Increasing Human Papillomavirus Vaccination Rates Among Adolescents in Primary Care

by

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Abstract

Problem and Purpose

Each year, 33,700 men and women in the United States are diagnosed with a cancer caused by infection from the human papillomavirus (HPV), 90% of which could have been prevented through vaccination. Despite the proven safety and effectiveness of this vaccine, rates of uptake are low nationwide, a mere 53.7% for females and 48.7% for males. The purpose of this quality improvement (QI) project was to implement and evaluate interventions guided by the 4 Pillars™ for Practice Transformation Program, an evidence-based tool-kit shown to increase HPV vaccination rates across settings, including in primary care.

Methods

A bundle of interventions was implemented using the 4 Pillars Program. Pillar 1 Convenience and Easy Access: all patient encounters of those aged 11-18 were used as an opportunity to vaccinate (not just well visits). Pillar 2 Patient Communication: providers issued a "strong recommendation" for the HPV vaccine using the Same-Way Same-Day strategy from the Centers for Disease Control and Prevention (CDC). Pillar 3 Enhanced Vaccination Systems: Immunization status was assessed as part of vital signs and Vaccine Information Statements (VIS) were given to all eligible patients' parents. Pillar 4 Motivation: progress toward improving HPV vaccination rates was tracked and posted in staff break room.

Results

Implementation of this tool-kit resulted in an increase in the HPV vaccination rate from 68% to 76.6%, an 8.6% increase ($p<0.01$). 100% of patients presenting for 11-year-old well child checks were vaccinated ($n=32$). 100% of eligible patients were given VIS and immunization status was assessed as part of vital signs for 100% of patient encounters. There was no real gender difference discovered in the final HPV vaccination rate. Among males ($n=521$), there was a 78% final rate and 76% for females ($n=574$), echoing the closing of the gender gap nationwide. 15 patients who previously refused, consented and were vaccinated.

Conclusion

This QI project demonstrated this vaccination tool-kit is an effective way to increase HPV vaccination among adolescents in primary care.

Introduction

Each year, 33,700 men and women in the United States are diagnosed with a cancer caused by infection from the human papillomavirus (HPV), 90% of which could have been prevented through vaccination (Centers for Disease Control and Prevention (CDC, 2019). Approximately 14 million new cases of HPV are reported annually, half of which are in individuals aged 15 to 24 (Markowitz et al., 2014). It is recommended adolescents receive the HPV vaccine at age 11, when they are due for their tetanus, diphtheria, and acellular pertussis (Tdap) and quadrivalent meningococcal conjugant vaccine (MenACWY) (CDC, 2017).

Despite the proven effectiveness of this vaccine, rates of uptake are low nationwide, a mere 53.7% for females and 48.7% for males (Walker et al., 2019). Healthy People 2020 (2018) has set 80% as the national target immunization rate for the HPV vaccine. While the recent change in recommendation from a three-dose to a two-dose series when initiated prior to age 15 is anticipated to increase compliance, additional efforts are necessary to reach the 80% target (Bernstein & Bocchini, 2017).

Primary care providers are responsible for recommending the HPV vaccine to adolescents but are often confronted with barriers to vaccine uptake. The purpose of this Doctor of Nursing Practice (DNP) project was to implement and evaluate the effectiveness of the 4 Pillars™ Practice Transformation Program in increasing uptake of the HPV vaccine among adolescents in a pediatric primary care clinic.

Literature Review

The American Academy of Pediatrics (AAP) (2020) recommends implementation of multiple strategies for primary care offices to improve vaccine uptake. The CDC (2019), the Immunization Action Coalition (2020), the American Cancer Society (2020), the Community

Preventive Services Task Force (2019), and the Maryland Department of Health (2020) have similar recommendations. Use of population-based interventions such as state-wide school-based vaccination programs and government initiated and required vaccination have been found to produce the highest vaccination rates. However, affecting these interventions exceeded the boundaries of this project. When population-based strategies are not available, as is the case in this project, multipronged interventions, targeting both the provider and the patient are recommended (Walling et al., 2016).

Many different multi-pronged interventions, or tool-kits encompassing differing types of practice changes are available through organizations such as the CDC, the Maryland Department of Health, and the AAP. Through background reading, the 4 Pillars™ Practice Transformation Program emerged as a successful, evidence-based tool for enacting change in regards to vaccine practices through strategies focused on each of the 4 pillars which include convenience and easy access, patient communication, enhanced vaccination systems, and motivation. This program was developed to assist primary care providers to increase vaccination uptake and is adaptable to each individual clinic through the selection of listed strategies within each of the categories, or pillars. This multi-pronged intervention tool-kit includes many of the interventions recommended by the literature such as improving vaccine systems, improving strength of provider recommendation, improving parental and adolescent education regarding the vaccine and disease, and others. Please see Table 1 for a review of the evidence supporting this intervention. Implementation of this program has been shown to result in significant increases in vaccine uptake across settings and populations, including adolescents in primary care clinics.

Current research demonstrates a need to improve adolescent vaccination rates. Familiarity with both the vaccine schedule and the diseases the vaccines target for prevention has been shown to result in improved vaccine rates. A foundation of adolescent preventive health care is timely vaccination; thus, each visit has been recommended to be viewed as an opportunity to update vaccinations (Bernstein & Bocchini, 2017). Health care provider recommendation and attitude have been shown to greatly affect parental decision to vaccinate. Rahman et al. (2015) showed that provider recommendation independently predicted HPV vaccine uptake, with parents preferring a clear, unambiguous recommendation, focusing on cancer preventive benefits of the vaccine. Lack of a strong recommendation has been shown to be the greatest barrier to immunization against HPV (Bernstein & Bocchini, 2017). Other significant barriers include infrequent adolescent visits and lack of awareness of the need for the vaccine (Oster, McPhillips-Tangum, Averoff, & Howell, 2015). The 4 Pillars program addresses each of these barriers.

Zimmerman et al. (2014) conducted a large enough study to analyze individual interventions within the toolkit for efficacy which can prove helpful in developing the individualized plan afforded within the 4 Pillars program. Common recommendations include implementation of many of the strategies within the 4 Pillars toolkit, one study recommended greater than 10 strategies, one reported results based on implementation of 14 strategies. While each study reported increased vaccination rates, Nowalk et al. (2016) documented the ability to maintain increased levels even after study completion, indicating sustainability of intervention.

Limitations within the body of evidence surrounding this intervention include problems with research design and true generalizability due to lack of geographical variation. This body of evidence provided data that was robust with large sample sizes with statistically significant results reproduced across practice settings and among multiple adolescent vaccines including HPV, Tdap, MenACWY, and influenza. Comparing current vaccination rates in the practice of interest with these publications, there is continued need for practice change increasing the rate of HPV vaccination across many population areas.

Theoretical Framework

The Health Belief Model was originally published in the 1950's in response to low rates of screening for tuberculosis. This model has since been used successfully to provide framework for health promotion interventions and to predict behavior with preventive care such as receiving immunizations (Glanz & Bishop, 2010). The Health Belief Model is made up of six constructs. The first two constructs encompass attitudes toward disease including perceived susceptibility and perceived severity. The next two constructs involve attitudes regarding expectations including perceived benefits and perceived barriers. The fifth construct requires a cue to action, in this case a recommendation to vaccinate. Finally, a perception of self-efficacy must be present. This model posits people's beliefs surrounding these constructs predict engagement, or lack thereof, in health promoting behaviors (Gargano et al., 2014).

This framework was applied within the interventions of the 4 Pillars program to maximize efficacy. The vaccine was presented with a strong recommendation, outlining the prevalence of HPV to ensure adolescents feel susceptible. Evidence was presented via discussion and VIS highlighting the cancer preventive aspects of the vaccine to address perceived severity and perceived benefits. To overcome perceived barriers, the system of vaccine delivery was enhanced through assessing immunization status as a vital sign and making vaccination available at each type of visit (not just well visits). The strong provider recommendation using the same-way same-day strategy of adolescent vaccination acted as the cue to action, as uptake for the other two 11-year-old vaccines (Tdap and MenACWY) is much higher than the HPV vaccine (AAP, 2018). Finally, self-efficacy was ensured by offering every eligible patient the vaccine, providing reminder phone calls, and providing VIS. All patients seen at this clinic have insurance coverage, be it private or state assisted, therefore financial burden was not a concern.

Methods

This quality improvement (QI) project was aimed at increasing HPV vaccination rates among adolescents age 11-18, implemented in a private pediatric primary care practice with two providers, one pediatrician and one pediatric nurse practitioner, located in suburban Maryland. In order to affect change, a number of structures and processes at the clinic were targeted for improvement. Please see Figure 1 for a process map depicting the project processes and Figure 2 for project timeline. The first change in structure involved education. Materials from the CDC were utilized to enhance learning. Providers were educated regarding implementing the "Same-Way Same-Day" strategy in order to provide a strong recommendation for the HPV vaccine for all eligible patients at their 11-year-old well child visit. Older adolescents who had not completed the series also received a strong recommendation for the vaccine utilizing the CDC communication sheets (Appendix A). The "Same-Way Same-Day" recommendation is listed at the top of the sheet and is as follows: "Now that your child is 11, s/he is due for vaccinations today to help protect from meningitis, HPV cancers, and whooping cough. Do you have any questions?" The sheet then provides potential parent questions and sample answers. These discussions will also serve to educate the parents and patients, in addition to the VIS which was provided to parents of all eligible adolescents (Appendix B).

The next change was in regards to documentation. In the event of parental decline of vaccine, the provider was responsible for documenting the reason for decline within the electronic health record. In addition, the medical assistants were responsible for documenting if vaccination status was assessed as part of vital signs. The next change addressed communication.

All patients due for the vaccine were notified via a robo-call system and advised to make an appointment to receive the vaccine. Staff motivation was enhanced by displaying a progress tracker publishing progress toward short and long-term goals of the project via run charts. All changes were discussed with staff via in-service training prior to implementation. Appendix C includes lesson plans for staff in-service training. A resource binder including all educational materials was available for staff throughout implementation.

Sustainability was provided for in that clinic leadership requested these changes and selected which specific interventions within the 4 Pillars™ Practice Transformation Program to implement according to the specific needs of this practice. There is no financial risk in taking on this project, nor is there any financial requirements for sustainability as this project is zero cost.

Baseline data was collected via chart review to obtain an initial rate (percentage) of HPV vaccination pre-implementation. Each week during implementation, data was collected to evaluate progress and guide feedback as necessary. This data included if vaccine status was assessed as part of vital signs, eligibility for the vaccine and if eligible, if a VIS was provided, if a strong recommendation was provided, if the reason for parental decline was documented if applicable, and if the vaccine was given. Progress poster displaying run charts was posted in the staff break room. Final data was calculated to obtain rate of HPV vaccination for this clinic. Audit tools (Appendix D) were used to create run charts. Tracking percentage of patients vaccinated against HPV is a measure that is recommended by the AAP, the CDC, the Maryland Department of Health, and nationally via Healthy People 2020.

HPV vaccination rate was calculated using the percentage of patients compliant with the Advisory Committee on Immunization Practices (ACIP) HPV vaccine recommendations. Therefore, the baseline rate was compared to the post-implementation rate to measure change.

Data was analyzed using Chi Square test to calculate a p-value using Microsoft Excel. University of Maryland Institutional Review Board (IRB) approval for a Non-Human Subjects Research (NHSR) determination was obtained prior to project start.

Results

This primary care pediatric clinic was successful in changing key structures and processes in order to implement this QI project. Immunization status was assessed as part of vital signs for 100% of patient encounters. 100% of eligible patients were given VIS upon check in. The Same-Way Same-Day approach of presenting a strong recommendation for the vaccine resulted in a 100% vaccination rate for 11-year-old well child checks (n=32). Of the 103 HPV vaccines that were given during the project (Figure 3), 31% were given at the 11-year-old well child check, 14% (n=15) were to patients who had previously refused, 47% (n=48) were given as subsequent shots in the series to those who were overdue, and 8% (n=9) were given as part of an HPV vaccine specific appointment. Vaccine refusals were also tracked in effort to gain understanding of the reasoning. During the project, 22 patients eligible for the HPV vaccine refused (Figure 4). 27% (n=6) declined the vaccine because they were being seen for a sick visit, as opposed to a well child check or physical. 50% (n=11) preferred to defer the vaccine until it is made mandatory for school entry, and the remaining 23% (n=5) had no reason for refusal documented.

Analysis of the HPV vaccination rate throughout the project revealed continually improving results (Figure 5). Initial HPV vaccination rate in the clinic as a whole was 68% and the final rate was 76.6%, representing an 8.6% increase ($p<0.01$). No real difference in gender was discovered in the final HPV vaccination rate. Among males enrolled in the clinic, (n=521), there was a 78% post-implementation HPV vaccination rate and the rate among females (n=574) was 78%, echoing the closing of the gender gap nationwide.

Discussion

Multi-pronged interventions, such as vaccination tool kits, have been shown to be an effective way to increase uptake of vaccines in primary care (Walling et al., 2016). Tool-kits are most effective when they can be tailored to the specific needs of an organization, as is the case with the 4 Pillars™ Practice Transformation Program. The literature supports this tool-kit as an evidenced-based way to increase HPV vaccination rates among primary care. The results of this project support the literature, finding the 4 Pillars™ program to be an effective way to increase HPV vaccination rates among adolescents in primary care in a statistically significant manner. Results support the following components as part of a bundle of interventions within the 4 Pillars™: use each patient encounter as an opportunity to vaccinate; provide a strong provider recommendation using the CDC's Same-Way Same-Day strategy; assess vaccination status as part of vital signs and provide VIS to all eligible patients; and track progress toward goals to motivate staff. Strong recommendation at the 11-year-old well visit proved 100% effective, echoing literature findings of strong recommendation for vaccine being the single most effective intervention outside of a multi-intervention tool-kit (Rahman et al., 2015).

Multiple factors enhanced the success of this QI project. First, the leadership in the clinic was invested in the change process and selected interventions within the 4 Pillars™ to include in the implementation plan. Second, the clinic had a pre-existing culture of teamwork that resulted in all staff members working toward the same goal. This allowed for shared accountability and a sharing of success. Other reasons for success include the use of free, printable, evidence-based resources from the CDC making the project no-cost.

Limitations of this project included lack of consistent documentation of vaccine refusal. This could be improved through an update in the electronic medical record to include a drop-down menu for reasons for refusal. Currently the only option is “parent refused”. If reasons for refusal are tracked, education and communication efforts can be better focused on combatting those documented reasons. An additional limitation was time constraint. Had the project been extended, the HPV vaccination rate may have risen above the national goal of 80%. Fortunately, the changes in structures and processes were sustainable and the clinic plans to continue using all appointments as an opportunity to vaccinate, providing a strong provider recommendation as guided by the CDC, assessing vaccination status as part of vital signs, and providing VIS to all eligible patients.

Conclusion

The results of this quality improvement project add to the body of knowledge and demonstrate successful implementation of the 4 Pillars™ Practice Transformation Program to increase HPV vaccination rates among adolescents in primary care. Decreasing vaccine hesitancy is important work in primary care as primary care providers are responsible for educating parents and families on vaccines (AAP, 2020). Enabling practices to work as a team to improve vaccination rates is helpful in enacting change. Future QI projects should build on the design by implementing more interventions from the 4 Pillars, or categories, as it has been shown that the more interventions included in the tool-kit, the more successful the outcomes are (Zimmerman et al., 2016).

Sustainability would be enhanced through the addition of formally tracking progress through tracking of HPV vaccination rate more frequently. Currently the rate is only tracked through state audits at this practice. This project included progress tracking as part of staff motivation and was shown to be successful as part of the tool kit but project design did not provide for sustainability of the tracking intervention. Additionally, providers should be encouraged to advocate for the HPV vaccine to be mandatory at the state level. This study found that 50% of HPV vaccine refusals encountered were due to parents opting to defer vaccination until mandatory for school entry. Further QI projects should be conducted using the 4 Pillars™ Practice Transformation program in order to provide a custom, individualized evidence-based tool-kit to increase HPV vaccination rates and to ascertain which individual interventions are the most effective.

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Tables

Table 1
Evidence Review

Author and Date	Objective	Study Design	Sample Size	Findings	Limitations	Level	Quality
Farmar, Love Osborne, Chichester, Breslin, Bronkan, & Hambidge, 2016	To evaluate the efficacy of a bundle of interventions/ tactics in achieving high rates of adolescent vaccination	Non-experimental Retrospective Analysis Comparison of national and state adolescent vaccination rates to rates (including HPV) in the health system studied over a 10-year time period Bundle included: Offering vaccines at every visit (acute or preventive), offering all 3 adolescent vaccines at the same time, standing orders for	N=11,463 Age: Mean 14.77 Range 13.00-17.92 More likely to be Hispanic, English speaking, and <200% of the federal poverty line	Coverage rates for all adolescent vaccines, including HPV, were significantly higher than national and state rates for both males and females. HPV Coverage: *National Rates:* Male=34.6% Female=57.3% *Study Rates:* Male: 89.3% Female: 89.8%	-Unclear if beginning of study (2004) correlated with initiation of intervention bundle, or just when the MCV4 vaccine was recommended. -Study was conducted in a large health system that also has school-based health clinics and a large proportion of poor families. This may limit generalizability. -Limited control, just compared to national and state rates, however this health system's rates are vastly higher.	IV	B

		administration, use of a vaccine registry, and occasional vaccine drives					
Zimmerman et al., 2014	To examine efficacy of 4 Pillars toolkit and early vaccine delivery in increasing childhood influenza vaccine uptake.	Cluster randomized trial Each individual practice enrolled in trial was considered a cluster, each of which were randomized into intervention or control arm. Each practice in the intervention arm was expected to implement a strategy/strategies from each of the 4 Pillars.	N=81,599 80% power analysis directed sample size of 20 clusters (10 intervention and 10 control primary care pediatric or family practices)	Intervention arm rate of vaccination was statistically significantly higher than control (p=0.001) -Of note, individual interventions of 4 Pillars Toolkit were analyzed for effectiveness and the most effective were found to be convenience of vaccination services, parental/patient education on importance of vaccine, enhanced office systems including physician prompts, staff/provider education on use of the toolkit, weekly feedback of progress,	-Inclusion of early vaccine delivery in intervention set not generalizable to HPV vaccine as this is not a seasonal vaccine, however the study reported the efficacy of this intervention separate from the toolkit itself. -Community educational outreach (unrelated to intervention) may have led to increase in both control and intervention arms of studies, but difference between two was still statistically significant.	II	A

				and educational posters. -Practices with pre-intervention vaccination rates above 58% did not significantly improve rates as a result of intervention, representing a possible threshold of effectiveness of toolkit. Recommended to use more strategies from each pillar.			
Zimmerman et al., 2016	To evaluate an intervention using the 4 Pillars™ Practice Transformation Program to increase HPV, MCV, and Tdap uptake among primary care practices.	Randomized controlled cluster trial	N=10,861 aged 11-17 80% power analysis directed a sample size of 18 clusters with at least 250 patients/cluster (11 intervention and 11 control primary care pediatric or family practices) 2 practices randomized into	Rates of HPV vaccination increased statistically significantly in the intervention group compared to control ($p<0.001$) Researchers found a decrease in the disparity between male and female rates of vaccination completion, representing a way to promote vaccination	-Moderate length of study (9 months) limited ability to observe differences in HPV series completion as the series takes 6 months start to finish. Study was ended at the 9-month mark so that the control groups could then receive the intervention (results from that intervention are described below) as promised in recruitment.	II	A

			intervention arm dropped out.	for adolescent males without specifically targeting them. Implementing >10 strategies from 4 Pillars was most effective.			
Zimmerman et al., 2017	To evaluate effectiveness of an intervention using the 4 Pillars™ Practice Transformation Program to increase adolescent vaccination uptake	Pre-post design Vaccination rates were measured at the beginning of the study, intervention was conducted, rates were measured at the end. Practices were expected to implement strategies from each of the 4 Pillars and were encouraged to use as many as possible to maximize impact on vaccination rates.	N=9,473 11 primary care practices, the control group from the above study that was subsequently offered this intervention upon completion of initial study.	HPV vaccination initiation rates increased significantly ($p<0.001$), HPV completion increased from 30.7% to 45.5% ($p<0.001$) Statistically significant increases in meningococcal and Tdap were also observed. Influenza vaccine rates were not increased significantly. Eliminated racial disparity noted in previous studies—likelihood of HPV completion 37%	Inherent limitation in study design: pre-post study with no control/randomization.	III	A

				higher for non-white adolescents.			
Nowalk et al., 2016	To determine the ability of the 4 Pillars Toolkit to maintain increased rates of vaccination after 2 years.	Repeated-measures, pre-post design: This study is reporting the maintenance of increased vaccination rates one year following intervention in a cluster randomized trial, included here to ascertain longevity and sustainability of proposed intervention.	N=44,923 Power analysis directed sample size of 20 clusters (20 practices were included) Practices were expected to implement strategies from each of the 4 pillars	During active intervention phase, influenza vaccine uptake increased significantly ($p<0.01$) and this uptake was sustained during maintenance resulting in an overall increase of 12.7% ($p<0.001$) Decrease in racial and sex disparities in vaccination noted as the differences between whites and nonwhites and between males and females decreased over time. Likelihood of vaccination in the maintenance year was 2% higher than active intervention year, indicating sites were able to sustain practice improvement.	Examined influenza vaccine, not specifically HPV vaccine Potential for increased uptake to be reflective of secular trend, however this does not account for 9-18 year olds in this study being vaccinated at higher than the state and national rate.	II	A

Walling et al., 2016	To identify effective strategies to optimize uptake of the HPV vaccine.	Systematic review	51 studies reviewed according to the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) model to evaluate quality and external validity. Interventions studied: N=2 Informational interventions; N=18 behavioral interventions; N=31 environmental interventions	Environmental interventions (such as government-initiated/required HPV vaccine programs) achieved highest vaccination rates. However, if population-based vaccination strategies are not feasible, multipronged interventions targeting both provider and patient were found most effective.	Heterogeneity of interventions limited ability to evaluate quality. Heterogeneity of outcomes reporting complicated interpretation of success making direct comparison difficult. Preintervention vaccination rates were rarely included in the studies. Many studies lacked a control group. Consistent lack of race/ethnicity/socioeconomic states making trend identification for health disparities difficult.	I	B

Note. Evidence Level and Quality Rating were assigned using Newhouse's (2006) Rating System.

Figures

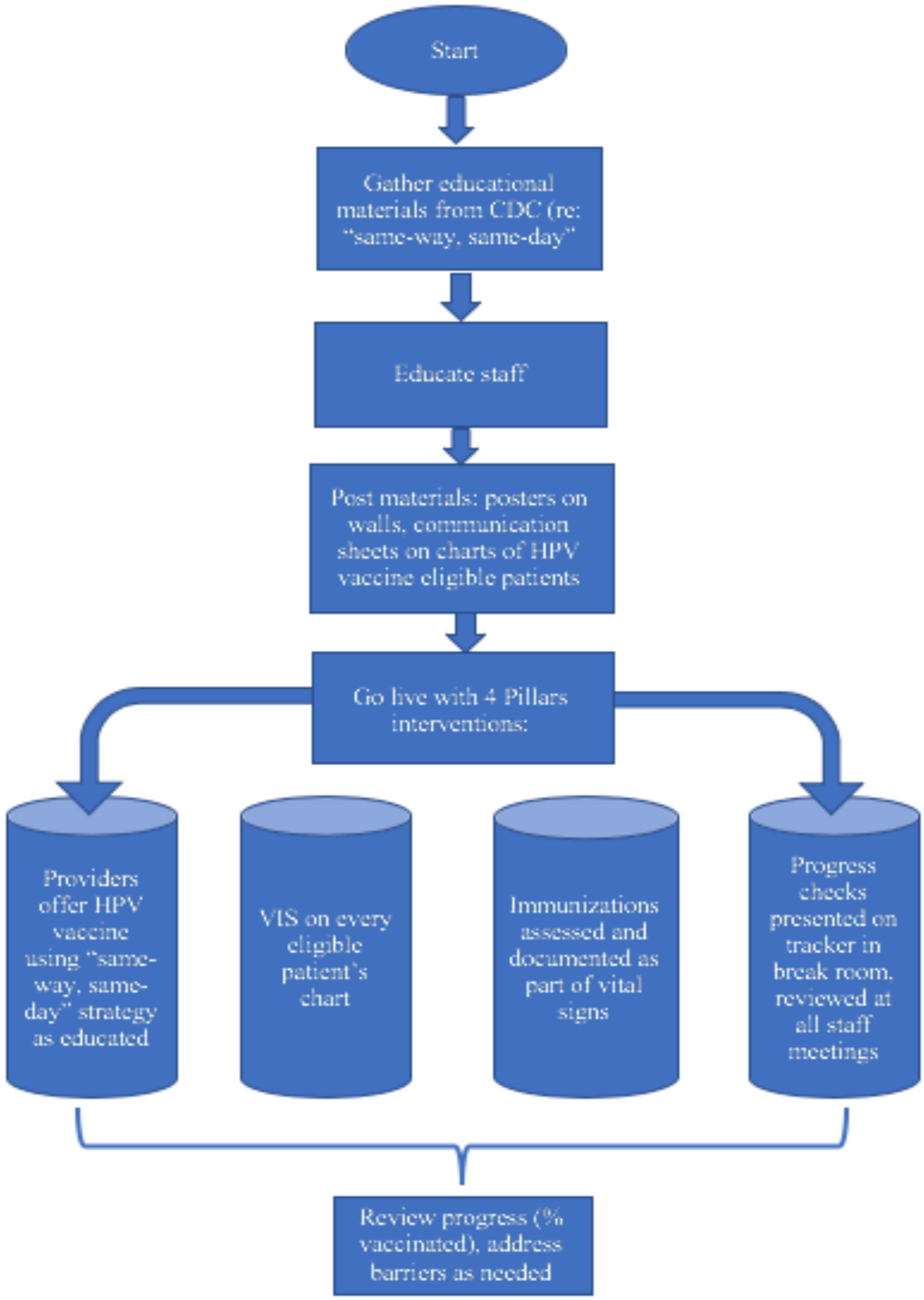

Figure 1. Process Map of Implementation Plan for Increasing Humanpapilloma Virus Vaccination Rates Among Adolescents in Primary Care.

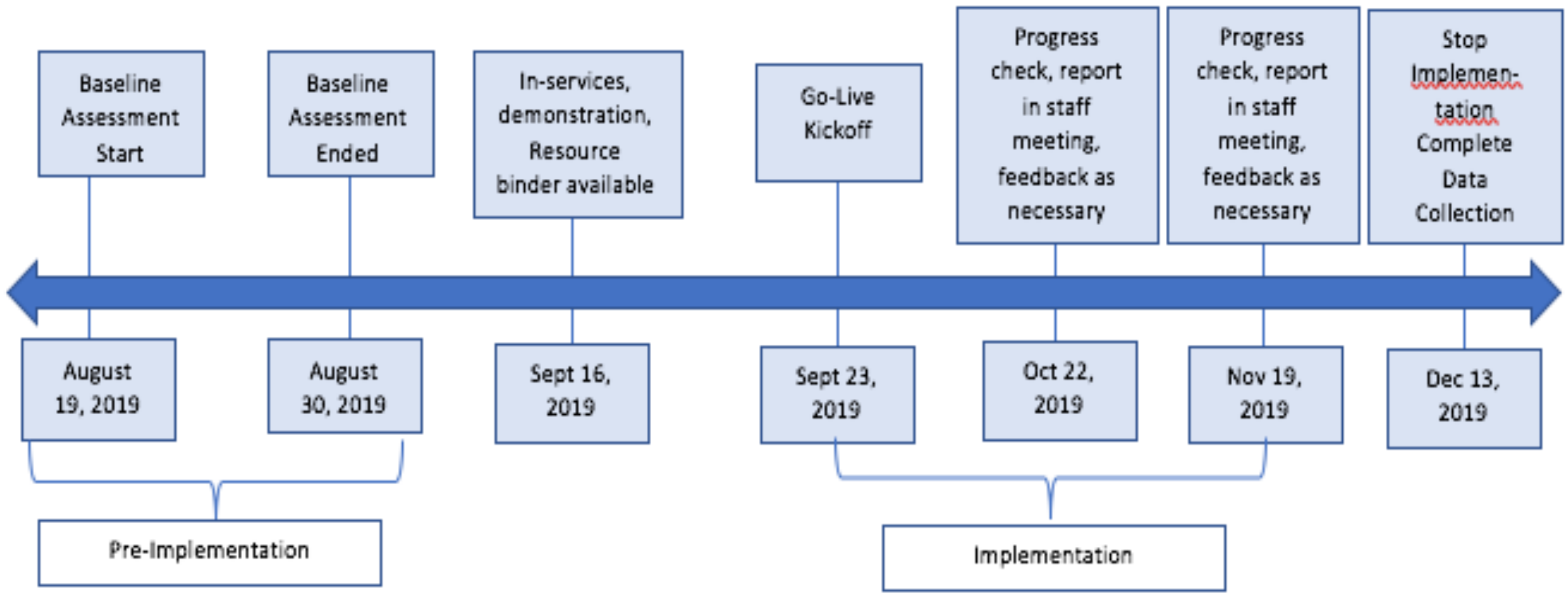

Figure 2. Timeline of Implementation Plan.

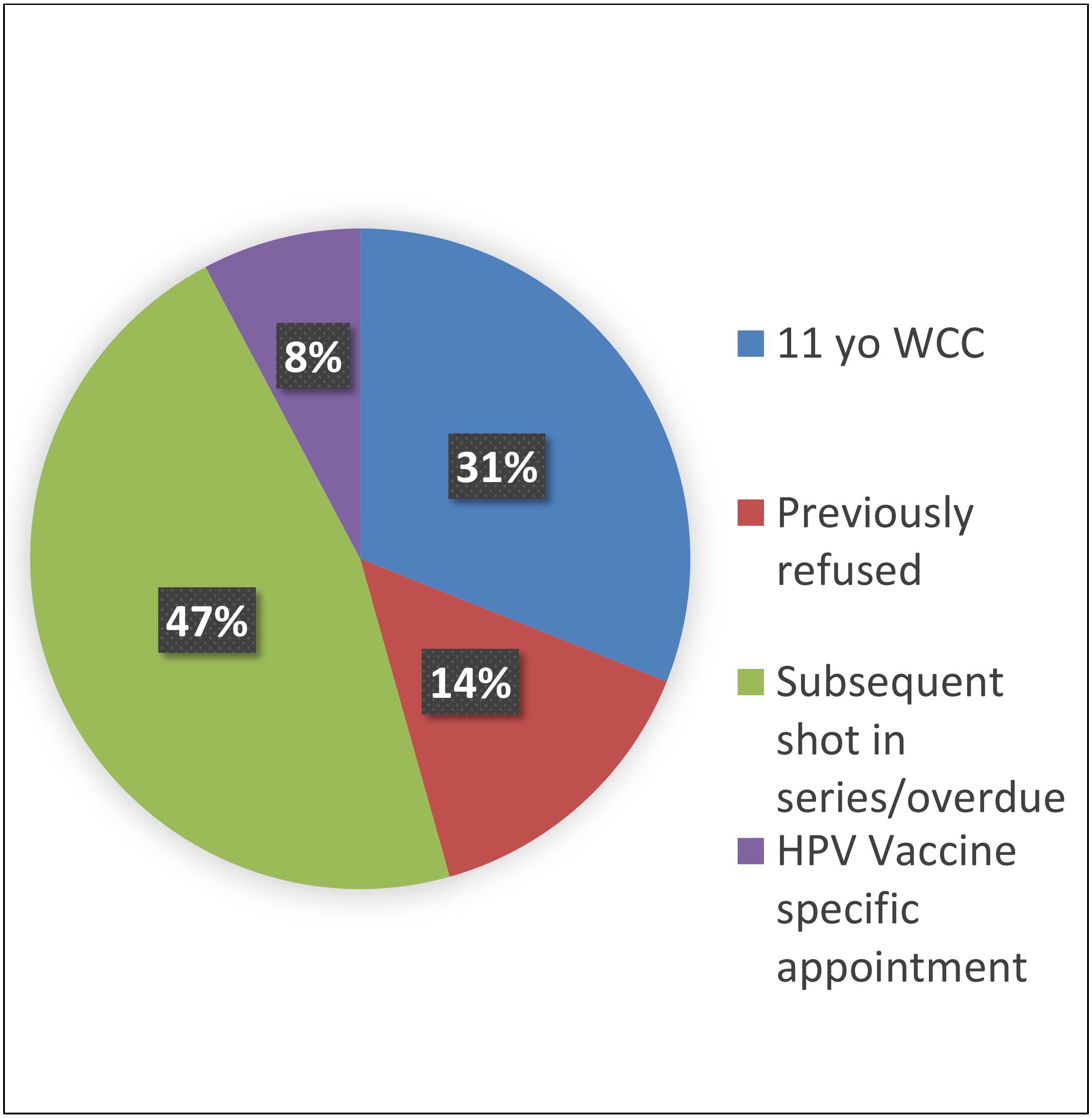

Figure 3. HPV Vaccines Given During Project (n=103)

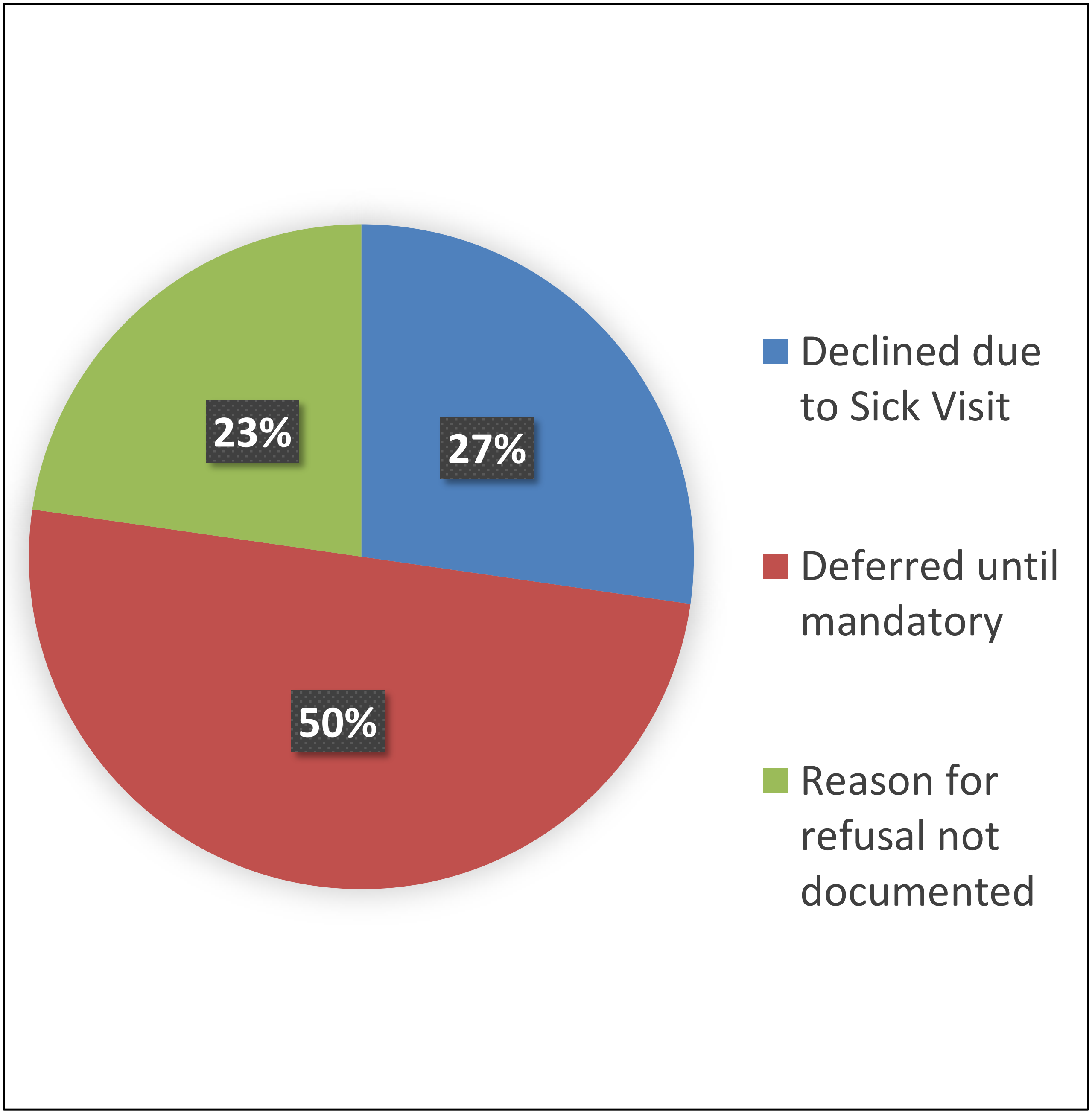

Figure 4. Reasons for Vaccine Refusal (n=22)

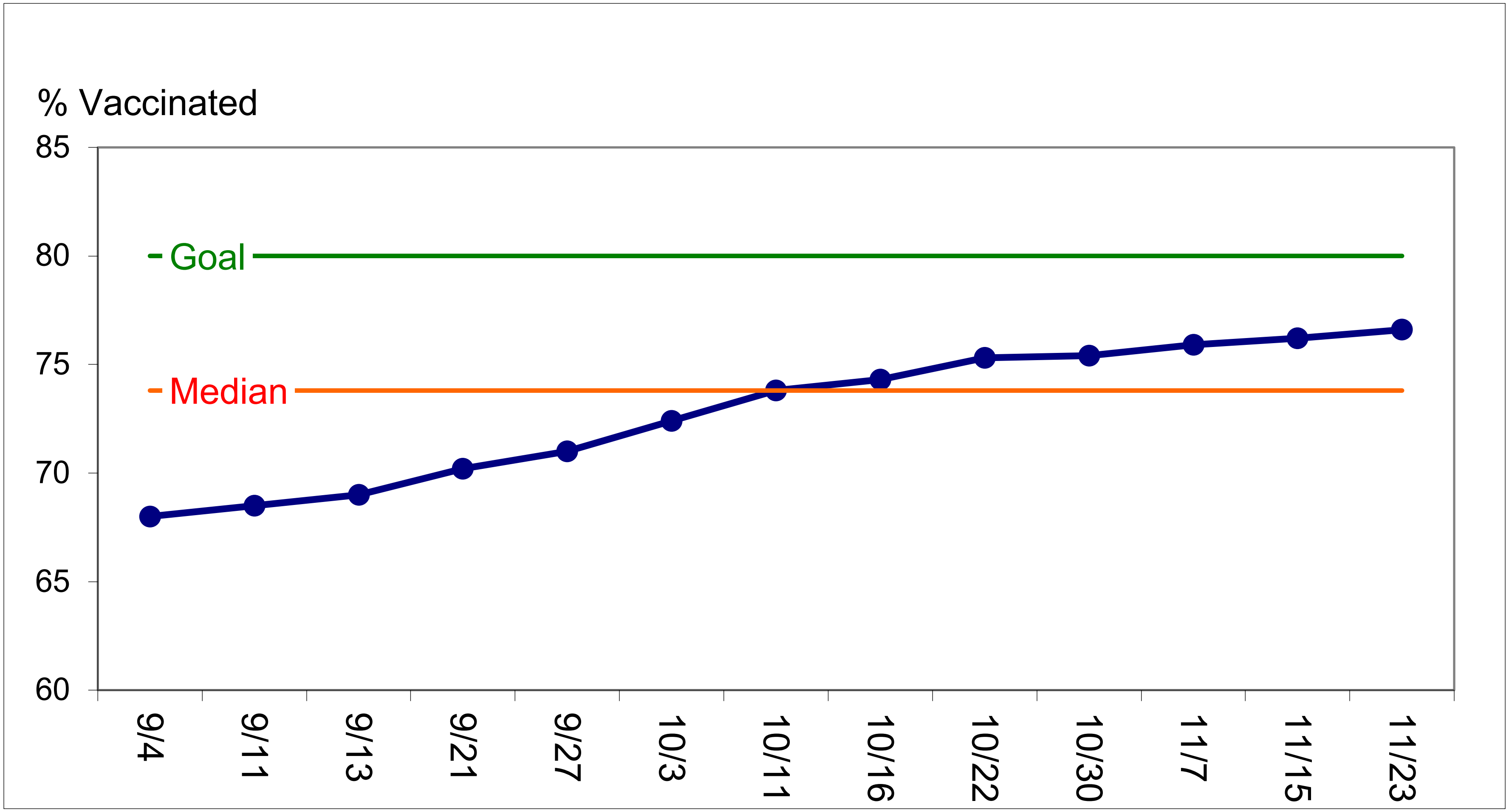

Figure 5. Overall Clinic HPV Vaccination Rate

Appendix A:

CDC Communication Sheet

Talking to Parents about HPV Vaccine

CDC

HPV VACCINE IS CANCER PREVENTION

Recommend HPV vaccination in the **same way** and on the **same day** as all adolescent vaccines. You can say, "Now that your son is 11, he is due for vaccinations today to help protect him from meningitis, HPV cancers, and whooping cough. Do you have any questions?" Remind parents of the follow-up shots their child will need and ask them to make appointments before they leave.

Why does my child need HPV vaccine?

HPV vaccine is important because it prevents infections that can cause cancer. That's why we need to start the shot series today.

How do you know the vaccine works?

Studies continue to prove HPV vaccination works extremely well, decreasing the number of infections and HPV precancers in young people since it has been available.

Why do they need HPV vaccine at such a young age?

Like all vaccines, we want to give HPV vaccine earlier rather than later. Getting the vaccine now protects your child long before they are ever exposed. If you wait until your child is older, he/she may end up needing three shots instead of two.

Why do boys need the HPV vaccine?

HPV vaccination can help prevent future infections that can lead to cancers of the penis, anus, and back of the throat in men.

Are all of these vaccines actually required?

I strongly recommend each of these vaccines and so do experts at the CDC and major medical organizations. School entry requirements are developed for public health and safety, but don't always reflect the most current medical recommendations for your child's health.

Would you get HPV vaccine for your kids?

Yes, I gave HPV vaccine to my child (or grandchild, etc.) when he was 11, because I wanted to help protect him from cancer in the future.

What diseases are caused by HPV?

Some HPV infections can cause cancer—like cancer of the cervix or in the back of the throat—but we can protect your child from these cancers in the future by getting the first HPV shot today.

Is my child really at risk for HPV?

HPV is a very common infection in women and men that can cause cancer. Starting the vaccine series today will help protect your child from the cancers and diseases caused by HPV.

I'm worried my child will think that getting this vaccine makes it OK to have sex.

Studies tell us that getting HPV vaccine doesn't make kids more likely to start having sex. I made sure my child (or grandchild, etc.) got HPV vaccine, and I recommend we give your child her first HPV shot today.

I'm worried about the safety of HPV vaccine. Do you think it's safe?

Yes, HPV vaccination is very safe. Like any medication, vaccines can cause side effects, including pain, swelling, or redness where the shot was given. That's normal for HPV vaccine too and should go away in a day or two. Sometimes kids faint after they get shots and they could be injured if they fall from fainting. We'll have your child stay seated after the shot to help protect him/her.

Can HPV vaccine cause infertility in my child?

There is no evidence available to suggest that getting HPV vaccine will have an effect on future fertility. However, women who develop an HPV precancer or cancer could require treatment that would limit their ability to have children.

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Appendix B:

Vaccine Information Statement

VACCINE INFORMATION STATEMENT

HPV (Human Papillomavirus) Vaccine: *What You Need to Know*

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

HPV vaccine prevents infection with human papillomavirus (HPV) types that are associated with many cancers, including:

- **cervical cancer** in females,
- **vaginal and vulvar cancers** in females,
- **anal cancer** in females and males,
- **throat cancer** in females and males, and
- **penile cancer** in males.

In addition, HPV vaccine prevents infection with HPV types that cause **genital warts** in both females and males.

In the U.S., about 12,000 women get cervical cancer every year, and about 4,000 women die from it. HPV vaccine can prevent most of these cases of cervical cancer.

Vaccination is not a substitute for cervical cancer screening. This vaccine does not protect against all HPV types that can cause cervical cancer. Women should still get regular Pap tests.

HPV infection usually comes from sexual contact, and most people will become infected at some point in their life. About 14 million Americans, including teens, get infected every year. Most infections will go away on their own and not cause serious problems. But thousands of women and men get cancer and other diseases from HPV.

2 HPV vaccine

HPV vaccine is approved by FDA and is recommended by CDC for both males and females. It is routinely given at 11 or 12 years of age, but it may be given beginning at age 9 years through age 26 years.

Most adolescents 9 through 14 years of age should get HPV vaccine as a two-dose series with the doses separated by 6-12 months. People who start HPV vaccination at 15 years of age and older should get the vaccine as a three-dose series with the second dose given 1-2 months after the first dose and the third dose given 6 months after the first dose. There are several exceptions to these age recommendations. Your health care provider can give you more information.

3 Some people should not get this vaccine

- Anyone who has had a severe (life-threatening) allergic reaction to a dose of HPV vaccine should not get another dose.
- Anyone who has a severe (life threatening) allergy to any component of HPV vaccine should not get the vaccine.

  Tell your doctor if you have any severe allergies that you know of, including a severe allergy to yeast.
- HPV vaccine is not recommended for pregnant women. If you learn that you were pregnant when you were vaccinated, there is no reason to expect any problems for you or your baby. Any woman who learns she was pregnant when she got HPV vaccine is encouraged to contact the manufacturer's registry for HPV vaccination during pregnancy at 1-800-986-8999. Women who are breastfeeding may be vaccinated.
- If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get HPV vaccine do not have any serious problems with it.

Mild or moderate problems following HPV vaccine:

- Reactions in the arm where the shot was given:
  - Soreness (about 9 people in 10)
  - Redness or swelling (about 1 person in 3)
- Fever:
  - Mild (100°F) (about 1 person in 10)
  - Moderate (102°F) (about 1 person in 65)
- Other problems:
  - Headache (about 1 person in 3)

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety**/.

5 What if there is a serious reaction?

What should I look for?

Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your doctor.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your health care provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/hpv**

Vaccine Information Statement

HPV Vaccine

12/02/2016

42 U.S.C. § 300aa-26

Office Use Only

Appendix C:

Lesson Plans

Learning Objectives	**Content Outline**	**Method of Instruction**	**Time Spent**	**Method of Evaluation**
Staff will become familiar with reason for DNP Project	--Goals: short term/long term --Current HPV vaccination rate --Current stated concerns project seeks to address	In-Service	5 minutes	Training Log
Staff will become familiar with 4 Pillars for Practice Transformation program and interventions chosen by Dr. Kelly-Robinson to be implemented	Tenets of 4 Pillars program: 1. Convenience 2. Communication 3. Enhanced office Systems 4. Motivation	In-Service	5 minutes	Training Log
Providers will be proficient in use of Same-Way Same-Day Strategy in order to provide a strong recommendation for vaccine	CDC Communication Sheets	In-Service	15 minutes	Role-play communication
Providers will be proficient in documentation of reason for parental decline if applicable	Where to document reason	In-Service	5 minutes	Training Log
Medical assistants will be proficient in assessment and documentation of vaccine status as part of vital signs/placement of VIS on chart of all eligible patients.	Where to document status What constitutes an eligible patient	In-Service	5 minutes	Training Log

Training Log: DNP Project In-Service Training			
Printed Name	**Position**	**Date**	**Signature**

Appendix D:

Audit Tools

Baseline Data	
De=Identified patient ID	Compliant with ACIP recommendations? 1=Yes 2=No

Adolescent Visits During Implementation								
Date	De-Identified patient ID	Provider seen 1=Robinson 2=Johnson 3=Brown	Vaccination status assessed as part of vitals? 1=Yes 2=No	Eligible for vaccine? 1=Yes 2=No	VIS provided? 1=Yes 2=No	Strong Recommendation given? 1=Yes 2=No	Was reason for parental decline documented? 1=Yes 2=No 3=NA	Compliant with ACIP recommendations? 1=Yes 2=No

Final Data	
De=Identified patient ID	Compliant with ACIP recommendations? 1=Yes 2=No