite powerful, in the states where the vaccination is mandatory these are the groups that have opposed it the most, because they promote abstinence in accordance to the churches’ philosophy, and what we are promoting is a vaccination.” –002, Non-profit

“Hay un sector bastante amplio de la sociedad que considera que sus vidas deben estar guiadas más por lo que dicte la naturaleza y no por lo que dicte la ciencia, como con medicamentos, como con químico, como con producto procesados, como con productos biológicos, como son las vacunas.”—005

“There is a quite large sector of society that considers that their lives should be guided more by what nature dictates and not by what science says, like with medicine, like with chemicals, like with processed products, like with biological products, what vaccines are.” —005, Other
Stakeholders attributed this resistance to the level of misinformation related to the HPV vaccine and vaccinations in general. A stakeholder noted;

“La dificultad mayor obviamente siempre es el movimiento antivacunas que reacciona, y empieza a hacer política pública por ahí por los pasillos y a hacer ruido en la prensa y en la televisión, y a dar información errónea a los padres en cuanto a los supuestos daños.”

—009, Non-profit

“Obviously, the main barrier is always the anti-vaccine movement which reacts and starts doing public policy around there by the hallways and making noise in the press and in television and provide parents with incorrect information regarding the supposed harms.”

—009, Non-profit

Also, the misinformation included concerns from parents and religious groups regarding the (incorrect) relationship of the HPV vaccine with sexual activity in children. For instance, a pediatrician mentioned;

“Que no querían obligarles a poner, ellos decían que eso le daba libertad a los niños para tener relaciones sexuales ya que no van a tener que pensar, por alguna enfermedad venérea.”

—001, Other

“That they did not want to make them [anti-vaccination groups (religious)] get it, they said that it would give kids the freedom to have sexual relationships since they would not have to think of some venereal disease.”

—001, Other

A few participants attributed this misinformation to the incorrect information available in social media. As a researcher noted;

“Porque todo el mundo asume que todo lo que escriben en el Internet es correcto. Entonces es como, ¿cómo tú contrarrestas esto?”

—017, Researcher

“Because everyone assumes that everything that is available on the Internet is correct. Then, how do you challenge that?”

—017, Researcher

Stakeholders also mentioned specific anti-vaccination groups representing some of these views against the HPV vaccine and the requirement. These anti-vaccination groups included a Catholic priest who was very vocal, an online religious group, a feminist organization, an autism organization, and parents who said they did not want the vaccine to be mandated.
Administrative or legislative turnover.

Stakeholders mentioned changes in government positions as a factor that impacted the adoption process. The current Secretary of Health was named by the current Governor of PR, and both started in their positions on 2017. For instance, stakeholders noted about the changes in political parties and in the position of Secretary of Health;

“VOCES hace informe de un panel asesor que llega a la conclusión de que si la vacuna no es mandatoria no se hace, porque han habido proyectos de ley para la vacunación que se estancan cuando van a crear su proyecto de ley, por los detractores, porque viene una vista pública o viene un cambio de política, un cambio de partido, etcétera. Bajo la gobernación de Fortuño se firmaron las leyes de que será cubierta en varones. Viene luego el mandato de García Padilla, ahí se presenta un proyecto de ley si no me equivoco no se hace nada. Luego cambia el partido y ahí se le presenta el resultado del panel, el informe del comité asesor que viene secundario al informe de vacunación o al panel que hizo Obama, que hace algo local y ahí se le presenta al secretario cuando cambia al secretario de salud. [Previous Secretary of Health] nunca quiso firmar, no fue una de sus prioridades y el secretario toma esto como una prioridad y ahí es que lo firma.” –012

Moreover, this assignment of key government positions facilitating the adoption of the HPV vaccine school-entry requirement also included the changes in the person occupying the position of Sub-secretary of Health. A member of a medical professional organization described this factor noting that;

“VOCES creates a report with an expert panel that concluded that if the vaccine is not mandatory it [the vaccine] will not be done, because there have been vaccination bills previously proposed that get stalled when they [introduce] the bill, due to detractors, because there is a public hearing or there is an upcoming political change, a party change, etcetera. The laws that covered boys were signed during Fortuño’s [governor] administration. Then came Garcia Padilla’s [governor] administration, in which a bill is proposed but, if I am not mistaken, nothing was done. Then the political party changes and the panel’s results are presented, the advisory committee’s report is ancillary to Obama’s vaccination report, [the VOCES expert panel] does something local and that is when it is presented to the secretary, when the secretary of health is replaced. [The previous Secretary of Health] never wanted to sign, it was not one of his/her priorities and the [new] secretary makes this a priority and then he signs it [HPV school-entry requirement].” –012, Non-profit
“El hecho de que la Subsecretaría de Salud sea ahora pediatra, ella fue subsecretaria cuando Luis Fortuño era gobernador, y ahora es de nuevo Subsecretaria de Salud, no se logró cuando Luis Fortuño era gobernador, pero ciertamente se ha impulsado grandemente. [...] entonces eso ayudó que la doctora fuera subsecretaria, de convencer al secretario de que era importante que esta vacuna fuera requisito.” –003

“La realidad es que la Secretaria de Salud actual es pediatra, ella fue subsecretaria cuando Luis Fortuño era gobernador, y ahora es de nuevo Subsecretaria de Salud, no se logró cuando Luis Fortuño era gobernador, pero ciertamente se ha impulsado grandemente. [...] entonces eso ayudó que la doctora fuera subsecretaria, de convencer al secretario de que era importante que esta vacuna fuera requisito.” –003, Professional Organization

However, it was also noted that if the current Secretary of Health is changed, the HPV vaccine does not need to be kept in the list of required vaccination for school entrance by a new Secretary of Health. For instance, this was expressed by a member of a professional organization by stating;

“The legislative [process] is the most difficult, obviously, because you have all these religious and naturist groups that are against that lobby strongly, and that made it [the process] slower. It was done, it’s not permanent, it does not have a lot of sustainability, but at least it solved us the problem, for now, and it helps a bit that the DOH adopted it with creating awareness. The problem is that if the secretary of health is changed, the next secretary does not need to do it. We have to make this into a bill, and that is part of what we have to do.” –004, Professional Organization

Policy Windows.

Stakeholders noted that in the summer of 2018 was the moment during which the HPV vaccine was officially announced by the Secretary of Health to be a requirement for school entrance, but a previous announcement was done in 2017. This timeframe is described below by a stakeholder;
Stakeholders also noted the disposition and pro-vaccination views of the current Secretary of Health. These also contributed to the adoption of the HPV vaccine school-entry requirement during this moment in history. The Secretary of Health was receptive to the information and committed to decreasing cervical cancer rates in PR. As a stakeholder noted about the current Secretary of Health;

“I think that we had a historical moment where a lot of campaign was done, the negative resistance was not as strong as it has been in the United States, and we have a secretary of health that is very pro-vaccines.” –009, Non-profit

Policy entrepreneurs.

Stakeholders listed and described different organizations or sectors of the society that contributed to the process of adoption of the HPV vaccine school-entry requirement. In general, stakeholders commented about the composition of these sectors;

“This is an army of nonprofit organizations, of private entities, individual people, of health scientists and of course without the government’s support you cannot do it. Because they are who create and define public policy, one in the private sector, that is to say, nonprofit, or for profit, one can make suggestions, and one can have strategies for making recommendations, but one cannot create public policy, nor define it, that is up
recomendaciones, pero uno no puede crear la política pública, ni definirla, eso le corresponde al Gobernador junto a sus secretarios y directores de agencias.”—005

Another stakeholder mentioned a variety of organizations such as:

“Sí, la Coalición para la Prevención del Cáncer de Puerto Rico que tiene, obviamente entre tantos stakeholders, está el Departamento de Salud, está el Centro Compresivo de Cáncer, está la Coalición de Vacunación de Puerto Rico, etcétera.” –010

“Yes, the Coalition for Cancer Prevention of Puerto Rico that has, obviously among many stakeholders the Department of Health, the Comprehensive Cancer Center, the Vaccination Coalition of Puerto Rico, etcetera.” –010, Government

These groups or organizations mentioned by the stakeholders can be categorized in the following groups: the non-profit organizations, the academia, the medical professional organizations, government staff, and the private sector. Each sector had an important and distinctive role based on each of their expertise and/or area of interest. These sectors as well as their roles are described below.

Non-profit organizations: VOCES, a pro-vaccinations coalition, is a non-profit organization that was fundamental in the HPV vaccine school-entry requirement adoption process. It is important to note the VOCES includes many medical professional organizations, other cancer prevention coalitions, and members of the private sector. As a researcher noted;

“Lo que pasa es que VOCES reúne todos los pediatras, la asociación de pediatras, la obstetra ginecólogo. En realidad, VOCES lo que hizo fue unir a las distintas instituciones, que abogan por el departamento de salud, educación. En un foro hay gente de farmacéuticas, gente de farmacias, farmacéuticas como tal de farmacias. No de farmacéuticas, sino farmacéuticos.”—006

“What happens is that VOCES gathers all the pediatricians, the pediatrician association, the OB-GYN. What actually VOCES did was to unite different institutions, that advocate, the Department of Health, Education. In a forum, there are people from pharmacies, pharmaceuticals such as pharmacies. Not from pharmaceuticals, but pharmacists.” –006, Researcher
VOCES served multiple functions within its role. This coalition created awareness and provided education about the HPV and HPV-related cancers. They organized the experts that created the Report and supported its publication.

“El grupo VOCES fue instrumental en colaboración con ellos, que también diera la última política pública del secretario de Salud de lo de la vacuna mandatoria en las escuelas. Y nosotros como científicos les proveemos a ellos los datos para justificar que hace falta ese tipo de política pública en Puerto Rico, porque los virus asociados a VPH son un problema en nuestra población.” —014

“Collaborating with the VOCES group was instrumental, that the secretary of health gave the public policy making the vaccine mandatory for school. And we as scientists provided them with the data to justify that in Puerto Rico there is a need for that type of public policy because the HPV associated viruses are a problem in our population.” —014, Researcher

Additionally, they were active actors in undertaking advocacy, by promoting the HPV vaccine and the HPV vaccine school-entry requirement. As illustrated by this quote;

“Yo tengo que reconocer que en términos de liderato y de mayor exposición, ha sido VOCES. Uno por las estrategias que ellos han delineado y establecido y dos, por los esfuerzos de Advocacy a nivel de política pública y a nivel de legislación.” —019

“I have to recognize that in terms of leadership and major exposition, it has been VOCES. One because of the strategies they have delineated and established and two, because of their advocacy efforts on the public policy and legislation levels.” —019, Researcher

Other non-profit organizations mentioned by the stakeholders included the ACS, which mainly supported education and vaccination, the Head and Neck coalition, and the PR Cancer coalition.

Academia: Stakeholders listed members of the academia that included researchers from the University of Puerto Rico (UPR), the UPR Medical School, and UPR Public Health School, and the Comprehensive Cancer Center. Their role was to provide scientific information to the overall community including the DOH and Legislature. Their role was important because they provided evidence from studies conducted in PR. These studies provided relevant evidence about
the issues affecting the Puerto Rican population, such as the data on the incidence and prevalence of HPV and related diseases.

“We did the first studies in which we documented, for example, the prevalence of the human papillomavirus in women residing in San Juan’s metropolitan area, cervix and anal infections.” – 014, Researcher

Medical professional organizations: Many medical professional organizations supported HPV vaccine school-entry requirement adoption process by providing education and advocacy using their respective expertise. These medical professional organizations included the PR’s Pediatricians Society, the PR Pediatricians Academy, PR’s ACOG chapter, and PR’s Dentists Society.

“As I say, the different groups coming here today, our immunization program, the academy, but also the pediatricians, pediatricians are like the pillars here to make a clear and compelling recommendation on the importance of immunization. The pediatricians have a very important role, and also we have worked with them throughout the years.” – 008, Other

“In support of this vaccine requirement, and all the vaccines we will always the sector of the science professionals, of health, medicine, health educators, and of course always being guided by the DOH.”—005,

Government: The government category consists of employees of the DOH, such as the DOH vaccination program, that were mentioned as key actors of the adoption process. From the stakeholder’s perspective, the DOH’s vaccination program position was always on par with the
current scientific guidelines. The DOH had included the HPV vaccine as a recommended vaccine for adolescents following the ACIP guidelines since the HPV vaccine was approved.

“Es como te dije los oficiales del departamento de salud actuales de este gobierno han sido sumamente clave para que esto se dé, porque no todos son pro-vacuna” –009

“It is like I said the current Department of Health officers [officials] of this administration had been a key [factor] for this to be [achieved] because not everyone is pro-vaccine.” –009, Non-profit

“Sí, como te digo, ha habido el programa de vacunación del departamento de salud, definitivamente ha estado bien a la vanguardia de esto [...]” –018

“Yes, as I said, the vaccination program of the DOH, they have been at the forefront of this for sure [...]” –018, Non-profit

Stakeholders also noted the key role of the current Sub-Secretary of Health. The Sub-Secretary of Health was described by the stakeholders as a strong supporter of the requirement and the HPV vaccine. The following quote by a member of a medical professional organization describes the role of the Sub-Secretary of Health as helping in the process;

“entonces eso ayudó que la doctora fuera subsecretaria, de convencer al secretario de que era importante que esta vacuna fuera requisito.”—003

“hence it helped the sub-secretary was a physician, of convincing the secretary that it was important for the vaccine to become a requirement.” –003, Professional Organization

It is important to note that the Sub-Secretary of Health was also part of VOCES at some point, as noted by this member of a non-profit organization;

“La subsecretaria de salud, [nombre] es inclusive parte de la junta de directores de VOCES de la coalición de vacunación, ella es pediatra y también es una persona que está muy envuelta y muy al tanto de esta problemática.”—009

“The sub-secretary of health [name] actually she is part of the board of directors of VOCES the vaccine coalition, she is a pediatrician y she is very involved and up-to-date in this problem.” –009, Non-profit
Private sector: The private sector included organizations such as hospitals, pharmacies, physicians from private practice, a private group of gynecologists, and Merck which is the HPV vaccine manufacturer. Overall, this sector collaborated by providing information, funding for research, promotion related to the HPV vaccine, and support indicating their agreement to the HPV vaccine school-entry requirement. For instance, stakeholders stated about the private sector including Merck and physicians in the private practice;

“Obviamente Merck que son los que lo hacen, ellos han dado mucha ayuda financiera para campañas publicitarias, foros y ese tipo de cosas, ellos han ayudado mucho económicamente.”—009

“Muchos pediatras, profesionales de la salud están a favor de este requisito, médicos, ginecólogos. Muchos médicos están a favor de este requisito.”—020

Another active role undertaken by the stakeholders was to take part in public policy advocacy. Members of nonprofit organizations such as VOCES, professional medical associations, and the academia talked about their support for not only the HPV vaccine as a public health prevention mechanism, but also for policy changes that were needed to increase education and access to the HPV vaccine. The following quotes illustrate this advocacy role;

“El departamento [university] en pleno hemos sido unos grandes advocates del uso de la vacuna para prevención, desde el primer día.” –017

“The department [university] in general, since the first day we have been big advocates of use of the vaccine for prevention.” –017, Researcher

“Desde entonces ha habido una lucha y un trabajo que se ha realizado, ya no solo por vacunación en el departamento de salud sino por diferentes sectores de la comunidad médica y de la comunidad en general, las sociedades que agrupan los pediatras, la

“Since then there has been a struggle and work that has been undertaken, no longer just by vaccination [program] in the department of health but by different sectors of the healthcare community and the community in general, the societies that group
Sociedad Americana del Cáncer, Centro Compresivo del Cáncer de la Universidad de Puerto Rico, por mencionarte algunos. – 014

Pediatricians, the American Cancer Society, the University of Puerto Rico’s Comprehensive Cancer Center, just to mention some.” – 014, Researcher

Lastly, stakeholders noted that with the pass of the years the narrative surrounding the HPV vaccine changed. When the HPV vaccine came out the narrative used was related to a vaccine-preventable STI. The current narrative is about the opportunity to prevent cancer, specifically, cervical cancer. A participant noted;

“El tema de VPH es un tema que ha venido a través de muchos años trabajándose con la prensa, yo creo que en este año es que vamos a ver más cobertura en los medios a raíz de eso, porque el tema de VPH y de cáncer cervical y de los canceres asociados al virus se ha venido trabajando por mucho tiempo y ha ido evolucionando. Al principio se veía como una infección de transmisión sexual y tenía unas connotaciones fuertes.” – 008

“The HPV topic has been a topic that has been worked on with the press throughout many years, I think that this year we will see more media coverage because the topic of HPV and cervical cancer and the virus-related cancers has been worked on for a long time and it has been evolving. At the beginning, it was seen as a sexually transmitted infection and had strong connotations.” — 008, Other

Aftermath of hurricane María

Participants were asked if they thought that the passing of hurricane Maria could affect the implementation of the HPV vaccine school-entry requirement that was announced to start on August 2018. All stakeholders agreed that hurricane Maria affected the vaccine availability and the operation of the vaccination clinics and private medical offices. However, most stakeholders did not anticipate any major barriers to HPV vaccine availability. They noted that, for the most part, public clinics were going to be open and were going to have enough vaccinations, and that private providers should be prepared.

“Los proveedores de vacunas, todavía no están al 100% que estaban pero, estamos cerca, estamos como a un 90%. O sea que en cuanto a accesibilidad de vacunas no debe ser el problema”. – 010

“The vaccine providers are not 100% yet, but we are close, we are about 90%. So, in terms of vaccine accessibility, that should not be the problem.” — 010, Government
“María trastocó pero, lo que es el programa de vacunación y el sistema de vacunación, ha vuelto a la normalidad en un gran porciento, no 100% pero un gran porciento.”—015

“A few stakeholders seemed unsure about the current situation of the healthcare/vaccination system but sounded optimistic about the implementation process. For example, a Researcher said;

“yo pensaría que ya a estas alturas esto se ha restablecido. Pero sinceramente cómo esa infraestructura se afectó y cómo está corriendo en estos momentos, tampoco tengo esa información, discúlpame.”—014

“Maria affected but, the vaccination program and the vaccination system, has returned to normal by a large percentage, not 100%, but a large percentage.”—015, Government

Phase 2: Content analysis of newspaper articles

Reliability

An inter-coder Kappa score of 0.80 was achieved with the second coder after independently coding a random sample of 10% of the articles. An intra-coder Kappa score of 0.95 was achieved after the researcher coded a randomly selected sample of 10% of the articles a second time.

Overall sample description.

After removing the repeated news articles, there was a total of 286 news articles that included the key terms (Figure 2). As stated in the methods, these key terms included “HPV” and “HPV vaccine” (in Spanish). Most articles were published in 2016 (Table 6). Figure 3 shows the average number of articles per month because data for 2018 only covers the first seven months of the year.
Figure 3. Average number of articles per month

For this study, primary focus means the main message the article was providing. Each article could have more than one message, but the main one was captured during data abstraction. To make this decision the researcher was guided by the title and the first paragraph of the article. A list of the overall sample of articles, based on their primary focus, can be found in Table 7. The most common primary focus category included educational articles with information about the HPV and the HPV vaccine (23.8%), followed by the advertainment category (16.8%). This category included adds promoting the HPV vaccine (e.g., by VOCES and others by Merck), announcement of health fairs providing the HPV vaccine, and adds about professional and health conferences. The third most common focus was articles providing general information about vaccines (11.2%), such as types available, their benefits and appropriate ages for inoculation. Articles focusing mainly on providing information about cervical cancer and the importance of cervical cancer screening compromised about 11% of the sample. The HPV vaccine school-entry requirement was the primary focus of discussion in a total of 19 articles (6.6%). Other areas of focus included general health information (5.9%),
cancer information or information on other types of HPV-related cancers such as oropharyngeal, penile and anal (4.2%).

The distribution of the categories of primary focus was also evaluated by the year of publication. Most of the articles about HPV and the HPV vaccine, advertisement, cervical cancer and cervical cancer screening, as well as those providing information about cancer in general were published in 2016. Most of the news articles with the HPV vaccine school-entry requirement as their primary focus were published in 2017 (Table 8). Figure 4 shows the average number of articles per month of each of the top eight focus categories by year because data for 2018 only covers the first seven months of the year.

Figure 4. Average number of articles per month by the top eight primary focus categories
Further investigation of the news articles that mentioned the HPV vaccine school-entry requirement in PR.

To further investigate the sample, all the articles that mentioned the HPV vaccine school entry requirement were evaluated. Of the 286 news articles, 34 articles (12.2%) mentioned the HPV vaccine school-entry requirement. Note that ‘mentioned’ is broader than the primary focus category. The highest number of publications that mentioned the HPV vaccine school-entry requirement in PR occurred in 2017, and during the first seven months of 2018. The distribution of those articles by year and newspaper source is presented in Table 9. Furthermore, when explored by the month of publication, most of the news articles that mentioned the HPV vaccine school-entry requirement were published during June (n = 13) and July (n = 8).

From the 34 articles, 20 (58.8%) presented arguments in favor of the HPV vaccine school-entry requirement, five articles (14.7%) presented arguments against, and five articles (14.7%) showed both sides of the arguments. Four (11.8%) of the articles only mentioned the HPV vaccine school-entry requirement (n = 2) or were the DOH’s HPV vaccine school-entry requirement announcement (n = 2). These four articles were grouped in an ‘other’ category. Table 9 shows the distribution of these categories based on the argument presented in the article by year of publication. Three out of the five articles citing arguments against the HPV vaccine school-entry requirement were published in 2017. A similar pattern was observed in the articles about been in favor of the requirement, where most of the articles were published in 2017 (Figure 5). Lastly, an area to note is that no articles with the HPV vaccine school-entry requirement as the primary focus or mentioning it were published during 2016. This finding should be considered within the limitations of the content analysis phase that are discussed in the next chapter.
During Phase 1 of this study, only one person who identified as been against the HPV vaccine school-entry requirement was interviewed. Thus, in this section, a further analysis of the articles that presented arguments against the requirement is presented.

The people who were cited providing arguments against the HPV vaccine school-entry requirement in the articles reviewed included: a concerned mother, a couple of pediatricians, a policymaker member of the legislature, members of a feminist non-profit organization, a university professor, a member of an autism organization, and a representative of a religious group.

The arguments listed in the articles included concerns related to the side effects of the HPV vaccine (40%), the sexual nature of the transmission of the virus (40%), and that it should be the parents’ right to choose to vaccinate their children (40%). Other areas such as the HPV
clears by itself (20%) and that there is no consensus regarding the HPV vaccine (20%), were mentioned less frequently. Below are some quotes that represent these types of arguments.

For instance, a member from an autism organization mentioned the sexual nature of the transmission of the virus as one of the concerns;

“¿Qué necesidad tiene un niño o niña en edad escolar que no se ha iniciado sexualmente de ser protegido contra una enfermedad que se adquiere por contacto sexual? […] “Esta no es una enfermedad que el nene va a estornudar y se le va a pegar a otro”, indicó [nombre], quien dijo que otra preocupación son las muertes que, en algunos países, se le han atribuido a esta vacuna. Entre estos, mencionó a Japón.” –246

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In an article published in 2017, a member of a feminist non-profit organization noted that parents should decide, after reviewing the information, if they want to vaccinate their children.

“Las vacunas contra el VPH son una herramienta de prevención del cáncer cervical. Sin embargo, la vacuna no debe ser obligatoria” "Cada familia, luego de haber sido debidamente informada sobre ventajas y riesgos de la vacuna, debe decidir libremente cuáles de estas estrategias desean asumir para su salud y la de su familia” –243

“The vaccines against HPV are a tool for cervical cancer prevention. However, the vaccine should not be mandated.” “each family, after being rightly informed about the advantages and risks of the vaccine, should freely decide which of the strategies they would like to use to protect their health and their family’s health” –243, endi.com, 2017

In 2018 a policymaker was cited in one news article saying;

“(si se aprueba la medida [Proyecto 1303], no aplicaría (el requisito escolar de la vacuna contra el VPH) para entrar en vigor en agosto”, dijo [name of policymaker]” –203

“(if the Bill is passed [Bill 1303]), it would not be required (the HPV vaccine school-entry requirement) to start on August”, said [name of policymaker]” –203, El Nuevo Dia, 2018
The feminist group was emphatic that sex education and access to screening services should be provided by the Government, a factor that was also a concern for the interviewee against the HPV vaccine school-entry requirement. For example, in the article, the member of the feminist group was cited as discussing that:

“[...] es responsabilidad del Estado garantizar acceso a información completa y objetiva sobre los beneficios, riesgos, y limitaciones de cada una de las alternativas de prevención disponibles.” –243

“[…] it is the Government responsibility to guarantee access to complete and objective information about the benefits, risks, and limitations of every preventive option available.” –243, endl.com, 2017

Some of these reasons or concerns were also mentioned by the participant who self-identified as being against the HPV vaccine school-entry requirement. For instance, this quote describes the concern related to the lack of education regarding the HPV vaccine, despite it been mandated.

“Primero porque no viene acompañado de una adecuada educación realmente, la vacuna está siendo mandatoria, el pediatra lo está también fomentando, pero voy a ponerlo a nivel de escuela, en escuela te obligan hacerlo.”

“First of all, it does not come with adequate education, really, the vaccine is being required, the pediatrician is also encouraging it, it's going to be at the school level, at the school you are required to do.”

This participant also noted during the interview that this lack of education would later have effects on the girl’s future sexual decision making. This is illustrated in the following quote;

“La niña es la que tiene que decidir qué quiere, porque es la vida de ella y va a ser el futuro de su vida sexual, pero como no educan, cómo van a tomar una decisión responsable si no los educo, no pueden, nunca la tomaran, nunca.”

“The girl is the one who should decide what she wants, because it is her life, and it’s going to be the future of her sexual life, but since there is no education, how are they going to make a responsible decision if I don’t educate them, they can’t, they will never make it, never.”
Lastly, an argument that was present in the news articles and was echoed by the participant who identified as being against the HPV vaccine school-entry requirement, was the belief that the HPV vaccine was a sort of business or marketing strategy to make money based on fear. In a news article published in 2018 a university professor noted;

“Esto se ha convertido en algo que no es, y se vende la vacuna bajo el factor del miedo,” señaló.” –246

“This has become something that it’s not, and the vaccine it's being sold under the fear factor”, indicated.” –246, endi.com, 2018

The participant against the HPV vaccine school-entry requirement said during the interview;

“Dinero, millones que cuando dicen dar, desde apoyar campañas políticas, desde favores políticos, pero sobre todo y más que todo, dinero que igual pueden estar distribuyendo a nivel de gobierno y estoy hablando a nivel ya de Estados Unidos, porque acuérdate que por nuestra situación política, lo que pasa allá repercute acá y algún acuerdo que se haya dado que a partir de ahí se hace mandatorio y quizás es la colaboración que existen entre todas las agencias porque es mandato como quien dice presidencial o gubernamental, independientemente de.”

“Money, millions they say will give, from support to political campaigns, from political favors, but above all and beyond all, money that they may be distributed to the government, and I am speaking at the United States level, because remember our political situation, what happens there affects us here, and any agreement making it mandatory, and maybe is a collaboration that exists between all agencies because its mandatory, like they say presidential or governmental, regardless.”

Data triangulation

There are some areas of similarity between the results of these two phases. The top area of primary focus identified in the content analysis during the years before the adoption of the HPV vaccine school-entry requirement (i.e., 2015, 2016, and 2017), included educational and informative articles related to HPV and the HPV vaccine (Table 8). This type of information could be important in terms of better understanding the process of education and awareness that took place in PR and that stakeholders mentioned during the interviews. The second primary focus, advertisement, including HPV vaccine ads from Merck and VOCES, also seems to
support the findings from the interviews in which the stakeholders mentioned how the private sector, which included Merck, provided education and support towards the vaccine and the requirement.

It is interesting to note that the number of articles mentioning HPV as an STI or with other STIs as the primary focus, declined from four in 2015 to zero in the first seven months of 2018 (Table 8). This would seem to align with what the stakeholders said about framing the HPV vaccine and the HPV vaccine school-entry requirement as cancer prevention. Also, the number of articles with cervical cancer as their primary focus increased in 2016 and 2017, which also seem to support this idea.

One important finding of the interviews was the identification of the 2017 announcement of the HPV vaccine school-entry requirement as the starting point or opening of the window of opportunity. Findings from the content analysis show that the greatest number of publications with the HPV vaccine school-entry requirement as the primary focus occurred in 2017 (Table 8), followed by the year when the official announcement of the requirement was published and noted by the stakeholders. This trend is similar when looking at the articles that mentioned the HPV vaccine school-entry requirement (Table 9); most were published in 2017 and 2018.

During the interviews, stakeholders explained how the current immunization law facilitated the process of adoption of the requirement. Per the current immunization law, the DOH must publish every year the list of required vaccinations for school at least three months before classes start. In PR classes start in August, the increase in number of articles that mentioned the HPV vaccine school-entry requirement occurred during the months of June and July, soon after the DOH announcements were published (Table 5).
Another area of overlap between the findings of the two phases relates to the Report and the case of Rhaiza, both mentioned by the stakeholders as important events that occurred in 2015 in the overall process of adoption of the HPV vaccine school-entry requirement. The two news articles published in 2015 in favor of the requirement were about the presentation of the Report during which tribute was paid to Rhaiza, and in which a variety of stakeholders, including Rhaiza’s widower, advocated for making the HPV vaccine required for school entrance. It is also important to note that articles with Rhaiza as the primary focus were scarce (n = 2, Table 8). However, there were articles in the advertisement category that did mention Rhaiza and or used pictures of her to promote the HPV vaccine.

From the stakeholders’ viewpoint, the composition of the anti-vaccination groups varied. Some of the groups mentioned by the stakeholders, as well as the arguments against the HPV vaccine and the requirement, were also found in the articles. In both datasets a feminist non-profit organization, an autism organization, and a representative of a religious group were present. Also, the arguments against the HPV vaccine school-entry requirement that the stakeholders listed were also listed in the articles. The similar arguments included the concerns about the HPV vaccine safety and side effects, the religious concerns related to the sexual nature of the transmission of the virus, and that it should be the parents’ right to choose to vaccinate their children. However, an argument that was only present in the articles was the concern the member from a feminist group and the participant who identified as being against the HPV vaccine school-entry requirement mentioned regarding the lack of human sexuality education in PR.
Summary

This chapter presented the findings for both phases of the study. It included the themes based on the interview data, framed using the theoretical framework. Quotes were provided to show examples of the conversations that took place during the interviews and in support of the results. Additionally, this chapter presented the findings from the content analysis with a focus on the arguments against the HPV vaccine school-entry requirement. The chapter ended with the triangulation of the results from the interviews and the content analysis. The following chapter includes a discussion of the overarching findings of the study interweaving the results of the two phases in the context of the theory and the literature.
Chapter 6: Discussion

Introduction

Despite cancer-preventive properties of HPV vaccination and the effectiveness of prior vaccine mandates, HPV vaccine school-entry requirements have not been widely adopted in the US. There remains a public health need to understand the low adoption rates of the HPV vaccine school-entry requirement. Thus, the purpose of this study was to understand the macro-level factors that influenced the adoption of the HPV vaccine school-entry requirement in PR during the summer of 2018. To accomplish this purpose a macro-level theory, the MSA was used to guide the three research questions of this study. The following section includes a discussion of the findings in the context of the theory and the literature, a recognition of the limitations and strengths of this study, a description of the implications for research, policy, and practice, and areas for future research.

Intersection of Problems, Policy, and Politics

The MSA posits that when policy entrepreneurs purposely intervene with different tactics, the problems, policy, and politics streams will converge to create a window of opportunity that results in a policy output (Kingdon, 1995; Zahariadis, 2007, 2014). Briefly, the problems stream represents the issues that need to be solved. The policy stream includes the soups of ideas that compete for the policymaker’s attention. The politics stream refers to the political factors and pressure groups that influence adoption (Kingdon, 1995; Zahariadis, 2007, 2014). In the case of PR, findings from this study indicate that this window of opportunity opened during the summer of 2017; ultimately, the final output was produced in the summer of
2018 when the DOH, via the Secretary of Health, officially announced the requirement of the HPV vaccine for school entrance. To be able to understand how this intersection occurred, each of the streams will be discussed (Figure 6).

Stakeholders agreed that specific health factors, or indicators, as the MSA labels them, contributed to the process of adoption of the HPV vaccine school-entry requirement. As indicated, PR is among the US states/territories with the highest rate of estimated HPV-associated cancer (including anal, cervical, oropharyngeal, and rectal cancers), with a rate of 13.10 cases per 100,000 people who develop cancer. Moreover, PR has the highest rate of HPV-associated cervical cancer in the nation with rates of 11.70 cases per 100,000 women (Viens et al., 2016). The stakeholders in this study were concerned about the high incidence of HPV and HPV-related cancers, in particular, cervical cancer and the increasing rates of oropharyngeal cancer. These high rates of HPV and related cancers were among the main problems that

Figure 6. Application of MSA to study findings

Stakeholders agreed that specific health factors, or indicators, as the MSA labels them, contributed to the process of adoption of the HPV vaccine school-entry requirement. As indicated, PR is among the US states/territories with the highest rate of estimated HPV-associated cancer (including anal, cervical, oropharyngeal, and rectal cancers), with a rate of 13.10 cases per 100,000 people who develop cancer. Moreover, PR has the highest rate of HPV-associated cervical cancer in the nation with rates of 11.70 cases per 100,000 women (Viens et al., 2016). The stakeholders in this study were concerned about the high incidence of HPV and HPV-related cancers, in particular, cervical cancer and the increasing rates of oropharyngeal cancer. These high rates of HPV and related cancers were among the main problems that
stakeholders thought needed to be resolved by the HPV vaccine school-entry requirement. This finding is similar to the case of Virginia’s HPV vaccine school-entry requirement, where concerns regarding cervical cancer were noted as a health issue by the proposed legislation that passed in 2009 (Abiola et al., 2013). Additionally, stakeholders described the relatively high uptake HPV vaccination rates in PR as a facilitator; however, the low completion rates were an \textit{indicator} that was considered for the adoption process of the requirement.

In addition to the health indicators, there were two \textit{focusing events} that contributed to the initiation of the adoption process of the HPV vaccine school entry requirement in PR: 1) Rhaiza López Plumey died of cervical cancer [January 2015] and 2) the VOCES HPV Advisory Panel Report (Report) was published [May 2015]. The video posted on social media, and later the announcement of Rhaiza’s death, contributed to bringing awareness among the Puerto Rican population about the cervical cancer issue. The Report was meaningful because it included the epidemiological and cost-effectiveness data based on studies conducted in PR. Having available the local epidemiological data about the incidence of HPV and HPV-related cancers, and HPV vaccine uptake rates, as well as data on cost-effectiveness, facilitated the process of adoption. The results from the interviews show that stakeholders were guided by this Report, published after the passing of Rhaiza, and that included objectives recommending education efforts and the HPV vaccine school-entry requirement.

Before the window of opportunity opened, \textit{policy entrepreneurs} worked on other areas and issues that needed to be addressed to clear the way for the adoption of the HPV vaccine school-entry requirement. The results of this study narrate the background of efforts undertaken to address these areas. For instance, policies to make it mandatory for health insurance companies to cover the HPV vaccine were supported by the policy entrepreneurs and created at
the Legislature level. These policies allocated money and resources to pay for the HPV vaccine, making it available for the population in the private sector.

Another facilitator of adoption process was the education campaigns that took place in PR years before the adoption of the requirement and during the year between the DOH announcement in 2017 and the official requirement in 2018. This process of education created awareness of HPV, HPV-associated cancers, and the HPV vaccine. Findings indicate that, from the stakeholders’ perspectives, this education process was essential to reduce the likelihood of resistance from the anti-vaccination groups. The educational efforts also focused on the adoption of the HPV vaccine requirement as a form of cancer prevention, rather than prevention of an STI. This finding is similar to previous research in which the idea of preventing cancer is the primary driver of the decision to adopt such a policy (Abiola et al., 2013; Colgrove et al., 2010).

Additionally, based on the content analysis data, most of the articles mentioning the HPV vaccine school-entry requirement were published during the years of 2017 and 2018. Thus, the process of adoption did get media attention, in particular during the months of June and July, which are close to the dates of the DOH announcements. A previous content analysis of print news from three states (i.e., Texas, Virginia, and DC), also found increased media attention in response to governments’ discussions about HPV vaccine mandates (Casciotti et al., 2014).

In response to the DOH’s announcement of 2017, both the anti- and pro-vaccination groups presented policies to members of the Legislature. These other policy options were in the soup of ideas competing for the policymaker’s attention (Kingdon, 1995; Zahariadis, 2014). The policies that the stakeholders discussed included, HR Bill 537, Bill 1303, and Bill 1579. Policymakers gave attention to HR Bill 537 in 2017, and an investigation on the safety and efficacy of the HPV vaccine was conducted through public hearings in 2018 (Table 4). This
investigation resulted in a positive overview of the HPV vaccine, published in June 2018, after the Secretary of Health had already announced the official HPV vaccine school-entry requirement. Due to the positive results regarding the safety and efficacy of the HPV vaccine published in the Bill 537 resolution, the legislators let the HPV vaccine school-entry requirement continue its course. Despite that, at some point, policymakers were asking the secretary of health to retract it. It is important to note that, during the summer of 2018, HR Bill 1576, petitioned by members of the anti-vaccination groups, was presented but not discussed in plenary; neither was Bill 1303, petitioned by the pro-vaccination group. Thus, the adoption of the HPV vaccine school-entry requirement occurred despite the concurrent proposition of other policies.

An important finding from this study is that stakeholders thought that PR’s current immunization law made it technically feasible to adopt the HPV vaccine school-entry requirement. This regulatory approach may have facilitated the HPV vaccine school-entry requirement adoption because convincing the members of the legislature, whose decisions are highly influenced by the voters, can be difficult. Instead, policy entrepreneurs talked to and shared scientific evidence with the current Secretary of Health. This approach is similar to the case of the state of Rhode Island, where the Department of Health also established the requirement via its rulemaking powers (Barraza et al., 2016; Washburn et al., 2016). On the other hand, both Virginia’s and DC’ mandates were created through the legislature (Barraza et al., 2016).

Another way in which the HPV vaccine school-entry requirement was described as technically feasible by the stakeholders was because it only includes the 11 to 12 years old cohort of children. This was important for the stakeholders because it meant that the government and public health system would only spend money on the cost of two doses, which is the number
of shots required for the targeted cohort. This is in alignment with the current HPV vaccine ACIP recommendations (Centers for Disease and Control Prevention, 2016b).

Related to the technical feasibility aspects of the HPV vaccine school-entry requirement, findings support that there were considerations regarding the value of this policy approach. Mainly, participants noted concerns about the public health and economic implications of the HPV vaccine school-entry requirement. These were essential values captured by the HPV vaccine school-entry requirement, which included the protection and the overall wellness of the island population by preventing the physical, emotional, and economic implications of HPV-related cancers in the long term.

From a political perspective, the stakeholders frequently mentioned the anti-vaccination sector as active members of the society exercising pressure on the policymakers. These pressure groups varied in composition and posed a direct resistance to the adoption of the HPV vaccine school-entry requirement in PR. In an attempt to weaken the reach of the HPV vaccine school-entry requirement, one of the anti-vaccination groups petitioned Bill 1576. The purpose of this bill was to amend PR’s immunization law to include an opt-out option based on personal beliefs. However, during the summer of 2018, the bill was not discussed. In other scenarios, such as in the case of Virginia, the passing of an HPV mandate encountered less resistance. Here, a quick passing of a bi-partisan bill did not provide enough time for an anti-bill campaign to form and be a barrier for the passing (Abiola et al., 2013). Members for the RI’s DOH also noted minimal opposition to the addition of the HPV vaccine to the school entrance requirements in 2014 (Washburn et al., 2016). However, there have been actions taken through the legislature to limit RI’s DOH powers relating to its authority to establish vaccine requirements, particularly to requirements related to diseases not contagious in the school setting (Barraza et al., 2016).
Additionally, the *political turn-over* in key government positions seems to have facilitated the HPV vaccine school-entry requirement adoption process in PR. With a change in political party in the government of PR for 2017, new individuals were named to occupy positions in the governor’s cabinet, including the secretary of health. Results from the interviews indicate the policy entrepreneurs perceived the secretary of health as someone supportive of vaccinations and open to making the reduction of cervical cancer one of his priorities. This *political turn-over* in government positions was also considered a concern. Changes in administrations due to changes in political parties could mean that whoever is named to occupy the position of secretary of health may decide to remove HPV from the list of required vaccinations. This is a limitation of how the HPV vaccine school-entry requirement was created in PR, through an announcement of the secretary of health and not via the legislature.

**Policy Entrepreneurs**

The work needed for the *problems, politics, and policies* to intersect was conducted through collaborations efforts among different sectors composed of the *policy entrepreneurs*. Similar to the findings from Abiola et al. (2013), policy entrepreneurs were instrumental in the adoption process of the HPV vaccine school-entry requirement in PR. As the MSA describes (Kingdon, 1995; Zahariadis, 2014), and noted in the findings from this study, the role *policy entrepreneurs* played, and their participation in the adoption process indicates how they made the three streams intersect/converge. For instance, *policy entrepreneurs* worked in changing narrative related to the HPV vaccine; thus, creating awareness in the population. This change in narrative was a result of the education and campaigns and efforts discussed by the stakeholders. They were all giving the same message to the community, as noted before, that the HPV vaccine school-entry requirement is about cancer prevention.
In the case of the Virginia mandate, Senator Janet Howell and Delegate Hamilton were the policy entrepreneurs who achieved consensus in the legislature and support from stakeholder organizations (Abiola et al., 2013). In contrast, policy entrepreneurs in PR were from a variety of sectors of the population. For example, VOCES, PR’s pro-vaccinations coalition, played an important role unifying all the sectors to advocate for the HPV vaccine school-entry requirement with the scientific evidence needed to convince the secretary of health. Also, other sectors, some of which are part of VOCES, had additional roles based on each of their expertise and area of interest. In the case of DC’s mandate, the ACS provided a statement in support of the legislation (Barraza et al., 2016).

Comparison of PR’s HPV vaccine school-entry requirement to Virginia, Washington DC and Rhode Island’s HPV vaccine school-entry requirements.

Barraza et al. (2016) identified some areas of similarities and differences between the Virginia, Washington DC, and Rhode Island’s HPV vaccine school-entry requirements. These areas include when the requirement was adopted, mode or process of adoption, who the requirement applies to and the timing of the HPV vaccine doses, and the opt-out mechanisms available to the population. In this section, these areas will be compared to the PR’s HPV vaccine school-entry requirement.

Back in 2009, when the state of Virginia adopted its HPV vaccine school-entry requirement, it was done through the legislature (Barraza et al., 2016; Colgrove et al., 2010; Virginia Department of Health, 2014). This approach is similar to the Washington DC requirement, which was enacted in 2009 via the legislature (Barraza et al., 2016; Government of the District of Columbia Department of Health, 2015). In contrast, RI’s 2015 and PR’s 2018
requirements were adopted using the DOH regulatory and administrative powers (Barraza et al., 2016; Washburn et al., 2016).

The present HPV vaccine school-entry requirements vary with respect to who should get the vaccine and the timing of the HPV vaccine doses. Washington DC, RI and PR’s requirements, all currently indicate that girls and boys should get the HPV vaccine for school entrance (Barraza et al., 2016; Government of the District of Columbia Department of Health, 2015; "Ley de Inmunizacion," 1983; State of Rhode Island Department of Health, 2015). In the state of Virginia, the requirement only applies to girls. Virginia requires three doses to be completed before entering the sixth grade (Barraza et al., 2016; Virginia Department of Health, 2014). In Washington DC, three doses are needed upon starting sixth grade at 11 years old. The state of RI took a different approach and requires the first dose of the HPV vaccine before starting seventh grade and finishing the series before starting ninth grade (Barraza et al., 2016). In PR, the DOH requests the HPV vaccine for all 11 and 12 years old.

Lastly, in terms of opt-out options, there is a range of variation. Virginia has the most lenient process of exception. Basically, by just reviewing some educational materials and signing a documented waiver, parents can get the exception approved, without the need to provide any documentation at the school (Barraza et al., 2016; Virginia Department of Health, 2014). In the case of the Washington DC requirement, the three exceptions allowed are the religious, the medical and the philosophical (Government of the District of Columbia Department of Health, 2015). Both RI and PR only allow for medical and religious exceptions (Barraza et al., 2016; Puerto Rico Department of Health, 2013; State of Rhode Island Department of Health, 2015).

**Arguments in favor of and against the HPV vaccine school-entry requirement in PR**

Arguments influencing support for HPV vaccine mandates have been framed under the umbrella of women’s health and children’s welfare (Colgrove, 2006). Vamos et al. (2008)
summarized the arguments literature in favor of a school vaccine mandates describing them as those about the appropriate age for vaccination, those related the cost-effectiveness of requiring the HPV vaccine, those highlighting the need for the prevention and reduction of cervical cancer, and the parent’s participation in the health decisions concerning their children. In PR, the framing strategy used was to describe the HPV vaccine school-entry requirement as a tool for cancer prevention. Notably, based on the need to reduce the high rates of cervical cancer among Puerto Rican women. Additionally, the cost-effectiveness and the alignment with the ages of inoculation, 11 and 12 years old, were important for the policy entrepreneurs, as was the public health impact on the wellness of the population due to the reduction of HPV-related cancers. Studies among physicians have reported similar reasons in support of the HPV school-entry requirement such as its effectiveness in increasing immunization and its public health impact on immunization (Kahn et al., 2007; Tissot et al., 2007; Vercruysse et al., 2016).

Conversely, arguments against the need for HPV vaccine school-entry requirements are based on lack of transmission of the virus through casual contact, intrusion into parental autonomy, public distrust due to pharmaceutical lobbying during the policy development process, and the potential economic burden on the government, and health care system including the health departments and private physicians’ offices (Gostin & DeAngelis, 2007; Javitt et al., 2008; Mello et al., 2012). Some of these reasons were echoed in the findings from this study as described by the stakeholders and in the news articles reviewed.

Arguments against the HPV vaccine school-entry requirement seem to be intrinsically related to the HPV vaccine and the virus. For instance, concerns related to the side effects and safety of the HPV vaccine were mentioned by the stakeholders and present in the articles, as reasons to be against the HPV vaccine school-entry requirement. This reason has also been
discussed among parents in previous research who thought that the vaccine was new and had concerns about its safety and side effects and were more likely to be against the HPV vaccine school-entry requirement (Carlos et al., 2011; Horn et al., 2010; Perkins et al., 2010; Robitz et al., 2011; Smith et al., 2011).

Another argument mentioned by the stakeholders, and that also was presented in the reviewed articles, was the mode of transmission of the virus and its association with sexual activity. Previous studies among parents discussed the way of HPV transmission as a reason to be against the HPV vaccine school-entry requirement, while other studies have reported the lack of casual transmission (Perkins et al., 2013; Vercruysse et al., 2016), or emphasized the sexual transmission of the virus (Pitts & Tufts, 2013) as arguments against the HPV vaccine school-entry requirement. Similarly, Casciotti et al. (2014) found that in the print media that encouragement of sexual activity was an argument against the HPV vaccine school-entry requirement. Moreover, Vercruysse et al. (2016) found that parents discussed that adolescents were not sexually active; thus, there was no need for the requirement. A similar reason was presented in the news articles by one of the anti-vaccination groups.

Finally, parental rights to decide what is best for their children was another argument discussed during the interviews and published in the Puerto Rican news articles. Previous research with parents has also reported the parents’ choice or decision to vaccinate their children (Perkins et al., 2013; Pitts & Tufts, 2013; Smith et al., 2011; St John et al., 2010; Vercruysse et al., 2016) as an argument against the HPV vaccine school-entry requirement. The government imposition of the HPV vaccine to parental autonomy was the most common theme that was reported by Casciotti et al. (2014) in print news media from Texas, Virginia, and DC between 2005 and 2009.
Strengths and Limitations

As with any research study, some strengths and limitations should be noted. There are different types of biases that could have affected this study. For instance, researcher bias could be considered a limitation to this study. Based on my education and life experiences, I am a supporter of HPV vaccination and school-entry requirements. Therefore, I took steps to maintain a neutral position while conducting the interviews, and while analyzing both the qualitative and quantitative data. To address this issue, I was aware of and documented my biases, which are presented in the Reflexivity section of this dissertation. Recall bias from the participants may also be impacting the findings, more so in the narratives related to the work done before the summer of 2018, when data were collected.

Overall, purposive sampling limits the generalizability of the results. Additionally, there are problematic aspects of conducting interviews with stakeholders such as participant recruitment and participation. In terms of recruitment, the strategies that worked best in this study to access participants in favor of the HPV vaccine school-entry requirement were key informant introduction and snowballing. Nonetheless these strategies, the researcher had only one person who identified as been against the HPV vaccine school-entry requirement. Not having a key informant who could introduce the researcher to the community of stakeholders that were against the HPV vaccine school-entry requirement may have hindered the recruitment process.

This posits limitations to the findings of this study, which are mostly informed by the participants who identified as been in favor of the requirement. To address this limitation, the content analysis was conducted and emphasis was given to explore the argument against the HPV vaccine school-entry requirement.
It is important to note that this study lacks an in-depth exploration of the HPV vaccine school-entry requirement adoption process from the perspective of the stakeholders who were opposed to the mandate. Some participants from this study mentioned that the anti-vaccination groups mainly communicate and obtain their information via social media. Future research could look at the anti-vaccination groups utilizing social media as a means for recruitment or engaging with this type of stakeholder.

Regarding participation, the type of participant chosen for this study tends to have limited time to engage in activities not related to their primary duties, such as research studies. This limitation was addressed by using two different strategies to conduct the interviews, in-person or via phone. Providing the participant these options enabled them to choose the most convenient method for them. Thus, facilitating their participation.

Moreover, there could be issues related to saturation. Saturation is an iterative process in which the researcher is the one who notes if saturation has been achieved (Hennink et al., 2011) and has become the ‘gold standard by which purposive sample sizes are determined in health science research” (Guest et al., 2006, p. 60). The researcher noted saturation in the themes. However, saturation may not have been achieved for some sub-codes or sub-themes (e.g., misinformation available in the social media). Not achieving data saturation in these themes hinders their validity (Fusch & Ness, 2015); thus; careful consideration of these themes should be noted.

In terms of the content analysis, a limitation was that the search process for each newspaper’s database differed. These search engines are created for everyday use and leisure reading. They are not designed with rigorous algorithms needed for research (Lacy, Watson, Riffe, & Lovejoy, 2015). Thus, there may be a possibility that not all the news articles that were
published were captured in the searches executed. To address this limitation, the researcher used two newspaper search engines and online databases. The missing of the last five months of the 2018 year is another limitation related to the content analysis. Additionally, the articles were sampled purposively (a non-probabilistic sample), and the data are not truly dichotomous, thus; inferential analysis is not recommended (Guest et al., 2012a).

Besides these methodological limitations, there were also theoretical limitations. MSA assumes that each of the streams runs independent from each other and only converge at short times called the windows of opportunity (Kingdon, 1995; Zahariadis, 2007). Nonetheless, in the case of the HPV vaccine school-entry requirement adoption process in PR, it was difficult to evaluate the streams in isolation. From the data, it seems that the streams are always in contact with one another. They were influenced by the policy entrepreneurs who were in constant interaction with the streams at many points in time (Figure 6). Additionally, time was an important factor in the findings of this study. MSA posits that the window of opportunity is short in duration (Kingdon, 1995; Zahariadis, 2007). However, based on the findings of this study, the window of opportunity opened when the Secretary of Health made the announcement during the summer of 2017 and stayed opened for about a year until the official announcement was published in the summer of 2018. Moreover, the previous work conducted by the policy entrepreneurs dated years before the window of opportunity opened. This is noted by the blue arrows in Figure 6.

Also, this theory is ‘adoption biased.’ This means that not only it favors evaluation of the creation of policies, but it also falls short in looking at the implantation phase. This limitation about lacking a focus on the implementation of policies, was also discussed by Blackman (2005) her literature review of tobacco control policy development in California. To somewhat address
this limitation, the researcher asked about the potential effects that the hurricane Maria could posit to the implementation of the requirement. To this question, participants noted that for the most part it, the vaccine was supposed to be available. Nonetheless, the use of theory can also be a strength, since it did serve to guide the research questions, analyze, and summarize the data.

Several other strengths exist in this study. The data collection process of this study was opportune. This study took place amid the HPV vaccine school-entry requirement adoption process in PR and helps with reducing the chances of recall bias. Also, the addition of the content analysis served to gather more data on the reasons expressed against the HPV vaccine school-entry requirement. It was used to triangulate the data from the interviews that primarily had the perspective of people in favor of the HPV vaccine school-entry requirement.

**Research, Practice, and Policy Implications**

This study has the potential to contribute to *research* because it adds to the existing literature trying to understand the controversies surrounding the HPV vaccine school-entry requirements. Additionally, it helps to inform the application of a macro-level theory to data from a current policy issue. Similar interviews with stakeholder from other states, and even from other Spanish-speaking countries, can be conducted to explore additional contextual issues surrounding the potential creation of HPV vaccine-related policies. Furthermore, this study’s methodology could be applied to the exploration of the creation of other immunization or health policies. Thus, contributing to the development of health policy research.

Further research is still needed regarding the HPV vaccine school-entry requirement. For example, there is a need to study the HPV school entry requirement adoption process in PR from different perspectives, such as the perspective of parents with adolescent children, or staff from the school system. This can contribute to seeing the whole picture of the HPV vaccine school-entry requirement adoption process. Also, for a comprehensive content analysis of the newspaper
articles published in PR regarding the HPV vaccine school-entry requirement, future research should include the last five months of the 2018 year. Another area of interest would be to explore the misinformation regarding the HPV vaccine available in social media from PR. Lastly, future research should also look at the implementation process of the HPV vaccine school-entry requirement occurring in PR, taking into consideration HPV vaccination outcomes for evaluation of the policy.

Moreover, this study also has several practice implications. The study identified the relevant factors that facilitated the adoption process of an HPV vaccine school-entry requirement. Thus, messages could be created to raise awareness and support among parents and other key stakeholders towards this type of population-based strategy. Public health practitioners should also consider the importance multisector collaborations, that work cohesively towards the same goal and with the same message. Additionally, for the messaging and ultimately the adoption of these policies to be facilitated. Thus, having local epidemiological data seems to be meaningful for the decision makers, as well as, been purposeful in aligning the messages with the values of the policymakers. The timing of educational programs and interventions should also be considered, as it can potentially facilitate the process of adoption of similar policies. Also, the people in power and key administrative staff should also be considered and influenced to facilitate the adoption process. Public health practitioners and advocates of immunization policies can use this information to develop action plans for their states.

Finally, this research could impact public health policy in several ways. This study of PR’s HPV vaccine school-entry requirement provides an overview of an adoption process that recently took place and could inform other states and public health practitioners interested in making the HPV vaccine mandatory. This study also provides insight into the policies that may
need to be in place prior to the adoption of an HPV vaccine school-entry requirement. For instance, in the case of PR, a policy that made the month of January the cervical cancer prevention month, was used to create awareness among the population. As the participants of this study asserted, creating awareness of the issue before the HPV vaccine school-entry requirement was adopted may have contributed to the facilitation of the process. Additionally, the process that occurred in PR, in which the requirement was adopted via the DOH can also serve as an example to other states in which going through the Legislature may seem a difficult policy creation process. Lastly, findings from this study can inform other HPV vaccine policy initiatives to improve HPV vaccination rates across the US and target the prevention of HPV-related cancers.

**Summary**

The purpose of this study was to understand the macro-level factors that influenced the adoption of the HPV vaccine school-entry requirement in PR during the summer of 2018. MSA was useful to identify factors and understand the process that took place in PR for the HPV vaccine school-entry requirement to be created. *Policy entrepreneurs* actively guided the intersection of local *problems, politics, and policies* to educate the population and prevent cancer in PR. This timely look at the facilitators and barriers of the HPV vaccine school-entry provides practical information about the process of adopting a cancer prevention policy-based strategy. Findings from this study can inform other states and public health practitioners interested in adopting HPV vaccine policy initiatives to improve HPV vaccination rates across the US and target the prevention of HPV-related cancers.
Table 1: Information regarding available HPV vaccines

<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
<th>Manufacturer</th>
<th>FDA approval</th>
<th>Year recommended for routine vaccination</th>
<th>HPV strains covered by each vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>2vHPV</td>
<td>Cervarix®</td>
<td>GlaxoSmithKline</td>
<td>2009 F</td>
<td>2009 F</td>
<td>X X 6 11 16 18 31 33 45 52 58</td>
</tr>
<tr>
<td>4vHPV</td>
<td>Gardasil®</td>
<td>Merck and Co, Inc.</td>
<td>2006 F</td>
<td>2006 F</td>
<td>X X X X 6 11 16 18 31 33 45 52 58</td>
</tr>
<tr>
<td>9valent</td>
<td>Gardasil-9®</td>
<td>Merck and Co, Inc.</td>
<td>2009 M</td>
<td>2011 M</td>
<td>X X X X X X X X X X X X X X</td>
</tr>
</tbody>
</table>

Note: M = males, F = females, B = both sexes (Markowitz et al., 2014, Petrosky et al., 2015)
### Table 2: Studies about stakeholders’ reasons and factors associated with HPV vaccine school-entry requirement in the US: Studies’ characteristics (N=25)

<table>
<thead>
<tr>
<th>Authors, year</th>
<th>Type of Stakeholder</th>
<th>Location</th>
<th>Study Design*</th>
<th>Methodology</th>
<th>Date data collected</th>
<th>Sample size</th>
<th>Theory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kahn et al. (2009)</td>
<td>Primary care physicians</td>
<td>Texas</td>
<td>QT</td>
<td>web survey</td>
<td>2008</td>
<td>1,122</td>
<td>Model informed by Theory of Planned Behavior, the Awareness-to-adherence model and diffusion model</td>
</tr>
<tr>
<td>Millen et al. (2009)</td>
<td>Emergency department patients</td>
<td>Boston, Massachusetts</td>
<td>QT</td>
<td>researcher administered survey</td>
<td>2007</td>
<td>387</td>
<td>None mentioned</td>
</tr>
<tr>
<td>Sanderson et al. (2009)</td>
<td>HPV+ and HPV-Latina mothers</td>
<td>Texas</td>
<td>QT</td>
<td>researcher administered survey</td>
<td>2007-08</td>
<td>405</td>
<td>Mentioned in discussion – HBM (findings align with constructs)</td>
</tr>
<tr>
<td>Colgrove et al. (2010)†</td>
<td>Multiple: mostly policymakers, industry, medical prof. orgs., advocacy groups</td>
<td>6 states: California, Indiana, New Hampshire, New York, Texas, Virginia, and at National level</td>
<td>QL</td>
<td>Key informant interviews (face to face and phone)</td>
<td>2008-09</td>
<td>73</td>
<td>None mentioned (potentially the same as Abiola et al. 2013, since same database/participants) Data analysis: thematic content analysis</td>
</tr>
<tr>
<td>Ferris, Horn, and Waller (2010)††</td>
<td>Parents/guardians of children 9-17 years old</td>
<td>Atlanta, Georgia and North Augusta, South Carolina</td>
<td>QT</td>
<td>self-administered survey</td>
<td>2008</td>
<td>325</td>
<td>None mentioned</td>
</tr>
<tr>
<td>Authors, year</td>
<td>Type of Stakeholder</td>
<td>Location</td>
<td>Study Design*</td>
<td>Methodology</td>
<td>Date data collected</td>
<td>Sample size</td>
<td>Theory</td>
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<tr>
<td>Kahan 2010</td>
<td>National sample of American adults (did not specified if had to be parents)</td>
<td>National panel sample</td>
<td>Exp. 3 conditions (1.no argument, 2.unattributed arguments, 3.culturally identifiable advocated)</td>
<td>Online experiments</td>
<td>April and August of 2007</td>
<td>1,538 (n1=254, n2=252, n3=1,032)</td>
<td>Cultural Cognition/cultural theory of risk For data collection: previously validated scales, and new ones</td>
</tr>
<tr>
<td>Yeganeh, Curtis, and Kuo (2010)</td>
<td>Parents/guardians (all females) of girls ages 11-17 (mostly Latino)</td>
<td>Los Angeles, California</td>
<td>QT</td>
<td>Researcher administered survey</td>
<td>2008</td>
<td>95</td>
<td>None mentioned</td>
</tr>
<tr>
<td>Authors, year</td>
<td>Type of Stakeholder</td>
<td>Location</td>
<td>Study Design*</td>
<td>Methodology</td>
<td>Date data collected</td>
<td>Sample size</td>
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<tr>
<td>Carlos 2011 (Study looks at intent to follow/comply with HPV vaccination laws)</td>
<td>Mothers/caretakers (25-55 years old) of females 9 to 17 engaging in breast &amp; cervical cancer screening</td>
<td>Chicago, Illinois (urban site – mostly black) Southeastern, Michigan (suburban site – mostly white)</td>
<td>QT</td>
<td>mail-based self-administered survey</td>
<td>3/4 years after HPV vaccine approval Dec. 1, 2007 – Nov. 30, 2008 (retrospectively identified)</td>
<td>937</td>
<td>Data collection: previously used scales based on the Health Belief Model</td>
</tr>
<tr>
<td>Robitz et al. (2011)</td>
<td>Parents (mostly Hisp. Or AA) of 11 to 18 years old girls from communities with high-risk for cervical cancer</td>
<td>Los Angeles, California</td>
<td>QT</td>
<td>Telephone survey</td>
<td>2007-08</td>
<td>484</td>
<td>None mentioned</td>
</tr>
<tr>
<td>J. S. Smith et al. (2011)</td>
<td>Parents/guardians of girls 10 to 18 years old</td>
<td>Southeastern North Carolina</td>
<td>QT</td>
<td>Telephone survey</td>
<td>2007</td>
<td>866</td>
<td>Survey based on constructs of HBM</td>
</tr>
<tr>
<td>Sara E. Abiola, James Colgrove, and Michelle M. Mello (2013)†**</td>
<td>Multiple: mostly policymakers, industry, medical prof. orgs., advocacy groups</td>
<td>6 states: California, Indiana, New Hampshire, New York, Texas, Virginia, and at National level</td>
<td>QL</td>
<td>Newspaper articles and archival materials. Key informant interviews (face to face and phone). Interviews</td>
<td>2006-08</td>
<td>-</td>
<td>Multiple Streams Model (Theory) Data analysis: thematic content analysis</td>
</tr>
<tr>
<td>R. B. Perkins et al. (2013)</td>
<td>Low income and minority parents/guardians of boys 11 to 17 years old</td>
<td>Boston, Massachusetts</td>
<td>QL/qt with demographic data</td>
<td></td>
<td>2010-2011* “prior to universal recommendation for boys”</td>
<td>120</td>
<td>Health Belief Model (perceived severity, perceived susceptibility, perceived benefits, and perceived barriers)</td>
</tr>
<tr>
<td>Authors, year</td>
<td>Type of Stakeholder</td>
<td>Location</td>
<td>Study Design*</td>
<td>Methodology</td>
<td>Date data collected</td>
<td>Sample size</td>
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<td>Pitts and Tufts (2013) †††</td>
<td>Parents/guardians 4&lt;sup&gt;th&lt;/sup&gt; to 7&lt;sup&gt;th&lt;/sup&gt; grade (9 to 13) girls</td>
<td>Virginia</td>
<td>QL</td>
<td>8 Focus Groups</td>
<td>2008</td>
<td>33</td>
<td>For data analysis: thematic analytic procedures Cultural theory of Risk (cultural worldviews) and message framing theory (gained framed vs loss framed) some constructs of the Health Belief Model</td>
</tr>
<tr>
<td>Nan et al., (2014) (asked about HPV vaccine mandate for girls only)</td>
<td>Undergraduate students 18 to 29</td>
<td>Northeastern, US</td>
<td>Exp.</td>
<td>Web-based</td>
<td>Not reported: estimated to be 2012 (p. 34), asked about girls only law</td>
<td>559 Gain =292, loss =267</td>
<td></td>
</tr>
<tr>
<td>Pierre Joseph, Belizaire, et al. (2014)</td>
<td>Minority men 18 to 22 years old</td>
<td>Boston, Massachusetts</td>
<td>QL</td>
<td>In-person surveys with open-ended questions</td>
<td>2010-11</td>
<td>89</td>
<td>Health Belief Model – questions Data analysis: grounded theory and content analysis</td>
</tr>
<tr>
<td>Pierre Joseph, Clark, et al. (2014)</td>
<td>Minority women 18 to 22 years old</td>
<td>Boston, Massachusetts</td>
<td>M</td>
<td>In-person survey, semi-structure interview, medical record review</td>
<td>2007-09</td>
<td>132</td>
<td>Health Belief Model – qualitative questions Data analysis: grounded theory and content analysis</td>
</tr>
<tr>
<td>M. L. Smith et al. (2014)</td>
<td>18 to 22 college students</td>
<td>Texas</td>
<td>QT</td>
<td>Online survey</td>
<td>Not reported (probably same as Wilson, 2016)</td>
<td>1,322</td>
<td>None mentioned</td>
</tr>
<tr>
<td>Califano et al. (2016) (ask about HPV vaccine school-entry for all aged 11 to 12 years old)</td>
<td>Physicians (pediatricians and family physicians)</td>
<td>National panel sample</td>
<td>QT</td>
<td>Online survey</td>
<td>2014</td>
<td>775</td>
<td>None mentioned</td>
</tr>
<tr>
<td>Authors, year</td>
<td>Type of Stakeholder</td>
<td>Location</td>
<td>Study Design*</td>
<td>Methodology</td>
<td>Date data collected</td>
<td>Sample size</td>
<td>Theory</td>
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</table>
| Calo et al., (2016)  
(asked about HPV vaccine school-entry for all 11 to 12 year olds) | Parents of 11 to 17-year-old children | National panel sample | QT | Web-based survey | Nov. 2014 to Jan. 2015 | 1,501 | None mentioned – look at the literature to look for predictors, scale for psychologic reactance, items from the Carolina HPV immunization attitudes and beliefs scale, item for vaccine importance |
| Vercruysse et al. (2016)  
(asked about HPV vaccine school-entry for children to go to high and middle school) | Parents of 11 to 17-year old girls and health care providers | Boston, Massachusetts | QL/qt – chi-squares | Semi-structured interviews | 2012-13 | 129(parents) 34(providers) | Health Belief Model and Transtheoretical model – for the questions |
| Wilson and Smith (2016)  
College female students | 2 large Texas universities | QT | Internet-delivered questionnaire | Feb. 2011 to March 2011 | 1,105 | None mentioned – for data collection they used previously validated items. |

* QL = qualitative, QT = quantitative, M = mixed methods, Exp. = experimental. † = same dataset/participants, †† = same dataset/participants, ††† = same dataset/participants. ** This study is mostly about the policy formation process, but some opinions about school-entry requirements are discussed, thus, was included.
Table 3: Studies about stakeholders’ reasons and factors associated with an HPV vaccine school-entry requirement in the US: Main findings (N=25)

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Type of stakeholder</th>
<th>Support</th>
<th>Against</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissot et al. (2007)</td>
<td>Pediatricians</td>
<td>Maximize public health impact on immunization</td>
<td>HPV not casually transmitted, concerned about long-term safety and efficacy of vaccines</td>
</tr>
<tr>
<td>Kahn et al. (2009)</td>
<td>Primary care physicians</td>
<td>Effective strategy for vaccine uptake, access, policy guided by PH impact of vaccination, parents can opt-out (religious, philosophical and other)</td>
<td>Patients not covered by Medicaid or VFC may not be able to get vaccine, public poor understanding of HPV and the vaccine, not enough data on long-term efficacy, parents’ autonomy, clinicians experience with vaccine is limited, HPV not casually transmitted, risky sexual behaviors</td>
</tr>
<tr>
<td>Millen et al. (2009)</td>
<td>Emergency department patients</td>
<td>Higher support among those who knew that HPV was STD</td>
<td>Support was not higher among those who have heard of HPV or that knew it causes cervical cancer</td>
</tr>
<tr>
<td>Sanderson et al. (2009)</td>
<td>HPV+ and HPV- Latina mothers</td>
<td>Majority HPV+ and HPV- in favor of Texas law, HPV+ more than twice likely</td>
<td>8 factors: 5 – based on the characteristics of the vaccine (newness of the vaccine, sexually transmitted nature of HPV, HPV not transmittable in classroom, discomfort with involvement of the vaccine manufacturer, price) 3 – based on the vaccine policymaking process (government coercion, anti-vaccine activism, policymaking process)</td>
</tr>
<tr>
<td>Colgrove et al. (2010)†</td>
<td>Multiple: mostly policymakers, industry, medical prof. orgs., advocacy groups</td>
<td>Cervical cancer severity, efficacy of the vaccine, mandate promote uptake equity (less motivated or knowledgeable parents)</td>
<td></td>
</tr>
<tr>
<td>Ferris et al. (2010)‡‡</td>
<td>Parents/guardians of children 9-17 years old</td>
<td>Characteristic of parents – low SES, history of HPV-related disease, understand children susceptibility, interested in the HPV vaccine, know HPV vaccine reduces risk cervical cancer. Parents more likely to comply – children ages 12 to 14, knew vaccine reduces risks of genital warts and cervical cancer</td>
<td>In a scenario that HPV vaccine was required most allowed to vaccinate their children, those who don’t – autonomy</td>
</tr>
<tr>
<td>Author, year</td>
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<tr>
<td>Horn et al. (2010)††</td>
<td>Parents/guardians of children 9-17 years old</td>
<td>Most supported mandatory vaccine programs but only 43% if HPV vaccine included</td>
<td>Infringement on their rights, vaccine not well studied, vaccine has many side effects</td>
</tr>
<tr>
<td>Kahan 2010</td>
<td></td>
<td>“when subjects see the argument, they are disposed to reject being made by the advocate whose values they share, and the argument they are predisposed to accept being made by the advocate whose values they repudiate, polarization shrinks to the point of disappearing.” (P. 509)</td>
<td>No argument condition: Hierarchy correlated positively with risk (participants perceived &gt; risk as they became more hierarchical and &lt; risk as they became more egalitarian) unattributed arguments condition: “subjects exposed to arguments became more concerned about risk as their worldviews became more individualistic and less concerned as their worldviews became more communitarian.” (p. 508)</td>
</tr>
<tr>
<td>Rebecca B. Perkins et al. (2010)</td>
<td>Parents of girls 11 to 18 (included ethnic minorities)</td>
<td>62% of parents in favor but varied by ethnicity only 11% of Caucasians endorsed it, immigrants more likely to support. Reasons: to prevent cervical cancer, protect from sexually active adolescents, PH intervention good for all</td>
<td>Personal choice, transmission not through social contact, new vaccine with side effects</td>
</tr>
<tr>
<td>St John et al. (2010)†††</td>
<td>News media and parents/guardians of girls 9-13</td>
<td>This study is about an existing mandate. News: legislation aspects, opt-out amendment by the governor, support from the legislature, based on discourse from experts (lacked parents discussion), supporters – prevent Focus groups: positive about the HPV vaccine</td>
<td>News: concerns about marketing and lobbying of vaccine, recent approval by the FDA, not long on the market, critics – bill too quick Focus groups: skeptical of the motivations, concerns pharma lobbying, opt-out as a ploy to get to agree, lack of information, HPV vaccination should be a personal choice 20% disagree, 15% unsure.</td>
</tr>
<tr>
<td>Yeganeh et al. (2010)</td>
<td>Parents/guardians (all females) of girls ages 11-17 (mostly Latino)</td>
<td>64% agree with the mandate, 89% would get daughter vaccinated. More likely to support if thought vaccines were safe, had pap test in the last year, already vaccinated daughter, Latino.</td>
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<tr>
<td>Author, year</td>
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<tr>
<td>Carlos 2011</td>
<td>Mothers/caretakers (25-55 years old) of females 9 to 17 engaging in breast &amp; cervical cancer screening</td>
<td>Low intent 22.2%, undecided (14.3%), and high intent 63.5%.* When looking only at mothers of 11 to 12 years old – 29.3% low intent, 12% undecided, 58.7% high intent Univariate analyses – individual knowledge and attitudes, vaccination benefits, belief daughter medical provider recommends, daughter is sexually active or soon will be higher odds to intent to comply with the mandate Multivariate model – high vaccine benefits *scale had 11 items, collapse into 3 groups</td>
<td>Univariate analyses – demographics not associated Univariate analyses – safety concerns, daughter too young, and religious and moral beliefs had lower odds of intention to comply. Multivariate model – high safety concerns, daughter too young for vaccination,</td>
</tr>
<tr>
<td>Robitz et al. (2011)</td>
<td>Parents (mostly Hispanic or African American) of 11 to 18 years old girls from communities with high-risk for cervical cancer</td>
<td>59% thought the law was a good idea, mostly were Hispanics responding in Spanish, daughter’s HPV-vaccinated or intent to vaccine, belief the HPV vaccine works well. Agreement increased to 92% when including participants who think the law is ok if parents can opt-out.</td>
<td>African American less likely to support, belief vaccine not work well, daughters not vaccinated or no intent, HPV vaccine is too new</td>
</tr>
<tr>
<td>J. S. Smith et al. (2011)</td>
<td>Parents/guardians of girls 10 to 18 years old</td>
<td>47% agree to HPV-school entry laws, agreement increased to 84% when opt-out mentioned Predictors to support – daughters had initiated or intent to get the HPV vaccine, belief HPV vaccine effective against cervical cancer, beneficial if given at young age, regret if daughters not vaccinated and got HPV, belief that all children should get it.</td>
<td>Less likely to support predictors – concerns HPV vaccine safety, causing health lasting problems, daughter might initiate sex, belief HPV vaccine pushed by drug companies, new vaccine, decision is for parents alone</td>
</tr>
<tr>
<td>Sara E. Abiola et al. (2013) †***</td>
<td>Multiple: mostly policymakers, industry, medical prof. orgs., advocacy groups</td>
<td>Effective policy entrepreneurship – policy (any) would likely succeed</td>
<td>Factors against compulsory measures: HPV is sexually transmitted (not spread through social contact, girls would perceive can engage in sex, make parents have sexual intimacy conversations when not ready or willing) concerns of the new vaccine’s safety and efficacy, vaccine manufacturer too involved in the policy process</td>
</tr>
<tr>
<td>Author, year</td>
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<tr>
<td>R. B. Perkins et al. (2013)</td>
<td>Low income and minority parents/guardians of boys 11 to 17 years old</td>
<td>Prevention and protection, protect child, public health, perceived severity of HPV. All participants (supporters and not) thought requirements should be for males and females.</td>
<td>Personal choice, lack of information, not transmissible by casual contact, depends on age of the child</td>
</tr>
<tr>
<td>Pitts and Tufts (2013)†††</td>
<td>Parents/guardians 4&lt;sup&gt;th&lt;/sup&gt; to 7&lt;sup&gt;th&lt;/sup&gt; grade (9 to 13) girls</td>
<td>This study is about an existing mandate. Positive about the opt-out option</td>
<td>Parental rights and decision, HPV sexually transmitted, not enough research on the vaccine, not known long term efficacy of the vaccine, lack knowledge about the mandate, need for education</td>
</tr>
<tr>
<td>Nan et al., (2014) (asked about HPV vaccine mandate for girls only)</td>
<td>Undergraduate students 18 to 29 (ask about the mandate for girls on only)</td>
<td>Having the HPV vaccine predicted more perceived benefit and less risk Individualism-communitarianism – no prediction of benefits or risk. Pre-exposure attitudes, having the HPC vaccine strong predictor of support Support – loss-framed message support among the hierarchical, egalitarians supported policies with a gain-framed message</td>
<td>Female students perceived the mandate less beneficial and riskier than males Blacks perceived greater risk Stronger hierarchical worldview predicted less benefit and perceived more risk of the HPV vaccine mandate Females, Hierarchical worldview showed less support</td>
</tr>
<tr>
<td>Pierre Joseph, Belizaire, et al. (2014)</td>
<td>Minority men 18 to 22 years old</td>
<td>Latino (72%) and Haitian (58%) more pro-mandate, next Caucasian (57%) and African American (55%) Important for public health, benefit victims of sexual abuse</td>
<td>Might promote promiscuity, beliefs “Christian scientists” There might be some ethnic differences in supporting/against the HPV vaccine.</td>
</tr>
<tr>
<td>Pierre Joseph, Clark, et al. (2014)</td>
<td>Minority women 18 to 22 years old</td>
<td>Mostly supported because adolescents are engaging in sexual activity and parents don’t know, public health concerns</td>
<td>Personal choice, left to parents, students are not having sex in school</td>
</tr>
<tr>
<td>M. L. Smith et al. (2014)</td>
<td>18 to 22 college students</td>
<td>57.8% supported HPV vaccination mandates for both genders. 48.9% supported mandates for ages 18 to 26, 48.4% for ages 12 to 17, and 15.1% for ages 9 to 11. Mostly non-white, and engage in sex, friends had HPV vaccine</td>
<td>42% did not support HPV vaccination mandates for boys or girls</td>
</tr>
<tr>
<td>Author, year</td>
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<td>Support</td>
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<tr>
<td>Califano et al. (2016) (ask about HPV vaccine school-entry for all aged 11 to 12 years old)</td>
<td>Physicians (pediatricians and family physicians)</td>
<td>47% agree to HPV vaccine for school entrance, 18% with opt-out provisions only, 74% with or without opt-out Predictors: in practice longer than 20 years, giving quality HPV recommendation, HPV is as important as Tdap and meningococcal</td>
<td>Only 12% did not agree under any circumstances</td>
</tr>
<tr>
<td>Calo et al., (2016) (ask about HPV vaccine school-entry for all aged 11 to 12 years old)</td>
<td>Parents of 11 to 17-year-old children</td>
<td>21% parents agree that laws are a good idea When opt-out options were included agreement increased - 57% Factors (without opt-out) in multivariate model: Hispanic parents, HPV vaccine was as or more important than other vaccines, HPV vaccine effective in prevention cervical cancer, it would be hard to find a clinic or provider where they could afford it Factors (with opt-out) in multivariate model: believed HPV prevents cervical cancer and HPV vaccine was as or more important than other vaccines.</td>
<td>54% disagree Disagreement 21% Factors (without opt-out) in multivariate model: believed HPV vaccine was pushed by drug companies to make money, resided in the Midwest states compared to Northeast states Factors (with opt-out) in multivariate model: no other variable associated.</td>
</tr>
<tr>
<td>Vercruysse et al. (2016) (asked about HPV vaccine school-entry for children to go to high and middle school)</td>
<td>Parents of 11 to 17-year-old girls and health care providers</td>
<td>Parents: overall prevention or protection of their child’s health, support of other vaccines, the benefits overweighed risks, and the protection adolescents from STIs Providers: a third favored this mandate option, mentioned the common good and improving vaccination rates This study also addressed parents and providers attitudes - school-based programs.</td>
<td>Parents: limitation to parents’ autonomy, lack of transmission through casual contact, a new vaccine, and adolescents not been sexually active Providers: worried that implementation could be challenging and costly, society not ready and lack transmission through casual contact</td>
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Table 3: (continued)

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Type of stakeholder</th>
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<th>Against</th>
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<tbody>
<tr>
<td>Wilson and Smith (2016)</td>
<td>College female students</td>
<td>13% supported HPV vaccine mandates for 9 to 11, 47.5% for aged 11-17</td>
<td>59.5% believe mandates violate personal freedom, 47.0% believe mandates violate parental rights.</td>
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<td>Reasons: (agree/strongly agree)</td>
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<td>61% protect the public from disease, 51% to lower societal health-care costs, 70% to promote women’s health concerns, and 19.5% to make casual sex safer.</td>
<td>25% reported government is untrustworthy, safety concerns and 51.2% because of costs</td>
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<td>Participants characteristics associated – those who completed the HPV vaccine</td>
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<td>Participants supported mandates for both age-groups: sexually active, had Pap test, and had more friends who reported receiving the HPV series</td>
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<td>Participants who supported mandates for 12–17 years old were single &amp; engaged in sexual activity</td>
<td></td>
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<td>Beliefs associated mandates 9 to 11 years – HPV prevented by using condom, and getting a vaccine</td>
<td>small proportion is against vaccination mandates</td>
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<tr>
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<td>Mandate for 12 to 17-year-old - HPV is preventable by getting a vaccine aged 9–11</td>
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<td></td>
<td>significant larger proportion of participants completed the HPV vaccination supports for all reasons</td>
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</table>

Note: † = same dataset/participants, †† = same dataset/participants. ** This study is mostly about the policy formation process, but some opinions about school-entry requirements are discussed.
<table>
<thead>
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<th>Theme</th>
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<th>Quote Spanish</th>
<th>Quote English</th>
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<tbody>
<tr>
<td>Problems</td>
<td>Indicators</td>
<td>“Las estadísticas dicen que, &quot;Ocho de cada 10 personas van a verse afectadas en el virus&quot;, y yo acabo de tener un infográfico, que dice que, &quot;Una de cada 54 personas va a padecer con cáncer cervical asociado al VPH en Puerto Rico&quot;. [...] Nosotros somos más altos en HVP que en Estados Unidos, tenemos más cáncer, por ejemplo, 4.6 es la incidencia de cáncer cervical en Estados Unidos, en Puerto Rico creo es un 11.”—002</td>
<td>“Statistics say that, “Eight out of ten people will be affected by the virus”, and I just had an infographic that said, “One out of 54 people in Puerto Rico will suffer from HPV related cervical cancer.” [...] We are higher on HPV than in the United States, we have more cancer, for example, 4.6 is the cervical cancer incidence in the United States, in Puerto Rico, I believe it is 11.”—2, Non-profit</td>
</tr>
<tr>
<td>Focusing events</td>
<td></td>
<td>“yo te diría que un trabajo de muchos años; claro, en VOCES, desde que se constituyó ha tenido un rol bien importante la coalición porque ellos conformaron un grupo de paneles de expertos y desarrollaron el informe que habla específicamente sobre el informe en relación al Virus de Papiloma Humano con este comité, este panel asesor.” –008</td>
<td>“A work of many years I would say; clearly, in VOCES, since its founding, the coalition has had a very important role because they formed a group of experts and developed the report that specifically talks about the report in relation to the Human Papillomavirus with this committee, this advising panel.” –008, Other</td>
</tr>
<tr>
<td>Feedback</td>
<td></td>
<td>“Ahora mismo, hoy te puedo decir que hemos sido reconocidos recientemente, Puerto Rico obtuvo un premio en los Estados Unidos porque es uno de los países donde tiene una alta incidencia de vacunación. Así que yo creo que eso es positivo, pero tenemos que aspirar a un poquito más.” –021</td>
<td>“Right now, today I can say that we have been recently recognized, Puerto Rico obtained an award because it is one of the countries in which there is a high vaccination rate. So, I believe that is positive, but we need to aspire to a bit more.” –021, Government</td>
</tr>
<tr>
<td>Policy</td>
<td>Soup of ideas</td>
<td>“El proyecto de ley de la cámara 1303 apoya todos los esfuerzos que está haciendo el secretario de salud, no habla específicamente de la vacuna VPH, habla de todas las vacunas y de cómo mejorar el acceso a todas las vacunas, por ejemplo, con un reporte de la administración de cada vacuna para tener un sistema epidemiológico completo que nos va a permitir hacer proyecciones de qué regiones de las isla están más protegidas, tienen una inmunidad más completa, en caso de brote estamos mejor preparados para entrar a proteger, esos sectores que están más vulnerables.” –005</td>
<td>“The HR bill 1303 supports all the efforts that the secretary of health is doing it does not specifically talks of the HPV vaccine, it talks about all vaccines and how can access be improved for all vaccines, for example, with a report of each vaccine administered so that we have a complete epidemiological system that will allow us to create projections of which island regions are protected more, have a more complete immunity, in case of an outbreak we are better prepared to go in [and] protect the most vulnerable sectors.” –005, Other</td>
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<tr>
<td>Policy</td>
<td>Technical</td>
<td>“En Puerto Rico hay una peculiaridad bien importante y es que quien decide las vacunas y las dosis que se van a requerir para admisión escolares, es el secretario de Salud. “En otros estados es la legislatura. Aquí es un proceso que se ha determinado desde 1974, desde nuestro primer mandato legislativo en vacunación, que es una jurisdicción exclusiva de quien tiene la expertise en materia de salud científica.” –005</td>
<td>“In Puerto Rico there is a very important distinctiveness and that is that the one who decides the vaccines and the dosages that will be required for school entrance, is the secretary of health. In other states it is the legislature. Here it is a process that has been determined since 1974, since our first legislative immunization law, which is an exclusive jurisdiction of who has the expertise on the field of scientific health.” –005, Other</td>
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<td></td>
<td>Feasibility</td>
<td>“Así que dentro de los primeros 10 cánceres, vamos a poner tanto en hombres como en mujeres, cánceres asociados a VPH son las primeras razones de muerte. Por ende, esto es un asunto de salud pública que hay que atender.” — 002</td>
<td>“So in the first 10 cancers, including in men as in women, HPV-related cancers are the first [number one] causes of death. Hence, this is a public health matter that needs to be addressed.”— 002, Non-profit</td>
</tr>
<tr>
<td>Value</td>
<td>acceptability</td>
<td>“Hubo un consenso, uniforme de todos los participantes, de que en Puerto Rico se debía promover el uso de la vacuna y que, eventualmente, si queríamos bajar nuestras tasas de incidencia del virus, debíamos promocionar también que fuese uno de los requisitos de admisión escolar, ¿por qué? Porque durante las edades que es más efectiva crear la inmunidad en el cuerpo contra ese virus es las edades de adolescencia.” –005</td>
<td>“Hubo un consenso, uniforme de todos los participantes, de que en Puerto Rico se debía promover el uso de la vacuna y que, eventualmente, si queríamos bajar nuestras tasas de incidencia del virus, debíamos promocionar también que fuese uno de los requisitos de admisión escolar. Why? Because it is the most effective during the ages of adolescence to create immunity in the body against that virus.” –005, Other</td>
</tr>
<tr>
<td>Politics</td>
<td>Pressure-groups</td>
<td>“Muchos padres han hecho este comentario, pero no les gusta que se sientan obligados, que es obligatorio, que es mandado, por eso es que se usa la palabra requisito, no mandatorio.” –010</td>
<td>“Many parents have made this comment, but they do not like feeling forced, that it is mandatory, that it is mandated, that is why the word requirement is used, not mandatory.” –010, Government</td>
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<td></td>
<td>campaigns</td>
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<tr>
<td>Politics</td>
<td>Administrative or legislative</td>
<td>“No solamente en las esferas de salud, sino también las esferas legistativas o</td>
<td>“Not only in the health sectors, but also in the legislative sectors or in the organizational sectors, governmental, in this case the Department of Health in order to make the decision now of how important it is to include the human papillomavirus vaccine as a required vaccine, consider it and now in accordance to the Secretary of Health a vaccine schedule announcement was recently released for this new, where it is included. I understand that all of these efforts have helped other sectors, like these ones, take a genuine interest and take the task of getting to know a bit more, to the extent that now we have a secretary that is supporting the vaccine requirement.” –018, Non-profit</td>
</tr>
<tr>
<td></td>
<td>turnover</td>
<td>en las esferas organizacionales, gubernamentales, en este caso el Departamento de Salud, para que ahora se tome la decisión de cuán importante es incluir la vacuna del virus del papiloma humano como una vacuna requisito, considerarlo y ahora de acuerdo al secretario de Salud que salió la carta hace poco del schedule de vacuna para este nuevo donde, se incluye. Entiendo que todos estos esfuerzos han ayudado a que otras esferas, como son estas, hayan tomado el interés genuino y se hayan dado la tarea a conocer un poco más, al punto de ahora tengamos un secretario que sí está apoyando lo que es el requisito en la vacuna.” –018</td>
<td></td>
</tr>
<tr>
<td>Policy window</td>
<td></td>
<td>“[…] este año pasado nos sentamos con el secretario de Salud y con el Programa de Vacunación y demostramos que se habían cubierto todas las áreas que habíamos establecido, y que ya estábamos listos para dar el paso. No solamente estábamos listos para dar el paso, sino que era un momento importante […]” –002</td>
<td>“[…] this past year we sat with the Secretary of Health and with the Vaccination Program, and we demonstrated that we had covered all the areas that we had established, and that we were ready to take the step. Not only were we ready for taking the step, but it was [also] an important moment.” –002, Non-profit</td>
</tr>
<tr>
<td>Policy entrepreneurs</td>
<td>Non-profit organizations</td>
<td>“El Departamento de Salud, VOCES, que es la coalición de vacunación, el Centro Compresivo del Cáncer, las asociaciones que tienen que ver con cáncer cervical y eso, la Coalición de Cáncer de Puerto Rico, ese tipo de organizaciones o grupos. –011”</td>
<td>“The Department of Health, VOCES, which is the vaccination coalition, the Comprehensive Cancer Center, the cervical cancer related associations and that, the Cancer Coalition of Puerto Rico, that type of organizations or groups.” –011, Government</td>
</tr>
<tr>
<td>Academia</td>
<td></td>
<td>“Lo que ha pasado en Puerto Rico es que esto se ha seguido investigando y en la medida que tú tienes más investigación, más información; y me refiero, por ejemplo, a los estudios que ha hecho el Centro Comprensivo de Cáncer.”</td>
<td>“What has happened in Puerto Rico is that there has been ongoing research and as you have more research, more information; and I am referring to, for example, the studies conducted by the Comprehensive Cancer Center.”</td>
</tr>
<tr>
<td>Medical</td>
<td></td>
<td>“Obviamente tiene el endoso del presidente del Colegio de Médicos que es la asociación privada del sector privado más importante de salud en Puerto Rico, más el endoso de todas las organizaciones pediátricas.” –004</td>
<td>“Obviously, it has the endorsement from the president of the College of Physicians, which is the most important private health association in Puerto Rico, plus the endorsement of all the pediatrics organizations.” –004, Researcher</td>
</tr>
<tr>
<td>professional</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>organizations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Theme</td>
<td>Sub-theme</td>
<td>Quote Spanish</td>
<td>Quote English</td>
</tr>
<tr>
<td>-------------</td>
<td>------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Policy</td>
<td>Government</td>
<td>“Colaboramos mucho también con el programa de vacunación del Departamento de Salud. Yo creo que todas esas conversaciones han llegado también al secretario, y por eso es que se hace esta recomendación.” –014</td>
<td>“We also collaborated a lot with the Department of Health’s vaccination program. I think all of those conversations have also reached the secretary, and for that it is why this recommendation is being made.” –014, Researcher</td>
</tr>
<tr>
<td>Entrepreneurs</td>
<td>Private sector</td>
<td>“Sí, el sector privado también, no cabe duda de que hemos tenido un apoyo increíble de todos los sectores.” –005</td>
<td>“Yes, the private sector too, there is no doubt that we have had an incredible support from all the sectors.” –005, Other</td>
</tr>
</tbody>
</table>
Table 5: Timeline of policies and strategies leading to the HPV vaccine school-entry requirement in PR

<table>
<thead>
<tr>
<th>Date</th>
<th>Policy, Strategy or Event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 23rd, 1974</td>
<td>Act 235: Compulsory Immunization of students</td>
<td>First immunization law in PR*</td>
</tr>
<tr>
<td>Sept. 25th, 1983</td>
<td>Act 25: Immunization Law</td>
<td>Current immunization law*</td>
</tr>
<tr>
<td>Jan. 20th, 2010</td>
<td>Act 9: Insurance coverage</td>
<td>Private health insurance companies must cover the HPV vaccine for girls ages 11 to 18*</td>
</tr>
<tr>
<td>Sept. 15th, 2012</td>
<td>Act 255: Amendment to Act 9 of 2010</td>
<td>To include 11 to 18 boys to the HPV vaccine health insurance coverage*</td>
</tr>
<tr>
<td>January 2015</td>
<td>Rhaiza López Plumey</td>
<td>Passing and Interview video posted on social media</td>
</tr>
<tr>
<td>May 2015</td>
<td>VOCES HPV Advisory Panel Report</td>
<td>Sponsored by VOCES*</td>
</tr>
<tr>
<td>June 19th, 2015</td>
<td>Act 91</td>
<td>To declare the first week of August “The week of HPV awareness and prevention.”</td>
</tr>
<tr>
<td>June 12th, 2017</td>
<td>DOH announcement</td>
<td>The HPV vaccine was going to be required for school-entry for the 2018-2019 academic year*</td>
</tr>
<tr>
<td>Summer 2017</td>
<td>Education and promotion campaigns</td>
<td>By non-profit organizations, such as VOCES and the DOH</td>
</tr>
<tr>
<td>June 20th, 2017</td>
<td>Act 36: Make the month of January the “Cervical Cancer Prevention Month.”</td>
<td>Jan. 27 “Cancer Prevention Day” TEAL day</td>
</tr>
<tr>
<td>Aug. 30th, 2017</td>
<td>HR Bill 537: Investigation</td>
<td>To order the Health committee of the HR to investigate the efficacy and safety of the HPV vaccine. Approved on Sept. 15th, 2017</td>
</tr>
<tr>
<td>Nov. 1st, 2017</td>
<td>HR Bill 1303: New immunization law</td>
<td>To create a new immunization law for minors and students. Petitioned by VOCES</td>
</tr>
<tr>
<td>Feb. 8th, 2018</td>
<td>HR Bill 1303 and HR Resolution 537 - investigation</td>
<td>Public hearings</td>
</tr>
<tr>
<td>May 2nd, 2018</td>
<td>HR Bill 1576</td>
<td>Petitioned by an anti-vaccination group</td>
</tr>
<tr>
<td>June 11th, 2018</td>
<td>HR Resolution 537 – investigation published</td>
<td>Concludes that the DOH’s determination to include the HPV vaccine to the school required vaccine schedule aligns with the medical community position.</td>
</tr>
<tr>
<td>May 30th, 2018</td>
<td>DOH announcement</td>
<td>HPV vaccine school-entry requirement*</td>
</tr>
</tbody>
</table>

Notes: HR – House of Representatives, DOH – Dept. of Health, specific dates were obtained from the HR bills or announcements, * policies or strategies known by the researcher before data collection.
Table 6: Number of news articles published by year

<table>
<thead>
<tr>
<th>Year</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>65</td>
<td>22.7</td>
</tr>
<tr>
<td>2016</td>
<td>92</td>
<td>32.2</td>
</tr>
<tr>
<td>2017</td>
<td>82</td>
<td>28.7</td>
</tr>
<tr>
<td>2018*</td>
<td>47</td>
<td>16.4</td>
</tr>
<tr>
<td>Total</td>
<td>286</td>
<td>100.0</td>
</tr>
</tbody>
</table>

*Note: until July 31st, 2018

Table 7: Overall distribution of newspaper articles by primary focus

<table>
<thead>
<tr>
<th>Primary Focus</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Educational/informative about HPV &amp; HPV vaccine</td>
<td>68</td>
<td>23.8</td>
</tr>
<tr>
<td>Advertisement</td>
<td>48</td>
<td>16.8</td>
</tr>
<tr>
<td>Vaccines in general</td>
<td>32</td>
<td>11.2</td>
</tr>
<tr>
<td>Cervical cancer/screening</td>
<td>31</td>
<td>10.8</td>
</tr>
<tr>
<td><strong>HPV vaccine school-entry</strong></td>
<td><strong>19</strong></td>
<td><strong>6.6</strong></td>
</tr>
<tr>
<td>Health in general</td>
<td>17</td>
<td>5.9</td>
</tr>
<tr>
<td>Cancer in general</td>
<td>17</td>
<td>5.9</td>
</tr>
<tr>
<td>Other HPV-related cancers</td>
<td>12</td>
<td>4.2</td>
</tr>
<tr>
<td>Scientific/Research advancements</td>
<td>9</td>
<td>3.1</td>
</tr>
<tr>
<td>About STIs including HIV</td>
<td>8</td>
<td>2.8</td>
</tr>
<tr>
<td>School-entry/Other policies</td>
<td>8</td>
<td>2.8</td>
</tr>
<tr>
<td>DOH/government announcement</td>
<td>7</td>
<td>2.4</td>
</tr>
<tr>
<td>Reforma/Obamacare/insurance</td>
<td>3</td>
<td>1.0</td>
</tr>
<tr>
<td>Contraceptives</td>
<td>3</td>
<td>1.0</td>
</tr>
<tr>
<td>Other Focus</td>
<td>2</td>
<td>0.7</td>
</tr>
<tr>
<td>Rhaiza López Plumey</td>
<td>2</td>
<td>0.7</td>
</tr>
<tr>
<td>Total</td>
<td>286</td>
<td>100</td>
</tr>
</tbody>
</table>
Table 8: Articles published for each primary focus category by year

<table>
<thead>
<tr>
<th>Focus</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Educational/informative about HPV &amp; HPV vaccine</td>
<td>14</td>
<td>25</td>
<td>18</td>
<td>11</td>
<td>68</td>
</tr>
<tr>
<td>Advertisement</td>
<td>4</td>
<td>22</td>
<td>13</td>
<td>9</td>
<td>48</td>
</tr>
<tr>
<td>Vaccines in general</td>
<td>12</td>
<td>7</td>
<td>6</td>
<td>7</td>
<td>32</td>
</tr>
<tr>
<td>Cervical cancer/screening</td>
<td>4</td>
<td>15</td>
<td>9</td>
<td>3</td>
<td>31</td>
</tr>
<tr>
<td><strong>HPV vaccine school-entry</strong></td>
<td>1</td>
<td>0</td>
<td>13</td>
<td>5</td>
<td>19</td>
</tr>
<tr>
<td>Health in general</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>2</td>
<td>17</td>
</tr>
<tr>
<td>Cancer in general</td>
<td>5</td>
<td>7</td>
<td>3</td>
<td>2</td>
<td>17</td>
</tr>
<tr>
<td>Other HPV-related cancers</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>Scientific/Research advancements</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>About STIs including HIV</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>School-entry/Other policies</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>DOH/government announcement</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>Salud/Obamacare/insurance</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Contraceptives</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Other Focus</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Rhaiza</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>65</td>
<td>92</td>
<td>82</td>
<td>47</td>
<td>286</td>
</tr>
</tbody>
</table>

*Note: until July 31st, 2018

Table 9: Number of articles that mentioned the HPV vaccine school-entry requirement published by year and newspaper source

<table>
<thead>
<tr>
<th>Source</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>El Nuevo Dia</td>
<td>1</td>
<td>0</td>
<td>9</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>Endi.com</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Vocero</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>vocero.com</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2</td>
<td>0</td>
<td>16</td>
<td>16</td>
<td>34</td>
</tr>
</tbody>
</table>

*Note: until July 31st, 2018
Table 10: Type of argument included in the articles that mentioned the HPV vaccine school-entry requirement by year of publication

<table>
<thead>
<tr>
<th>Type of argument</th>
<th>2015</th>
<th>2017</th>
<th>2018*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Against</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>In favor of</td>
<td>2</td>
<td>10</td>
<td>8</td>
<td>20</td>
</tr>
<tr>
<td>Both arguments</td>
<td>0</td>
<td>1</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>16</td>
<td>16</td>
<td>34</td>
</tr>
</tbody>
</table>

*Note: until July 31st, 2018
References


boys and girls. *Hum Vaccin Immunother, 12*(6), 1519-1527. doi:10.1080/21645515.2016.1157673


Osazuwa-Peters, N. (2013). Human papillomavirus (HPV), HPV-associated oropharyngeal cancer, and HPV vaccine in the United States—Do we need a broader vaccine policy?


msanderson@mmc.edu. doi:10.1089/jwh.2008.1266


Appendix A: IRB Approval

April 9, 2018

Coralia Vazquez-Otero
Community and Family Health
Tampa, FL 33612

RE: Expedited Approval for Initial Review
IRB#: Pro00034887
Title: Understanding the adoption process of an HPV vaccine school-entry requirement in Puerto Rico

Study Approval Period: 4/9/2018 to 4/9/2019

Dear C. Vazquez-Otero:

On 4/9/2018, the Institutional Review Board (IRB) reviewed and APPROVED the above application and all documents contained within, including those outlined below.

Approved Item(s):
Protocol Document(s):
Protocol v.1

Consent/Assent Document(s)*:

InPerson Interview Eng_Version #1_4.5.18.pdf
InPerson Interview Span_Version #1_4.5.18.pdf
Telephone Eng._Version#1_4.5.18
Telephone Span._Version#1_4.5.18

*Please use only the official IRB stamped informed consent/assent document(s) found under the "Attachments" tab. Please note, these consent/assent documents are valid until the consent document is amended and approved. Telephone consent forms are not stamped forms.

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review
research through the expedited review procedure authorized by 45CFR46.110. The research proposed in this study is categorized under the following expedited review category:

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Your study qualifies for a waiver of the requirements for the documentation of informed consent as outlined in the federal regulations at 45CFR46.117(c) which states that an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. (Telephone consent forms).

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval via an amendment. Additionally, all unanticipated problems must be reported to the USF IRB within five (5) calendar days.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

Kristen Salomon, Ph.D., Vice Chairperson
USF Institutional Review Board
Appendix B: Informed Consent Form

Study ID: Pro00034887 Date Approved: 4/5/2018

Consentimiento informado para participar en investigación que involucra riesgos mínimos

Pro # 00034887

Usted es invitado/a a participar de un estudio de investigación. Los estudios de investigación incluyen sólo a personas que deciden participar. Este documento se denomina formulario de consentimiento informado. Por favor, lea esta información atentamente y tome el tiempo necesario para decidir. Pidale al investigador o al personal del estudio que hable con usted acerca de este formulario. Por favor, pídale que le explique todas las palabras o la información que no entienda con claridad. A continuación, se describe la naturaleza del estudio, los riesgos, inconvenientes, molestias y otra información importante acerca del estudio.

Le invitamos a participar de un estudio de investigación llamado: Proceso de adopción del requisito de vacunación contra el VPH para las escuelas en Puerto Rico

La persona a cargo de este estudio es Coralía Vázquez-Otero. Esta persona se denomina el Investigador Principal. Ella es dirigida en esta investigación por las doctoras Ellen M. Daley y Dinorah Martínez Tyson.

El estudio se llevará a cabo en Puerto Rico.

Propósito del estudio

El propósito del estudio es entender los factores que influenciaron en la adopción del requisito de vacunación contra el VPH para las escuelas en Puerto Rico.

¿Por qué se le invita a participar?

Le invitamos a participar de este estudio porque usted fue una voz importante, independientemente de su posición (a favor o en contra), en el proceso de adopción del requisito de vacunación contra el VPH para las escuelas en Puerto Rico.

Procedimientos del estudio:

Si usted participa de este estudio, se le pedirá que:

- Participar en una entrevista por teléfono o en persona (como usted prefiera).
- Las preguntas serán acerca de los factores que influenciaron el proceso de adopción del requisito de vacunación contra el VPH para la escuela en Puerto Rico.
- La entrevista durará alrededor de 30 a 45 minutos y será grabada (audio).
Las grabaciones serán transcritas, y toda la data será guardada con un número de identificación
en una computadora protegida con contraseña.
Sólo los miembros del equipo de investigación tendrán acceso a las grabaciones y
transcripciones.
Toda la data será destruida después de 5 años del reporte final.

Cantidad total de participantes
Alrededor de 30 individuos participarán de este estudio en Puerto Rico.

Alternativas / Participación voluntaria / Retiro
Usted no tiene obligación de participar de este estudio.
Usted sólo debe participar de este estudio si desea ofrecerse en forma voluntaria. No debe sentirse
presionado o participar del mismo. Usted es libre de participar de este estudio o retirarse en cualquier
momento. No habrá sanciones ni pérdidas de beneficios a los que tiene derecho si deja de participar de
este estudio.

Beneficios
Usted no recibirá beneficio(s) por participar en este estudio de investigación.

Riesgos o molestias
Esta investigación se considera de riesgo mínimo. Es decir, que los riesgos que se asocian a la misma
son los mismos que enfrenta cada día. No se conocen riesgos adicionales para quienes participan de
este estudio.

Compensación
Usted recibirá una tarjeta de regalo de $20 dólares si completa toda la entrevista.

Costos
No costará nada participar en este estudio.

Privacidad y confidencialidad
Mantendremos la privacidad y confidencialidad de los registros del estudio. Es posible que
determinadas personas accedan a sus registros del estudio. Toda persona que acceda a sus registros
debe mantenerlos en forma confidencial. Estos individuos incluyen:

- El equipo del estudio, incluido el Investigador Principal, supervisores del estudio, y demás
  personal de investigación.
- Determinado personal del gobierno o la universidad que necesitan saber más acerca del
  estudio e individuos que supervisan para asegurarse de que realicemos el estudio de manera
  correcta.
- Toda agencia del gobierno federal, estatal o local que regule esta investigación.
• La Comisión de Revisión Institucional (IRB, en inglés) de la USF y personal relacionado que tenga responsabilidades de supervisión para este estudio, incluido personal de Integridad y Conformidad de Investigaciones de la USF.

Es posible que publiquemos lo que aprendamos con este estudio. Si lo hacemos, no incluiremos su nombre. No publicaremos nada que permita a los demás saber quién es usted.

**Usted puede recibir respuestas a sus preguntas, inquietudes o denuncias**

Si tiene preguntas, inquietudes o denuncias acerca del estudio, o experimenta algún problema imprevisto, llame a Coralía Vázquez-Otero al 813-810-2264.

Si tiene preguntas acerca de sus derechos como participante de este estudio, o si desea realizar alguna denuncia, tiene problemas o inquietudes que desea discutir con alguien externo a la investigación, llame a la IRB de la USF al (813) 974-5638 o contáctese por correo electrónico RSCIRB@usf.edu.

**Consentimiento para participar de este estudio de investigación**

Otorgo mi consentimiento libremente para participar de este estudio. Entiendo que al firmar este formulario acepto participar de este estudio. He recibido una copia de este formulario para mí.

Firma de la persona que participa del estudio

Fecha

Nombre en imprenta de la persona que participa del estudio

**Declaración de la persona que obtiene el consentimiento informado**

Le he explicado cuidadosamente a la persona que participa del estudio lo que puede esperar de su participación. Confirmo que el sujeto del estudio habla el idioma que se usó para explicar la investigación y que recibe un formulario de consentimiento informado en su idioma principal. El sujeto de este estudio ha dado un consentimiento informado con validez legal.

Firma de la persona que obtiene el consentimiento informado

Fecha

Nombre en imprenta de la persona que obtiene el consentimiento informado