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Examining parent, child, and provider experiences with early childhood immunization for an HPV vaccine trial among four to eight-year-olds: a mixed methods study

BOSTON UNIVERSITY

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Thesis

EXAMINING PARENT, CHILD, AND PROVIDER EXPERIENCES WITH EARLY CHILDHOOD IMMUNIZATION FOR AN HPV VACCINE TRIAL AMONG FOUR TO EIGHT-YEAR-OLDS: A MIXED METHODS STUDY

by

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EXAMINING PARENT, CHILD, AND PROVIDER EXPERIENCES WITH EARLY CHILDHOOD IMMUNIZATION FOR AN HPV VACCINE TRIAL AMONG FOUR TO EIGHT-YEAR-OLDS: A MIXED METHODS STUDY

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ABSTRACT

Background: Since the introduction of the first vaccine against human papillomavirus (HPV) in 2006, there has been an 88% drop in HPV infection among US women, with a smaller, yet still significant, drop in men. Despite exemplary efficacy and safety data, HPV vaccine rates continue to lag far behind other routine childhood immunizations in acceptance and completion, with less than 50% of US adolescents completing the HPV vaccine series by the recommended age of 13 (Pingali, 2023).

Current Efforts: To improve on-time vaccination, the American Academy of Pediatrics (AAP) has begun recommending that the vaccine be offered for boys and girls beginning at age 9.

A Gap in Knowledge: Despite national efforts, there is still much progress needed to significantly improve completion rates, especially with emerging studies suggesting a downward trend for the first time since the introduction of the vaccine.

Objective: The primary objective of this study is to assess and adapt recruitment conversations with parents to better convey the efficacy, safety, and importance of early childhood HPV vaccination. This includes providing evidence-based information on vaccine efficacy, duration of protection, and safety to parents, while addressing misinformation, and fostering informed decision-making regarding HPV vaccination for their children aged 4–8 years.

Methods: Our team conducted a longitudinal exploratory mixed-methods study involving qualitative interviews of a subset of participants from the larger parent study, titled "An exploratory open-label clinical trial evaluating the immunogenicity and safety of the 9vHPV 2-dose vaccine regimen in children aged 4–8 years." Interviews were complemented by a cross-sectional survey at the baseline of the larger early childhood vaccine study. This information was used to understand participants' experience with HPV vaccination and to provide recommendations on how to improve vaccine communication strategies and increase parental confidence in HPV vaccination administered during early childhood.

Study Design: This mixed-methods study explores parent, child, and provider experiences with early childhood HPV vaccination, and identify both facilitators and barriers to vaccination at this young age.

Quantitative Analyses: Descriptive statistics were computed using SAS software for Study H-41686 Baseline Questionnaire comprising 100 children and their respective parents taken at the time of enrollment in the Pediatric HPV Study. Data analyzed included child demographic information, parent demographic information, and parent knowledge/experience.

Qualitative Analysis: Analysis of the qualitative data was achieved by collecting audio transcripts from interviews which were transcribed verbatim. Team members then identified recurrent themes within the transcript organizing and refining them until a master codebook was finalized. This codebook was then applied to every transcript.

Quantitative Results: The age range of the children spanned from 4 to 8 years, with a mean age of 6.01 years (SD = 1.49). Parents fell within the range of 30 to 42 years old with a mean age of 36 years (SD=8.27). Gender distribution among the children was 52% male and 47% female participants. Female parents predominated (83.33%). 57% of parents identified as African American, 15% as Hispanic, and others varied. Most parents reported that they relied solely on healthcare providers for health information, with a combination of healthcare providers and Internet/Google searches being secondary sources.

Qualitative Results: Parents endorsed an understanding that their children are susceptible to severe diseases, including cancers that can be caused by HPV infection. The majority of parents concurred that long-term health benefits outweighed any perceived risks of vaccinating. All parents felt responsible for managing their children's health throughout their childhood until they reached an age where they could make informed decisions on their own. Trust in providers' expertise and benevolence was another major motivator for parents to enroll in the study. Prior provider-patient relationships and comfortability with their pediatrician also facilitated children's acceptance of the study.

Conclusion: Routine HPV vaccination of children aged 4–8 is feasible for providers and acceptable to parents. Prior to enrollment parents relied on researchers to provide a foundation for their understanding of the impact of HPV and the benefits of vaccination in mitigating potentially poor outcomes. Following vaccination, parents reported that they were content with their decision and took comfort in knowing they took a necessary measure to protect their child from future disease. Children within the study demonstrated varied understanding of vaccination necessity, yet many verbalized a need to stay healthy as a primary motivator for vaccination. Providers expressed a willingness to recommend to this age and the ability to incorporate a new HPV schedule.

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LIST OF ABBREVIATIONS

9V ..... Nonavalent

ACIP ..... Advisory Committee on Immunization Practices

BMC ..... Boston Medical Center

CDC ..... Centers for Disease Control and Prevention

FDA ..... Food and Drug Administration

GSK ..... GlaxoSmithKline

HPV ..... Human Papillomavirus

IRB ..... Institutional Review Board

MenACWY ..... Meningococcal ACWY

RA ..... Research Assistant

STD ..... Sexually Transmitted Disease

STI ..... Sexually Transmitted Infection

Tdap ..... Tetanus-Diphtheria-Pertussis

US ..... United States

USA ..... United States of America

UTD ..... Up to date

VAERS ..... Vaccine Adverse Event Reporting System

INTRODUCTION

Human Papillomavirus and Cancer

Human papillomavirus is the most common sexually transmitted infection (STI) in the United States. In 2018, there were 43 million documented active HPV infections, with approximately 13 million new infections occurring that year (*STD Facts - Human Papillomavirus (HPV)*, 2022)). HPV exists within a group of over 200 related viruses that have varying effects on humans, with at least 40 infecting the genital area, and many that cause no visible health effect (*Human Papillomavirus (HPV) Infection - STI Treatment Guidelines*, 2022). The virus types that hold a higher risk of developing into sexually transmitted diseases (STDs) are categorized into, low-risk and high-risk. Low-risk HPV types are responsible for the development of warts that can develop in the oropharyngeal and anogenital regions of the body. These warts can lead to additional health impacts such as respiratory papillomatosis, a breathing condition caused by the development of warts in the respiratory tract. Twelve HPV types are labeled high-risk, as they are the most common causes of several types of HPV-associated cancers including cancers of the cervix, vulva, vagina, penis, anus, oropharynges, and other head and neck cancers (*HPV and Cancer - NCI*, 2019). Between 2012 and 2016, there were approximately 35,000 new HPV-associated cancer cases in the U.S. (*Human Papillomavirus (HPV) Infection - STI*

Treatment Guidelines, 2022). Of these cases, cervical cancer predominated among women, and oropharyngeal cancer in men. Cervical cancer is the only type of cancer caused by HPV that has a recommended screening test, the pap smear (Guillaume … Pierre-Joseph, et al., 2023). Lack of routine screening allows undetected cancers to worsen leading to serious disease (Moyer & U.S. Preventive Services Task Force, 2012).

Past research has shown that of the tens of thousands of new cases of cervical cancer each year, over 90% of them are preventable through the 9-valent HPV vaccine (Saraiya et al., 2015)(Joura et al., 2015). A yearly report published in January 2024 by the American Cancer Society reported that cervical cancer incidence for women aged 30–34 has increased in recent years. This data collected by central cancer registries and mortality data is in sharp contrast to younger birth cohorts, who had access to HPV vaccination beginning in 2006. Invasive cervical cancer incidence among women aged 20–24 years decreased by 65% from 2012 to 2019 compared with 24% from 2005 to 2012 (Siegel et al., 2024).

HPV Vaccine History

Gardasil, the first vaccine targeting HPV, was licensed in June 2006 as a quadrivalent vaccine indicated for prevention against viral types 6,11,16,18 for use among females aged 9–26 years. Later that year the Advisory Committee on Immunization Practices (ACIP) recommended its use for females aged 11 and 12. In 2009, the Food and Drug Administration (FDA) licensed Gardasil for use in males 9–26 for the prevention of genital warts caused by HPV types 6 and 11, and GlaxoSmithKline's (GSK) Cervarix was approved for use in women to prevent cervical cancer (*Center for Cancer Research*)(CDC, 2010). In February 2015 the ACIP recommended the newly licensed nonavalent (9v) HPV vaccine, Gardasil 9, a 3-dose series, for children ages 11 to 12 years old. This recommendation also included females ages 13–26 and males ages 13–21 who had not previously been vaccinated or completed the 3-dose series (Petrosky & et al., n.d.).

The latest recommendation from the ACIP regarding pediatric HPV vaccination was approved in 2016. This included new recommendations for the use of a 2-dose schedule for ages 9–14 years in both males and females (Meites, 2016). Currently, Gardasil 9 is the only HPV vaccine available for administration in the United States.

Vaccine Safety

Since vaccines are offered to most people in the United States who are otherwise healthy, there are stringent testing and safety procedures to ensure that their benefits significantly outweigh their risks. Vaccine development, manufacturing, and testing is a highly regulated process that can take upwards of 20 years and cost approximately 1 billion dollars before a vaccine is available to the general public (*Vaccine Safety*). Before receiving approval from the FDA, the HPV vaccines were tested in various stages of clinical trials consisting of upwards of 15,000 people. (CDC, 2021a)

Once approved for the public, data is collected by the Vaccine Adverse Events Reporting System (VAERS), a self-reporting system co-managed by the FDA and CDC that allows for early detection of safety concerns following widespread vaccination. This allows for further investigation to see if a pattern of side effects may indicate safety concerns. This passive surveillance system is open to reports from the public and providers and is especially useful for monitoring populations who may not be represented by a clinical trial cohort such as those with special medical conditions or pregnant women. If enough reports regarding similar adverse events are submitted to VAERS, a trigger is alerted, and the CDC further investigates. Of these cases, there are usually very few that are determined to be “definitely causally related to

vaccine received" (Loughlin et al., 2012). CDC reports have stated that between 2014 and 2017, 28 million doses of Gardasil 9 were given in the US, with only 7,244 adverse events reported. Of these adverse events, 97% were classified as non-serious including symptoms of dizziness, syncope, headache, nausea, fever, and pain/redness/swelling in the arm of the receiver (CDC, 2021a)(Shimabukuro et al., 2019).

Current Vaccine Trends

More than 270 million doses of the HPV vaccine have been given worldwide, including 135 million doses in the US (CDC, 2021b). This has led to hundreds of studies investigating the safety and efficacy of the HPV vaccine which have all led to a similar conclusion, the HPV vaccine is both safe and highly effective in cancer prevention (CDC, 2021b). Yet, despite its proven track record, the HPV vaccine has one of the lowest immunization rates among routinely recommended vaccinations. According to CDC data summarized in Figure 1, within the United States in 2022, only 76% of 13 to 17-year-olds have received the first dose of 9vHPV, compared to 88.6% Dose 1 Meningococcal ACWY (MenACWY), and 89.9% Dose 1 Tetanus-Diphtheria-Pertussis (Tdap) (Pingali, 2023)

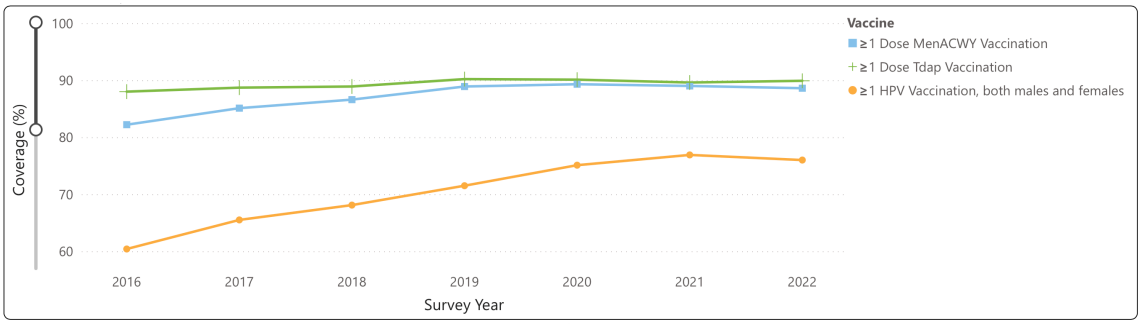

Figure 1: Vaccination Coverage by Year among Adolescents Aged 13–17 Years, United States, National Immunization Survey-Teen. This graph depicts the percent coverage of the first dose of MenACWY, Tdap, and HPV vaccination in both males and females over six years from 2016 to 2022. Taken from (TeenVaxView | Adolescent Vaccine Coverage Interactive Data | NIS | CDC, 2022).

Even worse, the completion rate of the HPV vaccine in adolescents aged 13 to 17 in the United States is a dismal 62.6%. Less than 50% of US adolescents complete the HPV vaccine series by the recommended age of 13 (Pingali, 2023). See Figure 2.

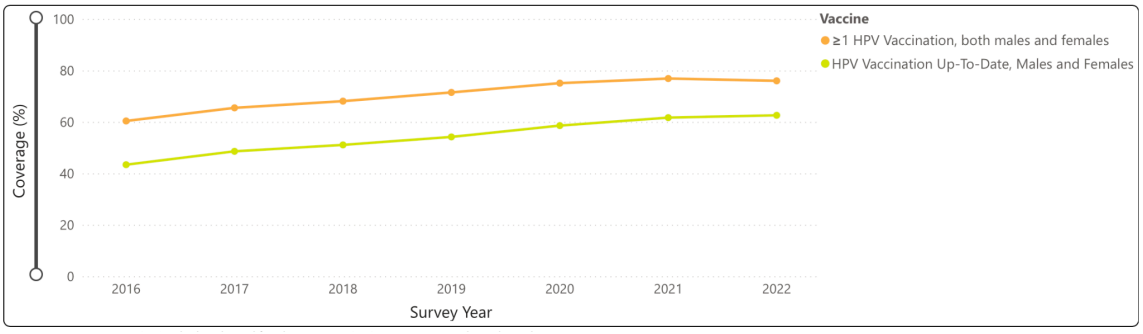

Figure 2: Vaccination Coverage by Year among Adolescents Aged 13–17 Years, United States, National Immunization Survey-Teen. This graph depicts the percent coverage of HPV vaccination in both males and females over six years from 2016 to 2022. Taken from (TeenVaxView | Adolescent Vaccine Coverage Interactive Data | NIS | CDC, 2022).

Data suggests that series completion of the HPV vaccination by age 13 is low, with only 32.8% of the US adolescent population in 2018 up to date (UTD) by their 13th birthday. According to researchers, the current state of HPV vaccination is "sub-optimal" (Chido-Amajuoyi et al., 2021)(Cox et al., 2022). Despite an overall improvement in uptake of HPV vaccination rates between 2008–2018, the time at which series completion is occurring is too late to achieve the greatest health benefit provided by Gardasil 9 (Chido-Amajuoyi et al., 2021). This is supported by past research that has shown that HPV vaccination is most effective when administered between ages 9 to 12, a time when higher levels of immunogenicity and efficacy can be incurred in a two-dose series (Bornstein et al., 2021).

Barriers to Vaccination

Many barriers to immunization exist that prevent the acceptance of vaccines across the United States. The age of social media has perpetuated both pro and anti-vaccine narratives that providers and parents must weigh when deciding whether and when to vaccinate. Common barriers to routine childhood vaccination include parents' safety concerns, parents' mistrust of science or pharmaceutical and/or government organizations that produce, recommend, and distribute vaccines, sentiment that HPV is a low-risk disease for their child, and

reluctance to return for series completion. System-level barriers also include issues with dosage schedules, difficulty with administration at an age when other vaccines are required, and access limitations, especially in rural or under-resourced areas (Cox et al., 2022). In addition to these barriers, the HPV vaccine faces increased scrutiny due to its associations with sexual activity and that it is not school-mandated in most states (see Figure 3/4). Inaccurate parent recall of HPV vaccine series status may also play a role (Apte … Pierre Joseph, et al, 2015).

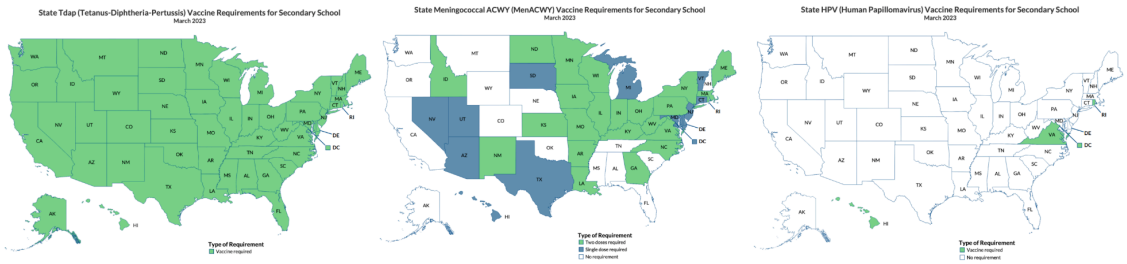

Figure 3: State Vaccine Requirements for Secondary School. This image depicts trends in state vaccine requirements to attend secondary school across the US for three routine childhood vaccination, Tdap, MenACWY, and HPV, respectively. Taken from State Vaccine-Specific Requirements - Immunization.org, 2023.

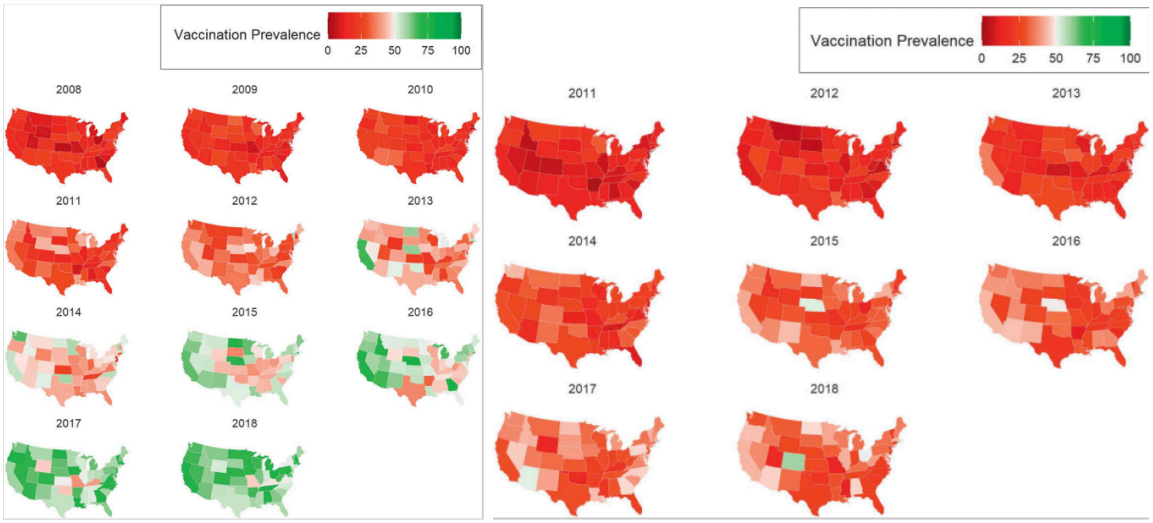

Figure 4: National Maps Depicting Trends in HPV Vaccination Initiation (Left) and HPV-UTD (Right) within Ages 9 to 12 Years by State 2008–2018. Data accumulated from NIS-Teen. Taken from Trends in HPV Vaccination Initiation and Completion Within Ages 9–12 Years: 2008–2018(Chido-Amajuoyi et al., 2021)

Due to these barriers, many studies have been conducted to try to understand the top factors that can promote vaccine acceptance. Of the contributing factors analyzed, provider recommendation ranks highest among parents for reasons to vaccinate (Dempsey & O'Leary, 2018)(Rosenthal et al., 2011). If a parent perceives that their provider discouraged HPV vaccination the uptake of vaccination will be low (R. B. Perkins … Pierre-Joseph, et al., 2014).

Social determinants of health also play an important factor in HPV vaccination. Such determinants include lack of healthcare access, transportation, and education opportunities to learn about HPV and vaccines. Another common reason that children are not vaccinated for HPV is simply that they were never offered the vaccine (R. B. Perkins …

Pierre-Joseph, et al., 2014). The HPV vaccine is covered under the Vaccines for Children (VFC) program, yet many children and adolescents are slipping through the cracks. An analysis of adolescent coverage produced in a 2023 CDC Morbidity and Mortality Weekly Report (MMWR) stated that for the first time since 2013, there was no increase in vaccine initiation among adolescents aged 13–17 and initiation dropped among adolescents covered by Medicaid, and those who are uninsured (Pingali, 2023)

Vaccination at Age 9

Longstanding trends of low HPV vaccination rates have challenged public health to institute initiatives to improve public knowledge and perception of the importance of HPV vaccination. Current ACIP recommendations state that the HPV vaccine should be given to adolescents aged 11 and 12 years old, with an option for providers to begin as early as age 9. Embracing earlier vaccination, the American Academy of Pediatrics (AAP) recommended that the HPV vaccine start to be administered beginning at age 9. The National HPV Vaccine Roundtable, a coalition of 70+ member organizations committed to fighting HPV, began to recommend vaccination at age 9 in 2020 based on the findings of a study published by the American Cancer Society highlighting the benefits, effectiveness, and improved vaccine acceptance

among a cohort of 9-year-old children vaccinated against HPV (Saslow et al., 2020). Together with their member organizations, there has been a strong push to begin routine HPV vaccination at age 9 across the country. These recommendations have recently been supported by a collection of 22 articles published in 2023 in *Human Vaccines & Immunotherapeutics* which highlighted the benefit of vaccination at age 9 (R. Perkins et al., 2023). The findings of these studies all lead to a similar conclusion, beginning routine vaccination at age 9 resulted in higher rates of on-time series conclusion (R. B. Perkins et al., 2023). By initiating vaccination earlier, providers will be able to reach more children and improve cancer prevention. Providers were initially skeptical of age nine recommendations, fearing parental acceptance would diminish. However, parents embraced the new recommendations that reduced sexual stigma and required fewer shots at one visit as the vaccine was no longer bundled with tetanus and meningitis (Biancarelli et al., 2020).

A New Approach

Recent data suggests that measures taken to improve HPV vaccination by lowering age recommendations have been effective. However, significant strides will need to be taken to drastically improve series completion by age 13 in the US. For these reasons, researchers at Boston Medical Center and Boston University Chobanian & Avedisian School of Medicine have begun a proof of concept, a one-armed study investigating the introduction of the 9vHPV vaccine in children 4 to 8 years old. Boston is a major metropolitan area in Massachusetts, USA. A 2017 report estimated that of Massachusetts adolescents aged 13–17, 67% of females and 64% of males have completed the HPV series (Vaccine-Preventable Diseases|Mass.Gov). Investigators seek to improve this statistic. Our team has hypothesized that by initiating the vaccination at an earlier age there will be improved vaccine uptake and series completion, along with equivalent safety and efficacy for the following reasons: First, Gardasil 9 is most effective when completed prior to first sexual contact as it cannot prevent progression of a current infection to disease (Markowitz & Schiller, 2021); Second, younger children are much more likely to attend routine health visits than preteens and teens and will be more likely to complete the series before late adolescence (R. Perkins et al., 2023); Third, the association between the HPV vaccine and sexual activity onset may be diminished when given

with other routine childhood vaccinations; Fourth, a two-dose series may provide the same protection as a three-dose series required for ages 15 and up (Bornstein et al., 2021). Fifth, by offering transportation and convenient appointment dates and times, our team attempting to make visits for under-resourced populations easier to attend (Cox et al., 2022).

Rationale:

By adapting recruitment conversations, improving children's understanding of the HPV vaccine, and addressing provider guidance and perceived barriers, this study aims to increase vaccine uptake and series completion rates. Through qualitative analysis of participant experience and sentiment, this thesis seeks to inform future vaccination strategies for early and young children, improve provider-parent communication, and ultimately contribute to the eradication of HPV-related cancer.

SPECIFIC AIMS

Despite exemplary efficacy and safety data, the HPV vaccine continues to lag far behind other routine childhood immunizations in acceptance and completion, with less than 50% of US adolescents completing the HPV vaccine series by the recommended age of 13.

To address this serious public health challenge, researchers have initiated a study to vaccinate children between the ages of 4 to 8 at Boston Medical Center in Massachusetts, USA. Our team has hypothesized that by initiating HPV vaccination at an earlier age we will achieve there will be improved vaccine uptake and series completion. To improve our recruiting and ensure parent confidence, our team began a quality improvement initiative with current participants. This led to a research study exploring participant and provider sentiments on early childhood vaccination to ensure that new recommendations will be met with support and enthusiasm.

Specific Aims

1. **Adapt Recruitment Conversations:** to enhance communication strategies between potential participating parents and research staff. Researchers aim to improve our initial conversations with parents to better provide (1) an explanation for why they should vaccinate their children at a younger age; (2) evidence of vaccine

efficacy and duration of protection; (3) vaccine safety data; and (4) responses to misinformation.

2. **Improve Children's Understanding of the Benefits of HPV Vaccination:** Assess children's comprehension of the importance of vaccination. Researchers will explore their understanding of the importance of vaccination thereby, promoting well-informed patients to make decisions about HPV vaccination later in life.
3. **Address Provider Barriers to Vaccination and Recommendation on Improving Patient HPV Vaccine Uptake:** Exploring primary care providers' perspectives on HPV vaccination among young children to identify strategies for overcoming barriers and promote vaccine acceptance. Primary care providers understand their patient's unique needs and can offer recommendations on how to best connect with parents and their children.

By completing this quality improvement study researchers will ensure vaccination among young children can be achieved by providers and welcomed by parents if proper counseling and proactive and enthusiastic recommendations are given during vaccine counseling.

THESIS OBJECTIVES

Objectives for Specific Aim 1 are:

1. To explore, assess, and adapt recruitment conversations with parents via semi-structured interviews to better convey the importance of early childhood HPV vaccination. This includes providing evidence-based information on vaccine efficacy, longevity, and safety to parents, addressing misinformation, and fostering informed decision-making regarding HPV vaccination for their children aged 4–8 years.
2. To explore patient, parent, and provider experience with HPV vaccination at ages four to eight years old to improve future messaging and discussions regarding early childhood HPV vaccination.

Objectives for Specific Aims 2 are:

1. To explore children's experience in the recruitment and enrollment process in the study via semi-structured interviews.
2. To explore children's comprehension of the HPV vaccine study and ways to improve communication with other children in the future.

Objectives for Specific Aim 3 are:

1. To explore and investigate primary care providers' perspectives, attitudes, and barriers toward HPV vaccination among young children.
2. To identify strategies for overcoming barriers and promoting vaccine acceptance.
3. To explore and assess via semi-structured interview recommendations by providers and gain an understanding of their patient's unique needs to allow researchers to attain rapport with parents and their children.

By achieving these objectives, this study seeks to improve vaccine confidence and enhance parent-early-child communication, ultimately increasing HPV vaccine uptake and contributing to the prevention of HPV-related cancers.

METHODS

Study Design

Researchers conducted a longitudinal exploratory mixed-methods study involving qualitative interviews of a subset of participants from the parent study titled “An exploratory open-label clinical trial evaluating the immunogenicity and safety of the 9vHPV 2-dose vaccine regimen in children aged 4–8 years.” Interviews were complemented by a cross-sectional survey at the baseline of the larger early childhood vaccine study.

Qualitative interviews included parent/patient dyads who were currently enrolled in the Pediatric HPV Study. Additionally, providers of children enrolled in the Pediatric HPV Study were interviewed to gather their professional opinions regarding early childhood HPV vaccination.

Quality Improvement PDSA Cycle Design

To ensure continuous enhancement of the research process and participant experience, a quality improvement initiative was integrated into the study methodology. This initiative employed the Plan-Do-Study-Act (PDSA) cycle, a systematic method for iterative improvement commonly used in healthcare settings.

The Quality Improvement Phase

The Quality Improvement Phase involved a Test Phase conducted prior to the Research Phase. This phase aimed to refine the interview process and optimize participant engagement.

The Planning Phase (P)

Researchers outlined goals for the interviews, including verifying participant understanding of the study, establishing baseline knowledge about HPV and the vaccine, obtaining opinions regarding routine vaccinations, and assessing parent interest in future vaccination initiatives.

The initial step involved drafting the interview guide based on the constructs of the health belief model, ensuring alignment with the study objectives.

Participants reviewed the interview guide and provided feedback. The guide was refined based on participant input and submitted for IRB approval.

The final interview guide for parents, children, and providers included questions aimed at:

1. Exploring participant understanding of HPV and HPV vaccine, obtaining attitudes towards vaccinations at an early age.

2. Exploring parent impressions of, and recommendations for recruitment conversations to enhance communication regarding the importance, efficacy, and safety of early childhood HPV vaccination.
3. Assessing children's experience in the study and understanding of the significance of vaccination to foster informed decision-making and recommendation of age-appropriate preferred methods/means of communication with other children.
4. To explore recommendations by providers and gain an understanding of their patient's unique needs to allow researchers to attain rapport with parents and their children.

A test phase was conducted where the interview guide was shared with participants ahead of virtual meetings, and feedback was solicited to identify areas for improvement.

The Interview Phase (D)

Following the Planning Phase, researchers conducted interviews with participants, adhering to the semi-structured interview guide. Interviews were conducted virtually using Zoom Video Communications, Inc., with verbal informed consent obtained from participants.

Parent interviews typically lasted approximately 30 minutes, while interviews with children lasted approximately 15 minutes.

Audio transcripts were collected using Zoom Dictation Services, ensuring accurate documentation of participant responses. Interviews with Spanish or Haitian Creole-speaking participants were facilitated with the assistance of BMC translators and bilingual team members.

To enhance recruitment conversations, qualitative interviews were conducted to assess parent impressions and provide insights for improving initial conversations with parents. These conversations aimed to better communicate the importance of early HPV vaccination, provide evidence of vaccine efficacy and safety and address misinformation.

To improve children's understanding of the HPV vaccine, semi-structured interviews with participating children were conducted to explore their comprehension of the benefits of the HPV vaccine.

To address provider perceived barriers and explore recommendations, semi-structured interviews with primary care providers were conducted to understand their patient’s unique needs to allow researchers to attain rapport with parents and their children.

The Study Phase (S)

Upon completion of the interview phase, researchers analyzed the collected data to identify recurring themes, sentiments, and areas for improvement.

Data analysis involved utilizing modified grounded theory and content analysis approaches to identify emerging codes and themes. Weekly meetings were held to ensure consistency in coding among team members and to resolve any discrepancies. Identified themes were compiled into a preliminary codebook, which underwent iterative refinement until a master codebook was finalized.

The Action Phase (A)

Based on the findings from the study phase, researchers continuously improved the interview guide and interview process. Feedback from participants during the quality improvement phase was carefully considered, and adjustments were made to address any identified shortcomings.

A final draft of the interview guide, incorporating revisions and improvements, was submitted for Institutional Review Board (IRB) approval.

Continuous monitoring and refinement of the interview process were conducted throughout the data collection period to ensure ongoing optimization of participant engagement and data quality.

Through the iterative application of the PDSA cycle, the quality improvement initiative facilitated the refinement of the interview process, enhancing participant engagement and the overall quality of the research endeavor.

Eligibility Criteria

- Parents of children participating in the Pediatric HPV Study (H-41686) at ages 4–8 that indicated willingness to participate in future studies.
- Children aged 7–8 at the time of enrollment in study H-41686.
- Providers of BMC Pediatrics whose patients are actively enrolled in study H-41686.

Exclusion Criteria

- Parents who indicated at enrollment that they were not interested in being contacted regarding future research opportunities.
- Children aged 4, 5, or 6 at the time of enrollment.

Recruitment

Parents currently enrolled in the Pediatric HPV Study were asked whether they would permit researchers to contact them regarding future research opportunities. Of those who expressed approval, investigators began the recruitment procedure. Parents were spoken to over the phone or in the clinic using an IRB-approved recruitment script. This script outlined the objectives of the study, that a decision to accept or decline participation would not affect their family's care, reiterating that participation was completely voluntary.

> *Hello, my name is (insert name), and I am a Research Assistant at Boston Medical Center. I am calling/ speaking with you today to ask if you would be willing to voluntarily participate in a research study. The purpose of this study is to adapt recruitment conversations, improve children's understanding of the benefits of HPV vaccination, and address provider barriers to vaccination and recommendations on improving patient HPV vaccine uptake. As a current participant in an early childhood pediatric HPV study, we would like to learn from your experience as to what parents may want to learn before their child receives HPV immunizations. If you agree, we will ask you to speak with us via a virtual meeting.*

Parents were enrolled in the study interview phase based on their demonstrated willingness to participate in the interview process. Children were enrolled based on parents' willingness for their child, and the child's indication that they were willing to participate in the interview process. Researchers decided to include only children ages 7 or 8 at the time of enrollment due to this age group's demonstrated ability to communicate with rational, or near rational thought and feelings

regarding immunizations. These children are patients who receive routine care at Boston Medical Center (BMC) in the Pediatrics/Adolescent Medicine, Pediatric Dentistry, and Family Medicine departments. BMC primarily cares for under-served populations that are racially and ethnically diverse. (62% Black, 15% White, 13% Latino, and 10% other) but largely socioeconomically disadvantaged (70% publicly insured, 30% privately insured). Participants will reflect this demographic data.

No compensation was offered for participants who completed interviews. Compensation is offered via the Pediatric HPV Study with a total of $400 awarded throughout the 5-year study. Children who participate in the Pediatric HPV Study receive age-appropriate toys and books following vaccination.

Interview Guide

The semi-structured interview guide, based on the health belief model, comprised three sub-sections: one for parents, one for children aged 7–8, and one for providers of enrolled children. Open-ended questions encouraged dialogue to gather insights on participants' experiences and opinions regarding HPV vaccination.

For example:

- For parents: “Why did you choose to vaccinate your child against HPV?”
- For children: “If you had to explain the importance of getting vaccinated to your little brother or sister, how would you do so?”
- For providers: “Do you think it is feasible to begin vaccinating children against HPV at age 4 at your clinic?”

Interview Process

Participants were scheduled for virtual interviews using a virtual conference room provided by Zoom Video Communications, Inc. After obtaining verbal consent, parent interviews were conducted over an approximately 30-minute period.

Following parental permission, children were interviewed for approximately 15 minutes. Audio transcripts were collected by researchers via Zoom dictation services.

Interviews with Spanish or Haitian-Creole-speaking participants were facilitated by BMC translators and the Project Manager. Audio transcripts were collected via Zoom dictation services and translated for non-English-speaking participants.

Transcript Preparation

Audio recordings were transcribed verbatim using Zoom audio dictation. Transcripts were reviewed for accuracy. For Spanish or Haitian Creole-speaking participants, translations were corrected by bilingual staff. Participants were identified using initials only.

Quantitative Data Analysis

Data was collected from the Pediatric HPV Study Baseline Questionnaire, completed by 100 children and their parents. The questionnaire gathered demographic information and assessed parent knowledge and opinions about HPV and vaccination.

Statistical analyses were conducted using SAS software to compute descriptive statistics, encompassing frequencies, percentages, means, and standard deviations, thereby summarizing the data and revealing trends.

Qualitative Data Analysis

Analysis followed modified grounded theory and content analysis methods (Charmaz, 2014; Elo & Kyngäs, 2008). Each interview followed an IRB-approved interview guide, was transcribed, and coded for analysis. Transcripts were coded for recurrent themes, with a preliminary codebook developed based on emerging codes. As new

themes were identified and organized, the codebook was refined until a master codebook was finalized (MacQueen et al., 1998). This codebook was then applied to every transcript. Weekly meetings took place to ensure consistency in coding by team members and to resolve discrepancies. Identified themes are described in the results and represented by model quotes. This research protocol was approved by the IRB.

RESULTS

Quantitative Data

Characteristics of Enrolled Parents in Parent Study

Researchers analyzed data from 100 parents enrolled in the larger study, the results are summarized in Table 1. Parental age exhibited a diverse range, with ages spanning from 20 to 61 years. Many parents fell within the age range of 30 to 42 with a mean age of 36 years (SD=8.27). Female parents predominated, representing 83.33% of the respondents, followed by males at 14.58%, with a minor percentage identifying as non-binary. Ethnicity data: African American (57%), Hispanic (15%), White (4%), Asian (2%), and Other (22%). Preferred languages included English (66%), Haitian Creole (18%), and Spanish (4.12%). 44% of parents were born in the US, while others hailed from countries such as Haiti (25%) and the Dominican Republic (23%). 44.33% of parents had completed college or university, and 39.18% completed high school. 98.94% of parents reported having health insurance.

Most parents relied solely on healthcare providers for health information (50.53%), with a combination of healthcare providers and Internet/Google searches being the next preferred sources (13.68%) in seeking health information. There were missing values in several variables of provided data across different categories. Specifically, there

were missing values in the variables related to age, gender, ethnicity, country of birth, language preference, and health information.

Characteristics of Children Enrolled in Parent Study

Researchers analyzed data from 100 children enrolled in the larger study (see Table 1). The age range of the children spanned from 4 to 8 years, with a mean age of 6.01 years (SD = 1.49). Gender distribution among the children was nearly balanced, with 52% male and 47% female participants. Ethnicity data: African American (58%), Hispanic (18%), White (4%), Asian (1%), and Other (19%). The majority of children (81%) were born in the United States, with smaller numbers originating from countries such as Chile (7%), Haiti (6%), Brazil (3%) and Dominican Republic (2%). Regarding language preference, 68% of the children preferred English, and 7% preferred Haitian Creole, with the remaining participants indicating preferences for various combinations of English, Spanish, and Creole. Additionally, 96.84% of the children were covered by health insurance.

Baseline Characteristic (N=100)	Child		Parent	
	Freq	%	*Freq*	%
Age Mean(SD)	6.01 (1.49)		36 (8.27)	
Gender				
Female	52	52	80	83.33
Male	47	47	14	14.58
Ethnicity				
African American	58	58	57	57
Hispanic	18	18	15	15
Others	24	24	28	28
Language				
English	68	68	66	66
Haitian Creole	7	7	18	18
Others	25	25	16	16
Country				
USA	81	81	44	44
Haiti	6	6	25	25
Dominican Republic	2	2	23	23
Others	11	11	8	8
Highest level of Education Attained				
College/University			43	44.33
High school			38	39.18
GED			12	12.37
Health insurance				
Yes	92	96.84	93	98.94
No	3	3.16	1	1.06
Health Information Sources (select all that apply)			48	50.53
Healthcare Provider				
Healthcare provider & Internet			13	13.68

Table 1: Demographic Characteristics at Baseline

Characteristics of Interviewed Parents

Of the 28 parents who fit the inclusion criteria, researchers were able to contact fourteen via telephone to obtain consent. Of these individuals, twelve consented to be interviewed. Two parents who declined to participate cited time constraints or disinterest. Of the parents who consented, eight attended interviews, and four did not attend interviews. See Table 2.

Characteristics of Interviewed Children

Of the parents who consented to be interviewed, four had children who were eligible for recruitment. Of these four parents, three agreed to have their children participate in the interview process. The one parent who declined to participate cited time constraints due to school and a lack of confidence in their ability to remember the enrollment appointment. In total, three children participated in qualitative interviews. See Table 2.

Baseline Characteristic	Child (N=14)		Parent (N=8)	
	Freq	%	*Freq*	%
Age mean (SD)	6.64 (1.59)		41.5 (10.96)	
Gender:				
Female	8	57.14	1	12.5
Male	6	42.86	7	87.50
Ethnicity:				
African American	11	78.57	5	71.43
Hispanic	1	7.14	1	14.29
White	2	14.29	1	14.29
Language:				
English	13	92.86	7	87.50
English, Haitian Creole	1	7.14	1	12.50
Country:				
USA	14	100	4	50
Haiti			1	12.50
Dominican Republic			1	12.50
Others			2	25.00
Highest Level of Education:				
Primary				
High School			1	12.50
GED			2	25.00
College/University			1	12.50
			4	50.00
Health insurance				
Yes	11	100	8	100
Health Information Sources (select all that apply):				
Healthcare Providers			3	50.00
Healthcare Providers, Friends, Family, Social Media			1	16.67
Healthcare Providers, Family			1	16.67
Healthcare providers, Family, Social Media			1	16.67

*Note: 1 missing for ethnicity. 2 missing for health information sources.

Table 2: Demographic Characteristics of Participants at Baseline

Variable (N=8)	QUANTITATIVE *Freq* %
Prior Knowledge of HPV Vaccine?	
Yes	5 (62.50)
No	3 (37.50)
If Yes, Which Information Source(s)? (select all that apply)	
School	1(16.67)
Health Care Provider	3(50.00)
Health Care Provider & Internet	1(16.67)
Health Care Provider, Family, Friends, TV	1(16.67)
Prior Knowledge of HPV	
Yes	3 (37.50)
No	2 (25.00)
Not sure	3 (37.50)
HPV Vaccine Protects from 9 Types of HPV	
True	4 (50.00)
False	1 (12.50)
Not sure	3 (37.50)
HPV Vaccine is 2 Doses	
True	5 (62.50)
False	1 (12.50)
Not sure	2 (25.00)
Received HPV Vaccine Themselves:	
Yes	1 (20.00)
No	1 (9.09)
Not sure	3 (60.00)

*Note: 2 missing for vaccine sources. 2 missing for health information sources.
2 missing for received HPV vaccine.

Table 3: Quantitative Data for Interviewed Parents

Characteristics of Interviewed Providers

Of the five providers who were asked to participate in the interview process, four agreed to participate in the interview process. In total two providers participated in the interview process. Those who did not participate in interviews cited time constraints and will be scheduled in the future for this ongoing study. Of the two providers, one was Haitian American, and one was White. Both providers were female.

Qualitative Data

Parent Interview Themes and Subthemes

1. Motivating Factors to Vaccinate:
    - Attainment of Long-Term Protection Against HPV
    - Perceived Susceptibility to Disease/Cancer
    - Means of HPV Transmission
    - Knowing Someone Affected by Cancer
    - History of HPV Vaccination
    - Taking Preventative Action for Child
    - Securing Peace of Mind
    - Trust in Provider
2. Vaccine Decision-Making Process:
    - Weighing Risks to Benefits
    - Desire to Make an Informed Choice
    - Seeking out Further Information
3. Preferred Source for Vaccine Information
    - Provider
    - Internet/Social Media
    - School
4. Recommendations to Improve Vaccine Uptake and Parent Knowledge:
    - Uninterrupted Vaccine-Specific Information Sessions
    - Preferred Communication Method
    - Empowering Parents to Seek Information
    - Share Social Responsibility to Protect One's Community

Motivating Factors to Vaccinate

Motivating factors to vaccinate included the following subthemes, attainment of long-term protection, perceived susceptibility to disease/cancer, means of HPV transmission, securing peace of mind, knowing someone affected by cancer, and history of HPV vaccination. See Table 4. A desire to mitigate future cancer risk by providing long-term protection via the HPV vaccine was strongly shared among parents. Parents endorsed an understanding that their children are susceptible to severe diseases, including cancers later in life that can be caused by HPV infection. This was especially true for parents who knew someone affected by cancer. Parental comment: “Personally, I feel the earlier, the better [to vaccinate] cause you, you never know when cancer could pop up in your child's life. It could be at 9, 10, 11, and then it will be a little too late … And I only say that because I've my little cousin, he has colon cancer. And they could have caught this when he was a baby ‘cause he was having issues with his colon, but they never paid attention to it until it was a little too late.”

Another major subtheme that promoted participation in the study involved parents’ history of vaccination against HPV. If a parent had been vaccinated themself, they felt an increased motivation to have their children receive equivalent protection. Moreover, parents with additional children who have already been vaccinated against HPV had an

increased comfortability with the HPV vaccine and therefore felt more comfortable with their younger children receiving equivalent protection as their older siblings at a younger age. “I've chosen to vaccinate because I have two older kids. I have seven kids in all and I have an 8-year-old boy and an 11-year-old girl who do have the vaccinations, so I am familiar, and that's why I chose to vaccinate my boy.” Research Assistant’s noted that parents with a history of HPV vaccination questioned researchers during recruitment as to why we were vaccinating for HPV earlier than currently recommended. “Actually, I was a bit off guard with the HPV start, cause like, I said, growing up I was given the shot between, I wanna say 12 and 13. So yes. Then they move down to like 9. And then. Now you're testing me out in 4 to 8.” This parent added that she was open to the idea but needed further information. “It's like, we've come so far into medicine. But like I wasn't really hesitant. But I needed to hear more to be like, okay, I'm gonna do it. I mean, cause I had it. So why not give my kids the chance to be better vaccinated than what I was at my age.”

Investigators found that a primary motivator to vaccinate early was a need to take preventative action for their child. Common sentiments included parents’ fear of waiting until it was too late for maximum protection, the need to avoid potential delays or complications with the vaccination process, desire to protect at an age when they are more

susceptible to contracting diseases due to an undeveloped immune system and knowing that if a cancer did arise in the future, preventative actions were taken.

Parents desired peace of mind, knowing that they did everything they could to protect their children from HPV, at a time when it is the parent's responsibility to make medical decisions for their children. "Even if cancer does pop up, or in life later down the line, you still know you went above and beyond to try to prevent it and not feel like you, oh well, they asked me, and I was like, no, and now you know, it's happening."

Parents cited trust in the provider/principal investigator as a significant reason for enrolling in the study. The consent process during which parents spoke with the principal investigator was optimal for answering parent questions and resolving lingering doubts. Parents overwhelmingly reported that the enrollment process was easy, and the vaccination process was "quick" and "nonpainful." Following vaccination, parents were content with their decision and endorsed that provider follow-up calls were positively viewed and further solidified their decision to vaccinate.

Vaccine Decision-Making Process

The vaccine decision-making process included the following sub-themes, weighing risks to benefits, desire to make an informed choice, and seeking out further information. See Table 4. In deciding whether to vaccinate, parents often endorsed that they attempted to measure the benefits and risks of vaccination. Parents claimed that through this process they found the benefits of vaccinating at an early age significantly outweighed the risks. As one mother stated, “Personally, I think I did [make the right choice to vaccinate] because I can only try to you know better her and I try to not hurt her. That was my main aspect of the whole thing. Like it wasn't something to hurt her, it was something to better her later down the line, or like help her prevent certain things.” As this was an optional research study, there was an added variable in the decision. Ultimately, parents deemed that their initial hesitations were not enough to prevent them from vaccinating. For them, the potential benefits made the study worth participating in. “I know it's a study, but you know there was only so many things that could go wrong. Nothing like risk [of HPV infection]. You know what I mean. And to take that risk to protect them in the long run, of course, I'd do it again.”

A popular piece of information that improved parent confidence in the necessity of HPV vaccination was learning that HPV can be contracted via skin-to-skin contact. As one parent described “children

are like human germs. Everything. It's like everything gets to them. You know what I mean. They're touching this. They're touching that. You gotta constantly wash their hands sometimes, you know, you can't get to them fast enough before they put it in the mouth." This led to her desire to protect her children as early as possible, "I think that you know, to protect the children early on is amazing. Before that they, you know, they aren't even thinking about the sexual. And with that HPV, you know, you can get that without sexual contact. So that was a big thing for me, just like you know, if they came up with something for that, hand, foot, and mouth, or you know, different things like that, that spread very quickly between our children. I would do it."

It was important for many parents to learn about the human papillomavirus, its associated cancers, and vaccine information before deciding to vaccinate their child. Information provided by researchers during the recruitment process was positively received by all parents. "He [Research Assistant] broke everything down like to the tee like I wouldn't change anything. It's the way he linked it. I just, you know, wanted him to give me a day or two to speak back to the doctor to make sure this was okay. But no, the way it was brought was perfect." After speaking with a researcher, parents often followed up with a conversation with their pediatrician to gain their input. This conversation could be supplemented by the primary investigator.

When asked whether they believed their children should be a part of the initial vaccine conversation, parents stated that in the future they would want their child(ren) to be a part of the conversation. However, while they are young, it is the parent's duty and responsibility to make such decisions. Once their children can understand new knowledge and make rational decisions, they are happy to include them in the conversation. One parent believed that understanding immunization benefits may not be feasible until the age of 16, and maybe even 18. Since protection against severe disease was a primary motivating factor for parents, discussions on the ability to improve immune response initiated by the HPV vaccine by vaccinating at age 4–8 helped to communicate benefits.

Preferred Source of Vaccine Information

Some parents had previous background knowledge on human papillomavirus that they received from three major sources, providers, internet/social media, and school. See Table 3. Of these sources, providers ranked highest among sources of vaccine information. One parent spoke of learning about HPV at school during her mandated health education course. A course that she claims no longer exists for her children. "First time was at school when I was younger. … So yes, growing up we had sex ed, so they taught us all these things. They don't

give sex education now in schools." Parents exhibited motivation to learn further about vaccines given a convenient opportunity. They understood the importance of this decision and wanted to make an educated choice.

Recommendations To Improve Vaccine Uptake and Parent Knowledge

Major subthemes that emerged from parent recommendations included uninterrupted vaccine-specific information sessions, preferred communication methods, empowering parents to seek information, and understanding there is a shared social responsibility to protect one's community.

Since vaccine conversations between parents and providers are often brief due to the time constraints of routine pediatric visits, parents expressed a desire to attain information at a time outside of the main visit before making a vaccine decision. Vaccine priority may also be limited if more than one child is being seen, it can be difficult for parents to acquire sufficient vaccine information. This was emphasized by a parent of seven, who recommended that offices hold informative virtual sessions on weekends. "Appointments experience it's like a busy thing. You're trying to do that [speak about vaccines] plus whatever so you know the appointment you want to keep it specifically what it's for. If people have time to do that extra they learn more about vaccines, but I

think if you find a different way maybe on Zoom, Zoom is like popping, to have them sign in like on Saturday to learn about you know the vaccines."

Investigators asked parents which media form was best for spreading information. Answers consistently endorsed video format since they provide a quick and effective way to obtain necessary information at one's convenience. "I think maybe more visual, like a video maybe, to like educate parents who don't have all the children like myself. Speak on everything about it, the foundation, and when, where it's at now, I think that will help with again to make people familiar and comfortable with the vaccine." As this parent alluded to, we found that many parents with older children often had some knowledge of HPV and the HPV vaccine from previous vaccine counseling sessions for their other children. First-time parents of children between four and eight had yet to have conversations with their pediatrician regarding the HPV vaccine and therefore often did not have any background.

Parents with multiple children often endorsed that their previous knowledge of HPV came from pediatric visits for their older children who have already received the HPV vaccine. "I was a mom at 14, and there's a lot of things that I didn't know, you know. But throughout the years I learned a lot of things, and that's why I know something like this is great for our children." Points of knowledge they wished to share with new

parents included that HPV is transmissible by means other than sexual contact such as skin-to-skin contact, HPV is widespread across all communities regardless of race, demographic, or socioeconomic status, and that HPV is most effective at cancer prevention when administered before first viral infection. “And not just African American children, all children, because it's everywhere. It's in every race, it's in every neighborhood. It's not, you know, it's not singling out one neighborhood or one race. It's spreading, like if you, if you pay attention. And if you read about this, you'll see. It's a lot of young people, lot of older people. you know, and at times cancerous.” This parent encouraged other parents, especially young parents, to seek out education about HPV through available readings and to pay close attention when their pediatrician brings up the topic. Emphasis was highly placed on the need for broad awareness and action to help protect communities from HPV.

Themes	Example Quotes
Motivating Factors to Vaccinate	"Children are like human germs. Everything. It's like everything gets to them. ... They're touching this. They're touching that you gotta constantly wash their hands sometimes, you know, you can't get to them fast enough before they put it in the mouth, ... they're in contact with so many different things. ... I thought that the HPV Vaccine at 4, 5 years old was amazing." It's just easier to when they're young. You get it out the way compared to when they're older." "I'm glad I had the option for them, with my other children I didn't have the option, and I wish I did because I coulda protected them at an earlier age." "I raised two of my brothers' kids as well, and they're teenagers. I think they got that shot after having sex." "Because why am I gonna wait to prevent something that's about to happen. It's gonna happen. ... That's why I'm the guardian. That's why, I have the choice to make these choices for you for your wellbeing." "An 8-year-old cannot make an informed decision about a vaccine. Even a 10-year-old cannot. I don't even, I don't know what the age cutoff is, but an 8-year-old certainly cannot. Even at 16 maybe not." "At the end of the day you as a parent have the last say, you know, but I think it's important that we do educate them, um, and try to make them understand as best as we can." "Personally, I feel the earlier, the better cause you. You never know when cancer could pop up in your child's life, it could be at 9, 10, 11, and then it will be a little too late cause. Not everybody's especially doctors. They're not out there to check for cancer. They're there to make sure that the child is 100% safe and healthy, but nobody's actually well, let's test for cancer. Let's test for this until it's a little too late."
Vaccine Decision Making Process	"I can only try to you know better her and I try to not hurt her. That was my main aspect of the whole thing. Like it wasn't something to hurt her, it was something to better her later down the line, or like help her prevent certain things." "Just a little bit just because of the age and it's research but I feel like I did the right thing because I have other children outside it not after he's like you know so I think it was a good decision at the end of everything at the end of my thoughts it was a good decision."

Table 4: Representative Quotes from Parent Interviews

Themes	Example Quotes
Preferred Source for Vaccine Information	"Well, the person who first brought it to me was, Dr. Joseph, yeah. She was the one that reached out to me and told me about it. It was very self-explanatory how she, you know, explained it to me. She just really opened my eyes into certain things. So, it was more like something I would do for my own children if I have a chance to, you know. … If it wasn't for her, I wouldn't never got my daughter vaccinated for COVID. So, these certain things like that were very helpful to get her aspect on it. ""First time was at school when I was younger. ... So yes, growing up we had sex ed, so they taught us all these things. They don't give sex education now in schools."
Recommendations to Improve Vaccine Uptake and Parent Knowledge	"Appointments experience it's like a busy thing. You're trying to do that [speak about vaccines] plus whatever so you know the appointment you want to keep it specifically what it's for. If people have time to do that extra they learn more about vaccines, but I think if you find a different way maybe on Zoom, Zoom is like popping, to have them sign in like on Saturday to learn about you know the vaccines." "I think maybe more visual, like a video maybe, to like educate parents who don't have all the children like myself. Speak on everything about it, the foundation, and when, where it's at now, I think that will help with again to make people familiar and comfortable with the vaccine." "I was a mom at 14, and there's a lot of things that I didn't know, you know. But throughout the years I learned a lot of things, and that's why I know something like this is great for our children. And not just African American children, all children, because it's everywhere. It's in every race, it's in every neighborhood. It's not, you know, it's not singling out one neighborhood or one race. It's spreading, like if you, if you pay attention. And if you read about this, you'll see. It's a lot of young people, lot of older people. you know, and at times cancerous." Well. I would just, I would just say, you know, get in the parent's ear and let them know how this is out here. You know what I mean. This is out here. It's not just sexual, you know you have. If you have children using bathrooms, if you have children touching stuff that you just protect your children. That's what I would tell them, you know. Give them the, you know, different scenarios, and just let them know like it's real. It's not fake. This can turn into a cancer. But the things that are preventable just go that extra mile for your children. It's worth it.

Table 5: Representative Quotes from Parent Interviews

Themes and Subthemes Regarding Children's Experience

1. Parental Report of Conversation with Children about HPV and Visit
    - Yes/No
    - Varying Conversation Depth (brief vs detailed)
    - Age-limitation

2. Self-Reported Barriers to Vaccination
    - Fear of needles
    - Dislike of vaccines

3. Facilitators of Vaccination in Children
    - Parent Support
    - Trust in Provider
    - Comfort with Research Staff
    - Gift Receival
    - Awareness of Vaccine Benefits

4. Children's Preferred Communication Methods
    - Video vs Cartoon Booklet

5. Self-Reported Reason for Thumbs Up/Why assent to vaccination
    - Desire for Protection
    - To Maintain Health

Parental Report of Conversation with Children about HPV and Visit

Most parents endorsed speaking to their child about the reason for going to the clinic on the day of vaccination. Reported conversations with their children were often brief, highlighting the need for vaccinations to protect oneself and remain healthy. “So, the way I have worded it to my children. Honestly, you're gonna go get a vaccine that's gonna protect you for the rest of your natural-born life. That's how I worded it to them. I didn't tell them what type. I will have to explain it to them in a when a bit older, because right now my children are younger so they wouldn't understand.” Whereas another parent felt that limited detail was ample. “No, I just said, oh, you know, we need to get a couple of shots today. … They at the time were like 8 and a half, … obviously, they don’t know HPV, and I really didn't feel the need to go into any detail with them.”

Self-Reported Barriers to Vaccination

Ahead of the enrollment appointment, parents reported that their children had increased anxiety and nervousness due to their fear of needles and belief in the pain of injection. In one child’s own words, “To be honest, I don't like vaccines.” We asked parents whether their child’s fear of needles influences their choice to vaccinate, and subthemes of yes or no were stated. Many endorsed that it is on their mind during the decision process. As one parent stated, “I have to make sure it's actually

worth it because I don't want to put them through that, if they don't have to go through it." In the end, the most common subtheme was "No" as parents were more concerned about the worthiness of the vaccine. In this case, the benefits outweighed the risk of fear of needles. Children's reactions to the second dose compared to the first were either equivalent, improved, or slightly worsened. "After the second time, my daughter got it. She started like, oh, mommy, I think there's a book on my arm, or I think it was just like more paranoia compared to the first."

Facilitators of Vaccination in Children

Mediators that improved the experience for children during vaccination included parent support, trust in the provider, comfort with research staff, gifts received, and awareness of vaccine benefits. For the children, parent endorsement was a significant factor in gaining acceptance. "So, we kind of went over it. And she wasn't mad about it, she was just nervous. That was her main thing. Yeah, she didn't want it to hurt her, or just the thought of pain that was the main thing that was on her head. But once I mentioned, you know, it could prevent certain cancers and stuff. She was really on board."

Children's Preferred Communication Strategies to be Informed About the Study and HPV Vaccine

Before asking for the child's consent during the enrollment appointment, researchers reviewed with the children an informative, cartoon booklet describing the importance of vaccination in terms we believe to be understandable for our age cohort. We asked the children whether they liked our booklet and if it could be improved via a different media form resulting in a theme of children's recommended communication/messaging strategy for other children. The most common subtheme was video, indicating that the children thought a video form of vaccine information would have been better than the booklet. To evaluate whether the booklet was effective, we asked the children how they would explain why vaccines were important to a friend or sibling. Major themes included the need for protection and to keep oneself healthy. "I would say. I think it is good for you to get this vaccination, because so you could stay healthy. And you could like prevent this from happening."

Self-Reported Reasons for Thumb's Up/Why Assent to Vaccination

As stated in the Pediatric HPV Study protocol, vaccination would not occur without verbal consent from the child. During our interviews with the children, we asked them why they consented by providing a thumbs-up signal. Despite common dislike for shots, we found that children ages 7 and older had begun to develop a rudimentary understanding that vaccination is necessary. When we asked one child why they gave a thumbs-up, she stated she did so, "because I wanted for me to, for me to get better." It has yet to be seen whether this basic understanding of necessity is enough to overcome trypanophobia. Her mother believed that she would not have been as accepting if it were not for a developed patient-provider relationship. "My daughter is already her previous patient. She admires Dr. Joseph. So even just like sitting with her and actually talking back and forth with her, really helped her to actually say yes. Compared to other doctors, she just look at them and say no, I think if it was somebody else she would have said no, but she's known Dr. Joseph since she was in my stomach. So, it was more of a comfortability with someone she knew." In this case, the consent process was improved by a longstanding relationship between the patient and the principal investigator (past provider).

Provider Interview Themes and Subthemes

1. Addressing the HPV Vaccine
    - Cancer Prevention
    - Risk to Benefit
    - Time-Limitations
    - Counseling from Outside Sources
2. Recognized Barriers to Vaccination in an Urban Area
    - Socioeconomic Factors
    - Health Literacy
    - Diverse Patient Population
3. Recommendations for Recruitment and Improving Acceptance
    - Addressing Social Determinants of Health
    - Understanding Differences in Patient Populations
    - Developing Trust
    - Parent Autonomy
4. Provider Impression on Children's Autonomy
    - Parent Focus vs. Child Focus
    - Impact of Fear of Needles/Shots
6. Feasibility for Providers to Offer HPV Vaccine at Early Childhood
    - Potential Initial Difficulty but Worthwhile
    - Experience with Updated Recommendation
    - Grouping Vaccinations is a Positive

Addressing the HPV Vaccine

Major subthemes that emerged among providers regarding methods for addressing HPV vaccination included focusing on cancer prevention and highlighting benefits. See Table 6. As one provider stated, “I just sort of talk about it in general as a way of cancer prevention. It's a, you know, a common cause of cancer, in young people. And this is a way to prevent it. And it's, you know, low stakes and low risk and low harm.”

Another important subtheme included awareness of time limitations during examinations. Providers appreciated the research assistants’ efforts to educate parents at times outside of the main visit. “I agree yes, it's better to have someone else to talk to them. And sometimes they may ask OK I'd like to talk to my provider to see what they think about it. And yes, it's very good to have someone else who has more time, and some paper [recruitment flyer] to show them and they can have a handout to go home to review then go from there.”

Recognized Barriers to Vaccination in an Urban Area

As providers who serve a highly urban patient population, they noted during interviews that they must be aware of the socioeconomic factors and limitations of health literacy that may affect their diverse patient population. See Table 6.

Recommendations for Recruitment and Improving Acceptance

Recommendations by providers to improve recruitment and HPV vaccine acceptance included addressing social determinants of health, understanding the different dynamics of patient populations, fostering trust between patients and research staff, and maintaining parent autonomy. See Table 6. One provider endorsed that she believes a vaccine trial should always maintain participant autonomy and ensure beneficence. "My only thoughts are the same thoughts I have had for any vaccine trial, which is you know, making sure that this is, you know, especially in our population, presented in a way that is appropriate and fair to patients that it offers them. You know, compensation enough, compensation of time, money, whatever transportation, to make it not feel like an additional burden on them with all the priorities within their healthcare, and that it's presented in a way that is cognizant of language and cultural you know, barriers."

Provider Impression on Children's Autonomy

Major subthemes that emerged exploring patient autonomy during a young age included directing conversation focus on the parent rather than the child, and awareness of the fear of needles on the patient's personal decision to vaccinate. See Table 7. One provider stated she keeps the conversation directed at the parent, which allows further conversation to occur between parent and child. "I tend to focus most of my counseling on the parents, and just kind of be very kind of like this is to keep you safe. I kind of let, I talk mostly to the parents, and I let them do most of the talking to the kids."

Feasibility for Providers to Offer HPV Vaccine at Early Childhood

Major subthemes that emerged among providers' belief in the feasibility of initiating new recommendations for HPV vaccine included awareness of potential initial difficulties, experience in adapting to updated recommendations, and preference for grouping vaccinations among a single visit. See Table 7.

Providers stated that if recommendations were updated, it would be feasible for their practice to begin vaccinating at age four. Yeah, I mean, it's just another vaccine. Year 4 is a big year for vaccines. … vaccine recommendations change all the time, and we incorporate them

and stay up with it. This is, sort of the way things work, so I don't have any particular concerns."

Providers acknowledge that age four is a popular time for giving other vaccinations. However, they believe grouping vaccinations is beneficial for ensuring series completion of all recommended vaccines. "I would say together is better because just asking the parents to come back to get the shot only, it could be hard to come back it would be more convenient for them to get it at the same time."

Themes	Example Quotes
Addressing the HPV Vaccine	"I do. I just sort of talk about it in general as a way of cancer prevention. It's a, you know, a common cause of cancer, in young people. And this is way to prevent it. And it's, you know, low stakes and low risk and low harm." "I was mostly about the cancer part. I said it would be good to have it because it can prevent cancer and when you say that they're very open about it." Yes, there's just the time is way too limited to do anything in depth during a physical, so yeah, I would agree with that approach [to have another source, such as a research assistant] present initial HPV vaccine information." "I agree yes, it's better to have someone else to talk to them. And sometimes they may ask OK I'd like to talk to my provider to see what those what they think about it. And yes, it's very good to have someone else who has more time, and some paper [recruitment flyer] to show them and they can have a handout to go home to review then go from there."
Recognized Barriers to Vaccination in Urban Areas	"I think there's lots of barriers to good primary care for children in Boston that are all related to social economic factors." "The only thing specific to HPV would just be kind of that level of health literacy."
Recommendations For Recruitment and Improving Acceptance	"My only thoughts are the same thoughts I have had for any vaccine trial, which is you know, making sure that this is, you know, especially in our population, presented in a way that is appropriate and fair to patients that it offers them. You know, compensation enough, compensation of time, money, whatever transportation, to make it not feel like an additional burden on them with all the priorities within their healthcare, and that it's presented in a way that is cognizant of language and cultural you know, barriers." "My initial thought was its early in my community. You know I see mostly Haitian patients and I was saying like doing this study in this group of Haitian they will be quite reluctant to participate. But I'm very excited about it to start at an early young age I'm very happy about it but for my community it would be very hard to convince them to take the vaccine at this age. They will say why, she's only 4, why does she need it know?" "I think I've gotten less pushy over time, because I think that the most important thing to feels always like preserving the trust in our relationship, and having patients feel like they have autonomy. And it sometimes it's felt like I'm going to break that trust if I push harder than I do."

Table 6: Themes and Representative Quotes from Provider Interviews

Themes	Example Quotes
Recommendations For Recruitment and to Improve Acceptance Continued	"Conversations mostly these days about Covid more than any other vaccine and, and I sometimes mentioned that I feel really safe about it for myself and my own kids that we were, you know, we were all fortunate to get all the doses of the Covid vaccine and that I feel really good about the state of the evidence, and that you know, and kind of empathize with their feeling anxious and how hard it is to weed through bad information online. And then I'm ready and willing to talk through all of their concerns, if they have any specific ones." "I was saying mostly about cancer part. I said if you would be good to have it because it can prevent cancer and when you say that they're very open about it."
Provider Impression on Children's Autonomy	"I mean, you know, no kid wants a vaccine. And sort of frustrates me when parents like kind of defer, like with the Covid, when they're like, I don't know 10-year-old do you want it? Like of course they don't want it. And I, I tend to focus most of my counseling on the parents, and just kind of be very kind of like this is to keep you safe. I kind of let, I talk mostly to the parents, and I let them do most of the talking to the kids." "Most of the time they [children] are here to listen. I remember once when I talked to them about the vaccines and Mom said "no" and the child said, "yes I would like to get it Mom." They are, but you know at four they won't be able to understand much but at 11,12 they do understand, yes. And sometimes the parents ask the child what do you think if you want to get it or not … Usually they say yes, but sometimes, sometimes just for thinking about taking a shot they may say no, but sometimes they say yes."
Feasibility for Providers to Offer HPV Vaccine During Early Childhood	"Yeah, I mean, it's just another vaccine. Year 4 is a big year for vaccines. … vaccine recommendations change all the time, and we incorporate them and stay up with it. This is, sort of the way things work, so I don't have any particular concerns." "I think yes, it could be hard at the beginning but in the long term yeah maybe in the future it would be easier." "I like to give them together as much as possible up to 4." "I would say together is better because just asking the parents to come back to get the shot only, it could be hard to come back it would be more convenient for them to get it at the same time."

Table 7: Themes and Representative Quotes from Provider Interviews

DISCUSSION

This study describes productive ways to adapt recruitment conversations, improve children's understanding of the benefits of HPV vaccination, and address provider-identified barriers to vaccination to improve HPV vaccine uptake.

Parents in this study were overall supportive of vaccination. Many endorsed that they initially felt reservations, due to this being a research study. Parents cited trust in the provider/principal investigator as a significant reason for enrolling in the study. This is in line with numerous studies that found providers to be the most important source of vaccine information (Rahman et al., 2015)(Dempsey & O'Leary, 2018) (Rosenthal et al., 2011)(R. B. Perkins … Pierre Joseph, et al., 2010). Data obtained in this study indicates that developing a strong provider-patient relationship may also be an important factor in improving children's trust and willingness to accept HPV vaccination. Investigators found that fear of needles, known as trypanophobia, was quite common for this age cohort. In creating positive experiences with vaccines, providers can foster healthy living norms that will continue into the patient's adolescence and adulthood.

Before the arrival of a final decision to enroll, parents attempted to attain satisfactory information to make an educated decision (Holman et al., 2014). Interviewed parents came from varied cultural backgrounds

and educational attainment, yet they all shared a similar desire to learn scientific evidence that would support their decision to vaccinate (R. B. Perkins … Pierre-Joseph, et al., 2010). To facilitate this learning, both parents and children believed the best format for education would be via informational videos.

Parent perception that their children were susceptible to severe diseases, including cancers that can be caused by HPV infection promoted vaccination at a young age. Overwhelmingly, parents endorsed feeling an obligation to protect their child as their primary caretaker. Given that prior literature has shown that emphasizing negative information can be harmful to a vaccine conversation, researchers decided to not pursue further questioning regarding sexual activity (Nyhan et al., 2014). However, many parents in our study endorsed that protection from STDs was a motivator to vaccinate. Parents are aware that their child will become sexually active in the future, yet since they have yet to reach puberty there is no discussion as to whether their child may or may not be sexually active which many providers indicate makes HPV vaccine counseling more difficult (R. B. Perkins … Pierre-Joseph et al., 2014). This allowed recruitment to focus purely on preventative measures that are fully up to the parent's control and not influenced by the patient.

The findings of this study are subject to limitations. A small sample of participants who receive pediatric care at Boston Medical Center were included in this study. BMC is a safety-net hospital within a highly urban setting. This limits our ability to generalize findings to those outside of this hospital network, including private healthcare settings, and other geographic regions. Additionally, recruitment did not include parents who declined to enroll their children during the recruitment process of the Pediatric HPV Study. Those who declined to vaccinate their children at ages 4–8 may represent an important group in understanding acceptance of early childhood HPV vaccination. Additionally, the time interval at which children were interviewed following enrollment varied which may lead to forgotten information. Finally, interviews were only completed with children ages 7 or 8 at the time of enrollment due to their increased comprehension ability compared to younger ages.

Opportunity for Future Study

The Pediatric HPV Study is currently ongoing having enrolled 123 of 150 patients. Therefore, researchers of this qualitative improvement will continue to recruit parents, children, and providers who are newly participating. As more data is coded and analyzed the results of this study may be modified.

As a proof-of-concept study, it is the team's goal that other clinical trials will occur to confirm our results and allow for further generalization across race and demographics.

CONCLUSION

Routine HPV vaccination of children aged 4–8 is enthusiastically accepted by parents and feasible for providers. By adapting future recruitment conversations to better relate with a diverse patient population, investigators may be able to increase HPV vaccination uptake. In doing so, researchers will help to diminish provider-identified barriers to vaccination and facilitate protection from HPV-associated cancers.

Implications for Practice and Policy

Providers remain the most trusted source for vaccination. When discussing HPV vaccination with parents of children aged four and older, practitioners should emphasize HPV is widespread across all communities, among both males and females and can be contracted by means other than sex. Parents understand that their children are at risk for developing diseases and confidence can be significantly improved with ample vaccine information. Time constraints may limit the depth of this conversation, which is why researchers, at the advice of interviewed parents, recommend providing further options for parent learning at a time that will allow ample learning and conversation to address questions and concerns.

APPENDIX

Recruitment Script for Investigator-Initiated Contact

1. Introduction of Investigator or Research Assistant

   Excuse me, are you (insert name)?
   Do you have a minute? My name is (insert name).
   I am a Research Assistant at Boston Medical Center, and I am working on a research study with Dr. (Insert name).
   As a current participant in an early childhood HPV vaccine study, you permitted us to contact you regarding additional research opportunities.

2. Immediate opportunity to opt out

   I am speaking with you today to ask if you would be willing to voluntarily participate in a research study. The purpose of this study is to learn parents' thoughts and feelings regarding early childhood vaccination. You should be aware that research is totally separate from the care you are receiving. Also, whether you decide to hear more about the research won't affect your care in any way.

   Is it OK for me to continue?
   - If the individual says "no, not interested" then recruiter will stop, say "thank you" and not continue.
   - If he/she says yes, then recruiter will continue or make plans to revisit at a more convenient time.

3. Why potential subject was selected

   I'm asking you about being in the study because as a current participant in an on-going Pediatric HPV Study, we would like to learn from your experience as to what parents may want to learn before their child receiving the HPV vaccine.
   If you agree, we will ask you to speak with us via a virtual meeting for approximately 30 minutes.

4. Whether he/she is interested in hearing more details.

   So, are you interested in hearing some details about the research study.
   - If the individual says "no, not interested" then the recruiter will stop, say "thank you" and not continue.
   - If he/she says yes, then the recruiter will begin the consent process.

Interview Guide for Parents

1. Why did you choose to vaccinate your child against HPV?
2. Were you aware of how HPV is contracted and the types of cancers that can result?
3. How comfortable are you with talking to your child about the HPV vaccine?
4. What did you tell your child was the reason for visiting the doctor on the day of enrollment?
5. Since your child received the vaccine, have you considered whether you made the right choice?
6. What did you think of the explanation the principal investigator gave to your child? How would you improve it?
7. Did knowing the principal investigator would call you following the appointment to check on your child affect your decision to vaccinate? How did you feel about the call?
8. Has your sentiment towards early childhood vaccination changed at all since participating in the study?
9. Did you tell anyone else about our study? What did you say? What was the response?
10. How was the research assistant's explanation of the study to you?
11. How was the principal investigator's explanation of the study to you? How did her explanation bring more clarity if you were undecided?
12. Do you have any advice for us on how we can introduce our study to other parents?
13. Did you consult with anyone else regarding our study such as your doctor, family, or friends? What about the internet?
14. Some parents want their children to have a say in whether they receive the HPV vaccine and therefore wait until they are old enough to make such a decision. How do you feel about this? Do you anticipate having a conversation with your child once they are older about the reason why you had them vaccinated against HPV?
15. If you elected for your child to receive the Hepatitis B vaccine at infancy, was there something that made you make this decision, such as a conversation with your doctor? If so, what did your doctor say to you? How do you think we can translate that trust into the HPV vaccine?
16. If the HPV vaccine were available for infants, would you have elected to have your child receive the vaccine at infancy?
17. Have you ever turned down any vaccine offered to you or your child?

Interview Guide for Children

1. What do you know about vaccines? Why is it important to receive?
2. What did Mom/Dad say to you about why you needed to be vaccinated?
3. When the doctor was explaining our study, you told us you were ok with participating by giving us a thumbs up. Can you tell me why you did that?
4. If you had to explain the importance of getting vaccinated to your little brother or sister, how would you do so?
5. How do you feel about receiving another vaccine in the future?

Interview Guide for Providers

1. During your time as a physician, have you felt that vaccinating children against HPV is particularly more difficult than with other vaccines?
2. Are there any specific barriers to vaccinating children in Boston?
3. When the primary investigator first introduced our study to you what were your initial thoughts?
4. Did any parents ask your opinion about our study before enrolling?
5. Have you spoken to any parents about their experience in our study after enrolling?
6. As a provider who has limited time during an appointment, was it beneficial for you and your patients to have an outside source, in this case, our Research Assistant, hold an initial HPV vaccine conversation?
7. What vaccine counseling methods/strategies have worked well for you in the past during your conversation with parents about the HPV vaccine?
8. Do you have any advice about speaking with children about the importance of vaccination?
9. Some parents have stated they would be willing to learn about vaccines outside of the routine appointment, how do you think we could accomplish this?
10. Do you think it is feasible to begin vaccinating children against HPV at age 4 at your clinic?
11. Do you have any advice for other providers?

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