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Strategies to increase HPV vaccine uptake in primary care.

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Strategies to Increase HPV Vaccine Uptake in Primary Care

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Abstract

Purpose: The purpose of this project was to increase HPV vaccination initiation rates in a primary care setting. This was accomplished through evidence-based provider and parental education using presumptive language and distribution of a customized toolkit.

Design: The project protocol was designed using a theoretical approach about chosen health behaviors from the Health Belief Model. Outcomes included initiation rates, efficacy of a toolkit intervention, efficacy of a recall system, and provider satisfaction.

Methods: A two-sided Fisher's Exact Test was performed. Primary outcome results indicated a non-significant increase in vaccination rates. Of the 24 patients who received the toolkit, 25% chose to vaccinate while 75% never returned ($p = .159$). Of those who chose to vaccinate, all had previously declined. Overall, the recall system was ineffective for recruiting patients to return for vaccination. Providers were highly satisfied with the protocol and felt it was both feasible and sustainable. A major barrier was the simultaneous intervention implementation timeline and novel coronavirus pandemic.

Findings: This project demonstrated that while an intervention protocol for all patients did not yield a significant increase in vaccinations, there was an impact on patients who previously declined the vaccine. Providers expressed increased confidence and satisfaction with their communication and education skills regarding HPV and the vaccine.

Conclusions: While there were cases where patients who received the intervention chose to vaccinate, the results were not statistically significant. Providers expressed satisfaction with an education protocol emphasizing the use of a customized toolkit and presumptive language. There is substantial room for further investigation and quality improvement projects in the future.

Key Words: HPV, HPV vaccine, pediatrics, vaccine protocol, education for providers

Strategies to Increase HPV Vaccine Uptake in Primary Care

The Human papillomavirus, or HPV, is a sexually transmitted infection which has potential sequalae of malignancies and warts. Various types of neoplasms are linked to HPV, including oral, rectal, penile, and cervical cancers. The HPV vaccine was introduced in 2006 as a quadrivalent vaccine to prevent HPV strains 6, 11, 16, and 18. Since 2006, the vaccine has been expanded further and is presently available in a nine-valent form (Centers for Disease Control and Prevention, 2018). The vaccine is recommended for male and female patients ages 11-45. The nine-valent HPV vaccine is recommended as two-series regimen if initiated between ages 11-15 years and a three-series regimen if the patient is age 15 years or older (CDC, 2018).

This vaccine can prevent malignancies and genital warts by offering the patient protection throughout adolescence and their lifetime. While the vaccine is strongly recommended by the CDC (2018), the American College of Obstetricians and Gynecologists (2017), and the American Academy of Pediatrics (2017), there is a discrepancy between current recommendations and clinical implementation. Lack of effective provider communication and subsequent parental declination has been referenced as a barrier to vaccine uptake (Garbutt et al., 2018).

HPV-related cancer rates are still considerable despite the availability of a preventable vaccine (CDC, 2018). In the United States there are approximately 44,000 HPV cases per year, 25,000 among women and 19,000 among men, respectively (CDC, 2018). One-quarter of sexually active individuals will contract the Human Papilloma Virus (CDC, 2018). According to the CDC (2018), HPV is attributed to 90% of anal and cervical cancers, 70% of vaginal and vulvar cancers, and 60% of penile cancers. The CDC currently estimates that only 50% of adolescents in the United States are vaccinated (CDC, 2018). These statistics confirm that HPV is a highly prevalent, but preventable illness (CDC, 2018).

If HPV vaccination rates can be increased, HPV-related cancer incidence rates would decline (Office of Disease Prevention and Health Promotion, n.d.). While many providers recommend the vaccine, there is a general lack of knowledge on effective, specific approaches that result in parental consent. Although attempts in the past have been made to mandate the vaccine in the state of Kentucky, public opposition prevented passing of a law which would require adolescents to be vaccinated (Dekker, 2008). A goal of an 80% vaccination rate was identified in Healthy People 2020 (Office of Disease Prevention and Health Promotion, n.d.). Both the national and state rates fall short of the current Healthy People 2020 goal.

Kentucky is categorized poorly among states for HPV vaccination rates, with an estimated 39% being vaccinated (CDC, 2018). Kentucky ranks among the highest with HPV-associated cancers; between 13.09 and 15.67 per 100,000 people who developed cancer had an association with the virus (CDC, 2018). According to Wilburn, Vanderpool, Knight, and Evers (2016), Kentucky's 5-year invasive incidence rate for HPV-related cervical, vulvar, anal, penile, oral, pharynx, and vaginal cancers was consistently higher than the U.S. rate.

While primary intervention is the goal of decreasing HPV infections, there is a barrier to early vaccine initiation: obtaining parental consent. Lack of parental knowledge is cited as major barrier when providers introduced the topic during visits (Beavis et al., 2018). While providers may be making the appropriate recommendations, they are not focusing on areas of education where parents are expressing hesitation to vaccinate. Main areas of parental anxiety were identified as safety concerns, side effects, efficacy, and the influence of vaccination on sexual activity (Beavis et al., 2018.). Four years after the vaccine was approved for use, a subset of data from the 2010 National Health Interview survey were analyzed for parental awareness of the HPV vaccine. According to Allton et al. (2014), with a sample size of 5,735 parents, only 62%

had heard of the HPV vaccine. This rate only marginally improved to 68% three years later (Beavis & Levinson, 2016). According to Allton et al., parents who were white, female, college educated, and married were most likely to have heard of the vaccine. Patients who had been seen in the last year for a well-child check were also highly likely to have heard of the vaccine. Analysis of the 2016 National Immunization Survey-Teen revealed varying reasons for parental declination of the HPV vaccine. According to Beavis et al. (2018), 22% of parents cited safety concerns as the most common reason for electing not to vaccinate in female patients. This was followed by lack of necessity (20%), lack of knowledge (13%), lack of recommendation (10%), and sexual activity concerns (10%) with ($p < .01$). For male patients, areas of parental concern were quite different: lack of necessity (22%), lack of recommendation (17%), safety concerns (14%), lack of knowledge (14%), and sexual activity concerns being the lowest at 9%, ($p < .05$). Subsequently, Beavis et al. (2018) recommend that parental education be focused on knowledge, safety, and necessity, rather than gender or sexual activity.

The vaccination disparity in the United States and Kentucky populations implies a major health threat to society. Testing and treatment for HPV related cancers and pre-cancers result in major health impacts and high healthcare costs for patients (CDC, 2018). A key point to consider is the potentially life-saving effect, particularly for men. While screening for cervical cancer is routine, no such testing exists for penile and rectal cancer (CDC, 2018). Increased vaccination would bring down the overall healthcare costs associated with HPV and its potential disease sequelae (Office of Disease Prevention and Health Promotion, n.d.).

Significance of the Problem

Preventable cancers are the primary consequences of the current incongruities in HPV vaccinations throughout the nation. The risk of contracting HPV is direct result of opting not to

vaccinate. HPV related cancers can be eliminated or greatly decreased with primary prevention. Additional consequences include unwanted genital, oropharyngeal, and anal warts, all which impact physical and mental health.

Review of Literature

Evidence for the Intervention

Four interventions were determined to be effective in increasing HPV vaccine initiation rates: provider education, announcement-style communication, recall use, and parental education.

Provider Education and Announcement-Style Communication

Providers are trained proper techniques to recommend vaccines; however, recent studies indicate that further training specific to the HPV vaccine is warranted. Brewer et al. (2017) defined announcements as a "closed statement" which assumes the parent will vaccinate, in contrast to open-ended conversations which question their willingness to initiate the series. Twenty-nine clinics were selected with accessible health data to be included in the study. The study was a quasi-experimental design based on a pre- and post-intervention model and communication training implemented in this study took place over one hour. Data were analyzed using mixed-level Poisson regressions for each vaccination outcome. To determine if clinics were significantly different in characteristics, Fisher's exact test and analysis of variance were performed. Data were analyzed using a two-tailed test. A clinically significant increase in HPV vaccination rates for both males and females, 6.2% and 4.6% respectively, occurred (Brewer et al., 2017).

Dempsey et al. (2018) initiated a cluster randomized control trial using a covariate-constrained randomization. The trial included 16 clinics and over 43,000 patients. This study

implemented a multifaceted approach to combine vaccination education while integrating announcement-style communication training. This training taught providers to use a presumptive style of communication. The providers took classes regarding announcement style training and the intervention group implemented this tactic in practice. Data were analyzed using two-tailed testing and significance was defined as $\alpha = .05$. The control group received regular care. The intervention group had a significant increase in vaccine initiation rates (11.3% increase; $p < .001$). Intervention sustainability was also measured using unspecified surveys and indicated that 91% of providers would continue to use this communication style.

In a systematic review, Walling et al. (2016) found that provider-directed interventions greatly increased HPV vaccine initiation. Fifty-one articles were included with four main types of interventions: informational, environmental, educational, and behavioral. Reports that did not include post-intervention data analysis were not included. Articles were examined using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) to assess quality and validity. This review found provider education and communication training to be particularly important when increasing rates. These interventions also achieved increased provider approval and financial feasibility.

Krantz et al. (2015) conducted a quasi-experimental trial to evaluate the impact of provider-based interventions. This quality improvement project implemented an educational seminar for all clinical staff with a focus on assumptive message delivery. Didactic provider training and education increased vaccination rates in both males and females. Providers were encouraged to approach the vaccine objectively, with announcement style communication, like other scheduled vaccines. The providers found this intervention acceptable and the number of missed opportunities for vaccination were decreased. Vaccine completion rates were analyzed

pre- and post-intervention using Fisher's exact test. Overall vaccination rates increased for males (42.6% to 57.3%, $p < .001$) and females (60.0% to 66.5%, $p < .04$). Rand and Tyrrell (2018) had similar findings with a pre- and post-intervention quality improvement study. Forty-seven clinics were included with the primary goal to measure missed opportunities and series initiation and completion. Providers were educated with didactic sessions; recalls were used in facilities with the electronic health record capabilities. There was no control group. Providers were taught to use presumptive language. The McNemar chi-square test and logistic regression were used to compare baseline and post-intervention data. Missed opportunities for HPV vaccination decreased from 66% to 74% for female, 57% to 65% for male; $p < .01$. Overall vaccine initiation rates increased from 71% to 77%, $p < .01$.

Rand et al. (2018) found that education on announcements as a communication style impacted vaccine initiation. Eight clinics were included in this study. This quality improvement project assessed captured opportunities for vaccination and reasons patients were not immunized when due. Pre- and post-intervention vaccination rates were assessed with Pearson's χ^2 test and descriptive statistics. With the implementation of provider education and use of EHR recalls, vaccination rates improved at well child appointments and other types of visits. The well-child visit rate improved from 65% to 77% and other visits increased from 27% to 40%, $p < .001$.

The literature demonstrated statistically significant evidence to support provider education, specifically the use of announcement-style communication and presumptive language. Sustainability and satisfaction were also exhibited with this intervention as presented in multiple studies. Educational sessions with providers and staff increased vaccination rates and decreased missed opportunities

Parental Education

For the purposes of the quality improvement project, the primary outcome was initial vaccine uptake. The systematic review conducted by Walling et al. (2016) found that provider-based interventions resulted in higher initiation rates, while parent-based interventions increased series completion. Cassidy et al. (2014) found that an educational, evidence-based script for providers used in conjunction with provider recommendation increased vaccine uptake. According to the study, 62% of parents indicated that an educational brochure helped them with decision making, while 78.3% agreed that provider recommendation was also compelling. Palmeri et al. (2017) demonstrated that parental counseling would increase rates as well, with an increase in uptake in the intervention group. This study used a pre- and post-intervention design with telephone calls to parents versus usual care. In the control group, only 10.3% of girls completed the vaccination schedule compared to 27.1% who received questionnaire and counselling ($p < .0001$). While parental education was not the most effective intervention when used alone, when implemented in conjunction with provider education and recalls, it will help to increase knowledge and vaccine uptake.

Dela Cruz et al. (2017) conducted a qualitative, didactic interview study to determine important factors influencing parental education and decision making. Twenty participants were included in an interview style conversation; multiple types of written educational materials were presented. Content analysis of the conversations took place with four major themes emerging: the provider is essential in the decision to vaccinate, parents perception of child's sexuality influences their decision making, education materials should be provided and discussed by the provider, and educational materials should include familiar faces, immunization schedule, and address barriers to vaccination. This study indicated that a toolkit consisting of multiple materials

distributed to patients by the provider is very effective and preferred by parents. Educational materials should be culturally targeted and consider the health concerns of the geographic area.

Dempsey et al. (2017) found that use of a clinical fact sheet also produced significant increases in vaccination. This study used fact sheets customized to the facilities population in conjunction with a decision tree and customized web site. Health-care professionals reported that communication style training when used in conjunction with parental educational materials were satisfactory and effective.

Recall Use

Recalls, or reminders, are used in healthcare in a variety of ways and have become more self-automated since the system wide introduction of the electronic health record. In a systematic review, Walling et al. (2016) suggested that the use of reminder systems integrated into EHR is an effective intervention to increase vaccine uptake. In a quality improvement project, prompts were placed in the charts of eligible patients for vaccination. Parents in the intervention group were 9.4 times more likely than historical groups that received normal care to initiate the vaccine (Cassidy et al., 2014).

Rand et al. (2018) also used a multi-armed approach of physician recalls and announcement style communication to increase vaccine uptake from 46.9% to 63.3%. Zimet et al. (2018) explored the use of simple versus elaborated prompts. Elaborated prompts included suggested language, such as announcements, while simple prompts just stated the patient was due for the vaccine. The elaborated prompt arm had a higher rate of HPV vaccination (62%) than the control arm (45%) ($p < .05$). The investigators found that the combination of provider communication training and recall systems was very effective in raising provider awareness and

decreasing missed opportunities. Specifically, recalls that re-enforce communication training increased uptake (Zimet et al., 2018).

Rand et al. (2017) also demonstrated the importance of a parental reminder system. In this randomized control trial, 749 patients had a reminder system directed at parents put in place. Multiple intervention types were randomized. Participants received either: a phone call, a text message, or usual care. Cox proportional cumulative hazard models were created to assess differences among the groups who received each type of intervention. Secondary analysis, including a paired t-test, was conducted to analyze vaccination rates. The study found that some type of reminder system did increase dose compliance, but texts were the preferred method. There was a statistically significant increase in dose compliance with texts. Phone calls were reliable only when associated with dose one ($p < .005$).

Project Location Selection

Middletown Pediatrics (Louisville, KY) is a private primary care office which provides care for patients from birth to age 26. This setting was interested in increasing their provider knowledge and vaccination rates, specifically for those patients who had previously declined. The office sees approximately 2,000 patients per year and has a wide range of demographics. The private status of the office also allowed for the project manager to implement a well-controlled intervention and monitor it closely.

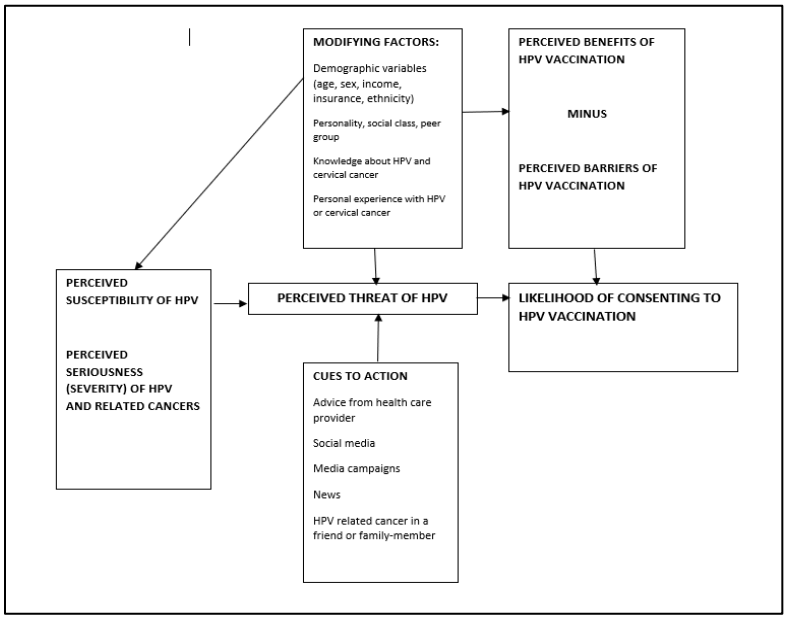
Theoretical Framework

The Health Belief Model (HBM) was adapted from the behavioral sciences to predict health behaviors, with specific attention to preventative services (McEwan & Wills, 2011). Figure 1 was adapted from McEwan and Wills (2011) to illustrate the HBM in the context of this project. The basic premise of the Health Belief Model states that a person is more likely to

choose a health behavior if they perceive that the threat of a disease applies to them. There are several constructs integrated into the HBM: perceived susceptibility of the health problem, perceived severity, perceive benefits, perceived barriers, and cues to action, and self-efficacy (Rosenstock, 1966). These constructs lead the person to determine if the disease is a threat. Simply put, the HBM proposes that a patient will make a behavior change if they feel there is a significant threat to their health; this threat serves as a motivation.

Figure 1

Health Belief Model and the HPV Vaccine



Over time, this model has been applied to various health behaviors to elicit change. This can include vaccination, health screenings, smoking, sedentary lifestyles, and nutrition choices. Vaccinating a child against HPV is a chosen health behavior. The HBM will guide the evaluation of the variables that impact this health behavior and how they relate to the desired outcome: vaccination. Using the HBM, interventions can be tailored knowing that the perceived threat of HPV or related cancers will drive parental decision making. The intervention falls into the 'cues to action' area of the HBM.

Setting and Organizational Assessment

Middletown Pediatrics (Louisville, KY) is a private primary care office which provides care for patients from birth to age 26. The target patient population were patients aged 11-26 years who had not received a primary dose of the HPV vaccine, with specific emphasis on the consenting individual (this may be the patient or parent). The providers, consisting of one physician and one nurse practitioner received an educational intervention. This environment is supportive of improving quality and there is a culture of providing best care. The only known barriers were consideration of time and cost. Permissions were obtained from the stakeholders, both the owners and the practice manager.

Purpose

The purpose of the quality improvement project was to implement an evidence-based protocol to increase HPV vaccination initiation rates within a primary care setting. Increasing provider education and recommendations was a specific aim, as well as examining feasibility and effectiveness of a provider-based intervention. The intended outcomes were to increase HPV vaccine initiation, increase parental knowledge, and increase provider confidence and satisfaction while speaking with parents and patients. The project goals aligned well with the needs of the practice as it focused on feasibility, sustainability, and promoted evidence-based care.

Intervention

The project leader, nursing/supportive staff, receptionist, and both the physician and nurse practitioner were included in the intervention team. While the intervention was primarily provider-led, there was significant interprofessional collaboration between the providers, nursing staff, and office staff. These interventions included provider education with emphasis on

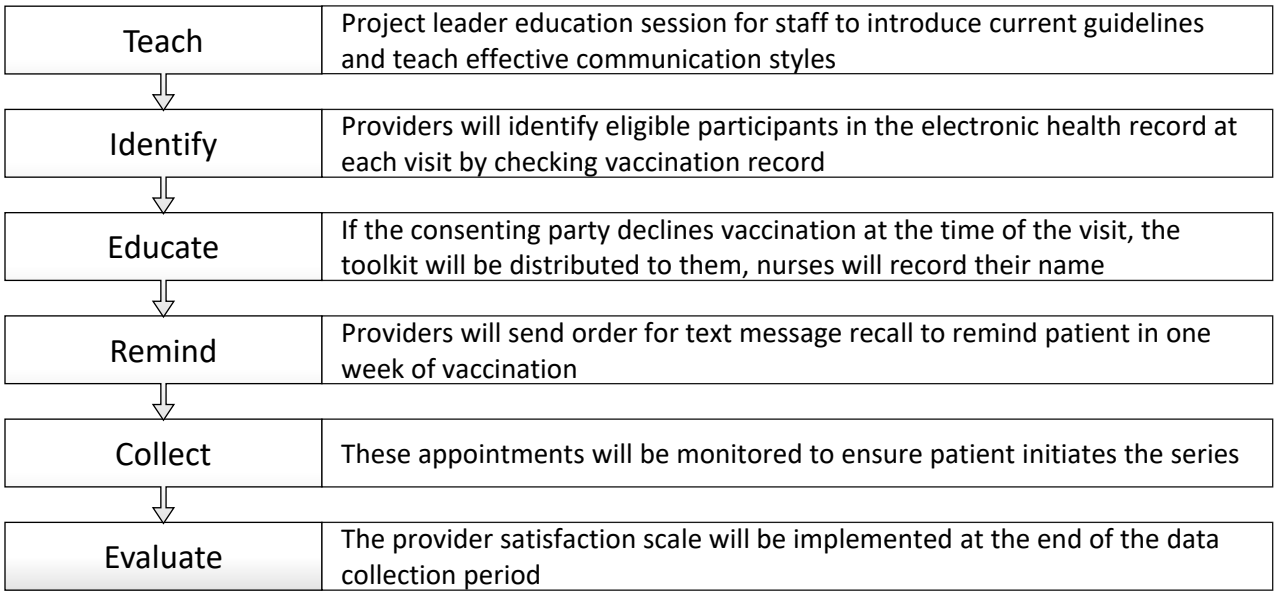
assumptive language, use of a recall system in the electronic health record, and parental education in the form of a toolkit.

Pre-intervention data was collected via the electronic health record. Variables collected included: vaccination status, age, gender, and insurance type. An educational session for providers and staff took place to establish project protocol and goals. Providers distributed educational toolkits at the time of the appointment to those who were determined to meet inclusion criteria. Following distribution of the toolkit, text-message recall orders were initiated by providers in the EHR system to be sent one week from the appointment date.

Post-intervention data were collected for the same variables and compared to pre-intervention data. This project was submitted and approved by the University of Louisville's Institutional Review Board as a quality improvement project to ensure ethical compliance. The agency had no further review requirements and accepted the IRB decision from the University. Figure 2 illustrates stepwise project protocol.

Figure 2

Project Protocol



Participants were regular, established patients of the practice. The group who received the intervention ranged from ages 11-24 years and included both males and females. No consent was required as this was an approved quality improvement project.

Inclusion Criteria

Patients must have been seen for well-child exam within the office in the last two years (from 2017 and forward) to be considered an active patient for the purposes of this project. They needed either a *consenting* parent or guardian who was 18 years or older with them at the time of the appointment or to have permission to consent to vaccines as independents who were at least 18 years old. Only patients who had not initiated the vaccine series were included in this project population.

Exclusion Criteria

Patients who had not been seen for a well-child exam in the last two years were not included in the target population. Those who did not have accurate vaccination records or did not bring updated records to appointment were not included. Patients or parents who *strongly and definitively* disagreed with the HPV vaccine during the provider intervention were not included in the educational and toolkit portion of the intervention, as requested by the facility to maintain positive relationships with patient.

Data Collection

The project leader had been trained in HIPPA regulations and procedures for this facility. When evaluating and presenting the data, only ages and gender were identified, along with relevant demographic data. Data were recorded by the project leader bi-weekly via Microsoft Excel. There was no identifiable data included in final analysis. Paper copies of the ongoing

participant list remained in the secure lab. Electronic data with identifiers was stored on a facility computer in the practice manager's locked office. After the participant had completed the intervention and initiated the series, their identifiable information was be omitted from the data collection system in a separate file from identifiable data. Total budget for the project was $105.20. This accounted for the colored copies of the toolkit.

Measurement

Electronic health records were used to ensure completeness and accuracy of data. Patient age was recorded in total years. Gender was recorded as male or female. Types of insurance were categorized either as private or Medicaid. Initiation rate was defined as the number of patients who received the intervention and initiated the vaccine within the data collection period. The toolkit was evaluated for effectiveness by assessing the vaccine initiation rate among those patients who received it. The effectiveness of the recall system was also evaluated. The survey, a provider satisfaction scale, assessed the concepts of confidence and sustainability. The scale was non-standardized and created by the project leader, therefore it did not require permissions.

Results

SPSS Grad Pack Basic v26 was used for all statistical analysis.

During the intervention period, 74 patients were seen who met inclusion criteria for the intervention. Of the 74 patients who met inclusion criteria, 24 received the intervention. Demographic data is presented for the intervention group (See Tables 1, 2, 3, and Figure 3). To determine effectiveness of the toolkit, a two-sided Fisher's Exact Test was performed. Primary outcome results indicated a non-significant increase in vaccination. Of the 24 patients who received the toolkit, 25% chose to vaccinate while 75% never returned for vaccination (p = .159).

All the patients who chose to vaccinate after receiving the toolkit had previously declined the vaccine. Providers implemented the intervention 32% of the time with 48 missed opportunities.

None of the patients who received a recall message following their visit chose to vaccinate. Analysis revealed 54% of patients received the recall after receiving the toolkit, 33% did not have the recall order placed, and 13% did not have the recall placed as they chose to vaccinate immediately after reviewing the toolkit.

Table 1

Frequency of Gender

Gender	Frequency	Percent
Male	18	75
Female	6	25
Total	24	100

Table 2

Frequency of Insurance Type

Insurance	Frequency	Percent
Private	22	91.7
Medicaid	2	8.3
Total	24	100

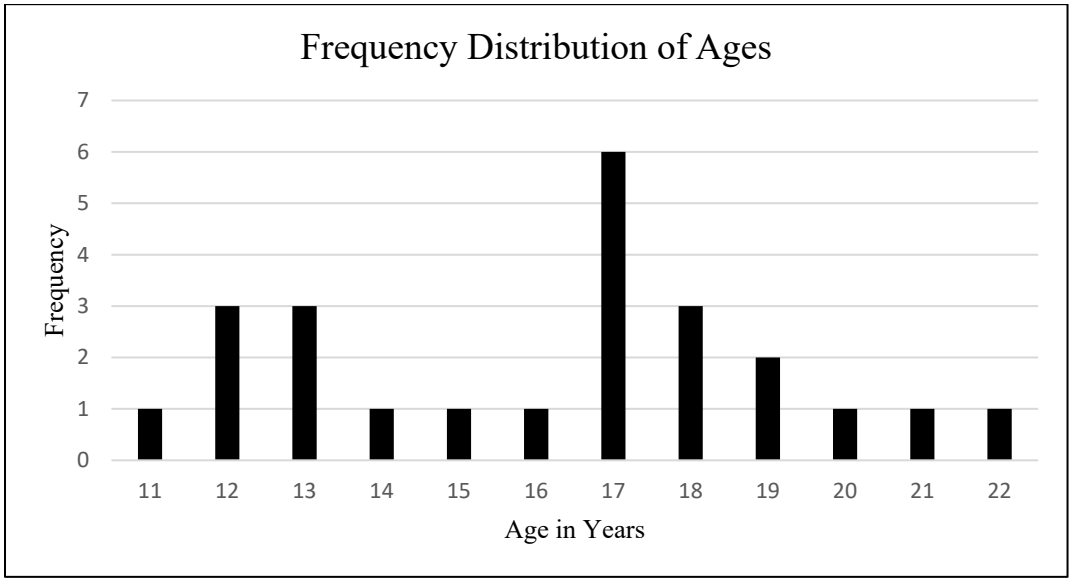
Table 3

Distribution of Ages

Variable	N	Mean	SD	Minimum	Maximum	Range
Age	24	16	3	11	22	11

Figure 3

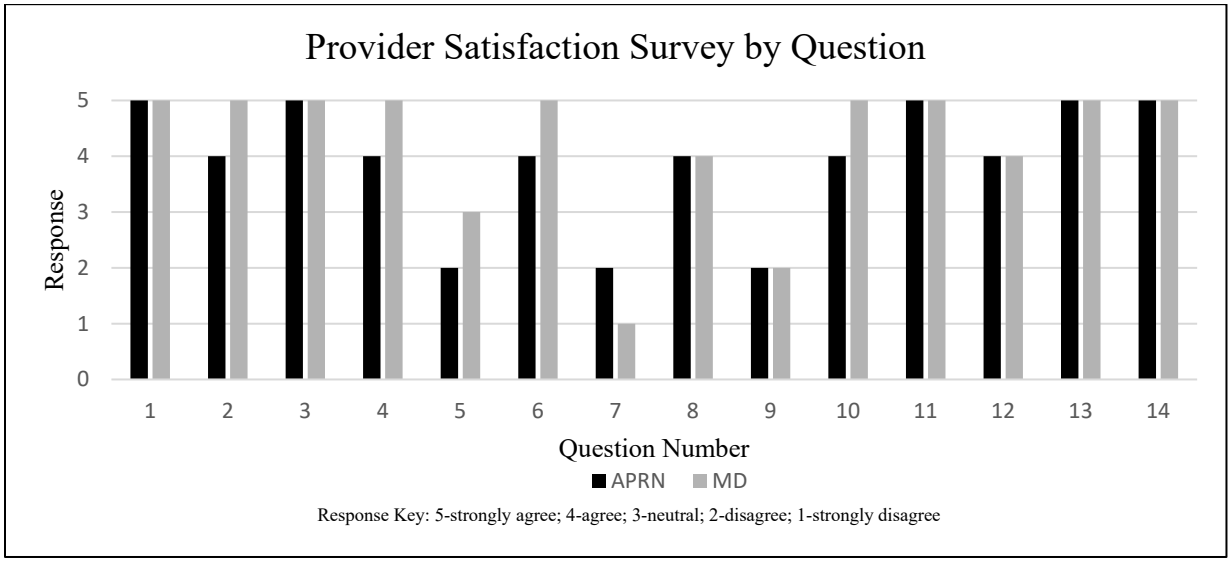
Frequency Distribution of Ages



Feasibility and sustainability were assessed using a provider satisfaction survey (Appendix A). This survey was a non-standardized questionnaire designed by the project leader to assess different areas of communication, project protocol effectiveness, and provider satisfaction. Overall, providers indicated that they were highly satisfied with the project protocol. They also indicated that the education session was appropriate in length and strongly agreed that this intervention process would be sustainable for them. Figure 4 demonstrates their responses to each question. Questions were grouped based on different topics. Questions 1-2 assessed comfort with announcement style communication. Questions 3-5 assessed satisfaction with the toolkit. Questions 6-9 assessed parental reaction to the intervention. Questions 10-12 assessed protocol satisfaction. Lastly, questions 13 and 14 assessed feasibility and sustainability. Responses ranged from 1-5. With 1 being strongly disagree, 2 being disagree, 3 being neutral, 4 being agree, and 5 being strongly agree. Notably, the physician was slightly more satisfied with the intervention than the APRN.

Figure 4

Provider Satisfaction Survey Responses



Discussion

Interpretation

While the data did not indicate a statistically significant increase in vaccination, there are still positive clinical takeaways from this DNP project. Primarily, it is notable that of the six patients who received the toolkit and vaccinated, all had previously declined the vaccine. This suggests that further education for patients who have previously declined or expressed hesitation could lead to vaccination. It is also notable that three of the patients chose to vaccinate immediately after receiving the toolkit. Therefore, it can be deduced that an intervention like this may be helpful for the specific group of patients who simply need more information. The text-messaging recall system did not prove to be useful in increasing vaccination. Recalls were ordered approximately half of the time. Missed opportunities to implement the intervention can be attributed to the type of visit or failure to review vaccinations at every appointment, especially sick visits.

Both providers demonstrated in their surveys that they had confidence in announcement-style communication and that the education session was appropriate and clearly informed staff of the intervention process and goals. Additionally, they indicated that they were greatly satisfied with the toolkit and that it is feasible to continue implementing it in their setting. The intervention process was successful. The staff and providers followed instructions and were able to carry out the project protocol without interruption to regular practice. Their willingness to continue to use the toolkit implies that this is an intervention which would be sustainable in other small practices.

Limitations

The primary limitation in this project was the novel coronavirus pandemic onset which was concurrent with the implementation timeline. During the implementation time frame visits to the physician office were greatly reduced, well-child checks were postponed, and patients were unwilling to vaccinate. It is likely that some of the patients who did not return after receiving the intervention toolkit and recall can be attributed to the pandemic. Due to low volume of in-office visits, sample size was negatively impacted. Missed opportunities may have been decreased if there were patients had been more willing to vaccinate. The other limitation was the text-messaging recall system. It was not able to generate a specific text message, only a generic "return to office" message. The literature had indicated that a specific message was more effective compared to generic. Due to time frame, only the primary dose in the series could be observed.

Conclusion

This project was useful in identifying educational tools to enhance patient knowledge regarding HPV and the vaccine. It proved useful for a small sub-set of patients who had

previously declined. There is potential for expansion with this intervention focusing on the group of individuals who previously declined the vaccine rather than the general pediatric population. Providers also found that this type of intervention was feasible and sustainable and were overall satisfied. It also is notable that, in the future, telephone recalls or specific text messages may be more impactful.

HPV is a substantial problem for the community and there is a vaccine to prevent HPV-related cancers. There is no consistent protocol recommended by major medical organizations at this time for HPV vaccines in the primary care. If a feasible and sustainable system improves vaccination acceptance rates, even with initial declination, it may help increase overall vaccination rates. A well-designed set of interventions could help other practices increase vaccination rates and meet the goals of Healthy People 2020. Small offices with similar settings may find the toolkit useful for their population. If a standard protocol is successful, it could help the healthcare community work towards greatly decreasing HPV-related cancers and consequences. These project strategies may prove useful in clinics that are struggling with their vaccination rates and need to improve different parts of the process. Lastly, there may be a future indication for implementation of quality improvement projects with adults as the FDA has recently approved the vaccine up to age 45 years. There will be room for expansion into the adult setting with increasing vaccination rates as more data emerges about this population and willingness to vaccinate.

References

American Academy of Pediatrics. (2017). *HPV vaccine implementation guidance.* American Academy of Pediatrics. https://www.aap.org/en-us/Documents/immunization_hpvimplementationguidance.pdf.

American College of Obstetricians and Gynecologists. (2017). *Human papillomavirus vaccination. Committee Opinion No. 704.* The American College of Obstetricians and Gynecologists. https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Adolescent-Health-Care/Human-Papillomavirus-Vaccination?IsMobileSet=false**.**

Beavis, A., Krakow, M., Levinson, K., & Rositch, A.F. (2018). Reasons for lack of HPV vaccine initiation in NIS-Teen over time: Shifting the focus from gender and sexuality to necessity and safety. *Journal of Adolescent Health*, *5,* 652–656. Doi: 10.1016/j.jadohealth.2018.06.024

Beavis, A. L., & Levinson, K. L. (2016). Preventing cervical cancer in the United States: Barriers and resolutions for HPV vaccination. *Frontiers in Oncology, 6,* 19. doi:10.3389/fonc.2016.00019

Brewer, N.T., Hall, M.E., Malo, T.L., Gilkey, M.B., Quinn, B., Lathren, C. (2017). Announcements versus conversations to improve HPV vaccination coverage: a randomized trial. *American Academy of Pediatrics*. doi: 10.1542/peds.2016-1764

Centers for Disease Control and Prevention. (2018). *HPV-associated cancer statistics.* https://www.cdc.gov/cancer/hpv/statistics/index.htm.

Centers for Disease Control and Prevention. (2018). *Vaccinating boys and girls.* https://www.cdc.gov/hpv/parents/vaccine.html.

Centers for Disease Control and Prevention. (2018). *HPV vaccine information for clinicians*. Centers for Disease Control and Prevention. https://www.cdc.gov/hpv/hcp/need-to-know.pdf.

Dekker, R.L. (2008). Human papillomavirus vaccine legislation in Kentucky: A policy analysis. *Policy, Politics & Nursing Practice, 9*(1), 40–49.

Campos, N., Sharma, M., Clark, A., Lee, K.F., Geng, F., Kim, J., & Resch, S. (2016) Comprehensive Global Cancer Prevention: Costs and Benefits of Scaling up within a decade. *American Cancer Society.* Advanced Online Publication. https://www.cancer.org/content/dam/cancer-org/cancer-control/en/reports/the-cost-of-cervical-cancer-prevention.pdf**.**

Cassidy, B., Baxter, B., Charron-Prochownik, D., & Schlenk, E. A. (2014). A quality improvement initiative to increase HPV vaccine rates using an educational and reminder strategy with parents of preteen girls. *Journal of Pediatric Healthcare*, *28*(2), 155–164. Advanced Online Publication. https://doi-org.echo.louisville.edu/10.1016/j.pedhc.2013.01.0.

Dempsey A.F., Pyrznawoski J, Lockhart S., Barnard J., Campagna E.J., Garrett K., Fisher A., Dickinson L.M., O'Leary S.T. (2018). Effect of a health care professional communication training intervention on adolescent human papillomavirus vaccination: A cluster randomized clinical trial. *JAMA Pediatr*ics. doi: 10.1001/jamapediatrics.2018.0016.

Dela Cruz, M., Tsark, J., Chen, J. J., Albright, C. L., & Braun, K. L. (2017). Human papillomavirus (HPV) vaccination motivators, barriers, and brochure preferences among parents in multicultural Hawai'i: a qualitative study. *Journal of Cancer Education: The*

Official Journal of the American Association for Cancer Education, *32*(3), 613–621. doi:10.1007/s13187-016-1009-2

Garbutt, J. M., Dodd, S., Walling, E., Lee, A. A., Kulka, K., & Lobb, R. (2018). Barriers and facilitators to HPV vaccination in primary care practices: A mixed methods study using the Consolidated Framework for Implementation Research. *BMC Family Practice*, *19*(1), Advanced Online Publication. https://doi-org.echo.louisville.edu/10.1186/s12875-018-0750-5

Henrikson, N. B., Zhu, W., Baba, L., Nguyen, M., Berthoud, H., Gundersen, G., & Hofstetter, A. M. (2018). Outreach and reminders to improve human papillomavirus vaccination in an integrated primary care system. *Clinical Pediatrics*, *57*(13), 1523–1531. Advanced Online Publication. https://doi-org.echo.louisville.edu/10.1177/0009922818787868.

Krantz, L., Ollberding, N. J., Beck, A. F., & Carol Burkhardt, M. (2018). Increasing HPV vaccination coverage through provider-based interventions. *Clinical Pediatrics*, *57*(3), 319-326. doi:10.1177/0009922817722014.

Melnyk, B.M., & Fineout-Overholt, E. (2015*). Evidence-based practice in nursing and healthcare: A guide to best practice* (3rd Ed*.). Making the case for evidence-based practice and cultivating a spirit of inquiry*. Wolters Kluwer.

Office of Disease Prevention and Health Promotion. (n.d.). *Healthy People 2020.* Office of Disease Prevention and Health Promotion. https://www.healthypeople.gov/2020/topics-objectives/topic/sexually-transmitted-diseases.

Palmeri, S., Costantino, C., D'Angelo, C., Casuccio, N., Ventura, G., Vitale, F., Pojero, F., & Casuccio, A. (2017). HPV vaccine hesitancy among parents of female adolescents: A

pre–post interventional study. *Public Health, 150,* 84–86. Advanced Online Publication. https://doi-org.echo.louisville.edu/10.1016/j.puhe.2017.05.009

Rand, C. M., Schaffer, S. J., Dhepyasuwan, N., Blumkin, A., Albertin, C., Serwint, J. R., & Szilagyi, P. G. (2018). Provider communication, prompts, and feedback to improve hpv vaccination rates in resident clinics. *American Academy of Pediatrics*, *141*(4), 1–8. Advanced Online Publication. https://doi-org.echo.louisville.edu/10.1542/peds.2017-0498

Rand, C. M., Tyrrell, H., Wallace-Brodeur, R., Goldstein, N. P. N., Darden, P. M., Humiston, S. G., Albertin C.S., Stratbucker, W., Schaffer, S.J., Davis, W., & Szilagyi, P. G. (2018). A learning collaborative model to improve human papillomavirus vaccination rates in primary care. *Academic Pediatrics Association*, *18,* S46–S52. Advanced Online Publication. https://doi-org.echo.louisville.edu/10.1016/j.acap.2018.01.003.

Rand, C. M., Vincelli, P., Goldstein, N. P. N., Blumkin, A., & Szilagyi, P. G. (2017). Effects of phone and text message reminders on completion of the human papillomavirus vaccine series. *Journal of Adolescent Health*, *60*(1), 113–119. https://doi-org.echo.louisville.edu/10.1016/j.jadohealth.2016.09.011

Rosenstock, I. M. (1966). Why people use health services. *Milbank Memorial Fund Quarterly*, *44*, 94–127.

Walling, E. B., Benzoni, N., Dornfeld, J., Bhandari, R., Sisk, B. A., Garbutt, J., & Colditz, G. (2016). Interventions to improve HPV vaccine uptake: A systematic review. *Pediatrics*, *138*(1), 1–11. Advanced Online Publication. https://doi-org.echo.louisville.edu/10.1542/peds.2015-3863

Wilburn, A., Vanderpool, R., Knight, J., & Evers, M.B. (2016). *Human Papillomavirus (HPV) vaccination in Kentucky: An environmental scan.* Markey Cancer Center and College of Public Health. University of Kentucky.

Wisk, L. E., Allchin, A., & Witt, W. P. (2014). Disparities in human papillomavirus vaccine awareness among U.S. parents of preadolescents and adolescents. *Sexually Transmitted Diseases, 41*(2), 117–122. doi:10.1097/OLQ.0000000000000086

Zimet, G., Dixon, B. E., Shan Xiao, Wanzhu Tu, Kulkarni, A., Dugan, T., Sheley, M., Downs, S. M. (2018). Simple and elaborated clinician reminder prompts for human papillomavirus vaccination: a randomized clinical trial. *Academic Pediatrics Association*, *18,* S66–S71. Advanced Online Publication. https://doi-org.echo.louisville.edu/10.1016/j.acap.2017.11.002.

Appendix A

Feasibility and Sustainability Survey

Feasibility and Sustainability: Provider Satisfaction Survey

Please indicate the varying level of consensus with each statement. For each statement, please select from the following options: Strongly Agree, Agree, Neutral, Disagree, Strongly Disagree.

1. HPV vaccination declination by parents presents a barrier to effective, preventative care.
   A) Strongly Agree
   B) Agree
   C) Neutral
   D) Disagree
   E) Strongly Disagree

2. There is a positive response when I recommend the vaccine using announcement-style language rather than posing a question.
   A) Strongly Agree
   B) Agree
   C) Neutral
   D) Disagree
   E) Strongly Disagree

3. The educational toolkit contained appropriate and useful resources.
   A) Strongly Agree
   B) Agree
   C) Neutral
   D) Disagree
   E) Strongly Disagree

4. The educational toolkit was an appropriate reading level for the parents and patients of this practice.
   A) Strongly Agree
   B) Agree
   C) Neutral
   D) Disagree
   E) Strongly Disagree

5. There were situations where the toolkit was indicated by protocol but was not available in the appropriate language.
   A) Strongly Agree
   B) Agree
   C) Neutral
   D) Disagree
   E) Strongly Disagree

6. I feel comfortable and knowledgeable on presenting a vaccine in a presumptive statement, rather than a question.
   A) Strongly Agree
   B) Agree
   C) Neutral
   D) Disagree
   E) Strongly Disagree

7. Consenting parties, such as parents, became upset when I approached the subject of vaccinating their child for HPV presumptively.
   A) Strongly Agree
   B) Agree
   C) Neutral
   D) Disagree
   E) Strongly Disagree

8. Parents expressed concerns over side effects of the vaccine.
   A) Strongly Agree
   B) Agree
   C) Neutral
   D) Disagree
   E) Strongly Disagree

9. Parents expressed concerns over increasing risk of promiscuity in their child.
   A) Strongly Agree
   B) Agree
   C) Neutral
   D) Disagree
   E) Strongly Disagree

10. The education session was appropriate in length.
    A) Strongly Agree
    B) Agree
    C) Neutral
    D) Disagree
    E) Strongly Disagree

11. The education session clearly informed all staff of the expectations of the project.
    A) Strongly Agree
    B) Agree
    C) Neutral
    D) Disagree
    E) Strongly Disagree

12. The recall system was simple to implement.
    A) Strongly Agree

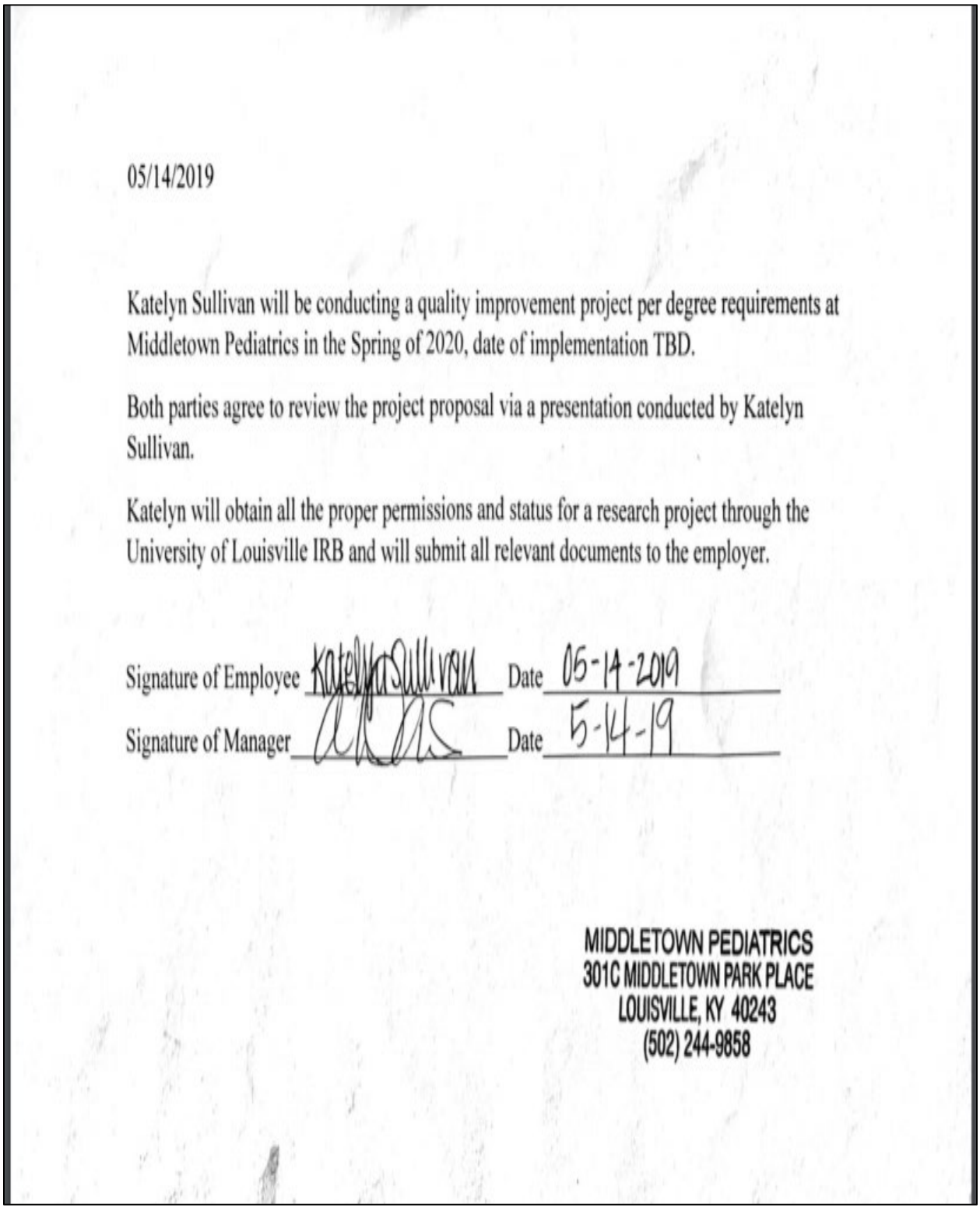
B) Agree
C) Neutral
D) Disagree
E) Strongly Disagree

13. I feel satisfied with this project protocol.
    A) Strongly Agree
    B) Agree
    C) Neutral
    D) Disagree
    E) Strongly Disagree

14. This protocol is sustainable in this office.
    A) Strongly Agree
    B) Agree
    C) Neutral
    D) Disagree
    E) Strongly Disagree

Appendix B

Letter of Approval from Agency



05/14/2019

Katelyn Sullivan will be conducting a quality improvement project per degree requirements at Middletown Pediatrics in the Spring of 2020, date of implementation TBD.

Both parties agree to review the project proposal via a presentation conducted by Katelyn Sullivan.

Katelyn will obtain all the proper permissions and status for a research project through the University of Louisville IRB and will submit all relevant documents to the employer.

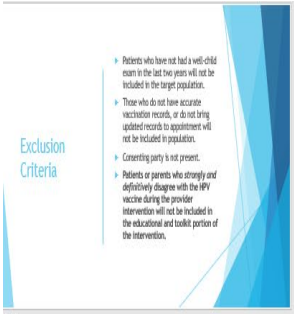
Signature of Employee Katelyn Sullivan Date 05-14-2019

Signature of Manager Date 5-14-19

MIDDLETOWN PEDIATRICS
301C MIDDLETOWN PARK PLACE
LOUISVILLE, KY 40243
(502) 244-9858

Appendix C

Educational Power Point



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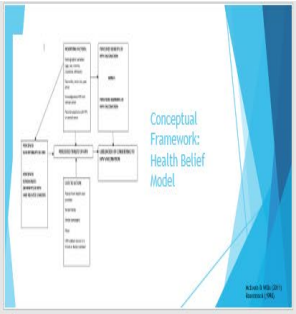

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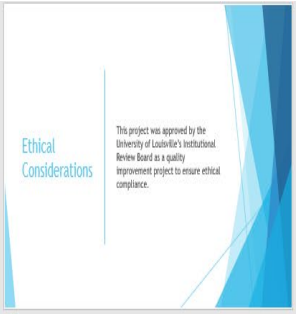

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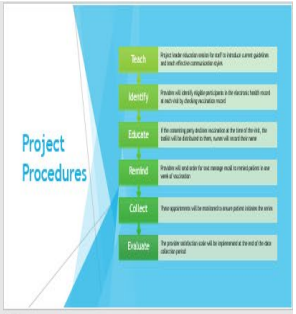

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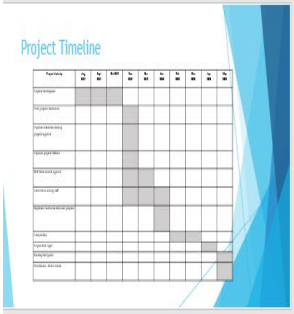

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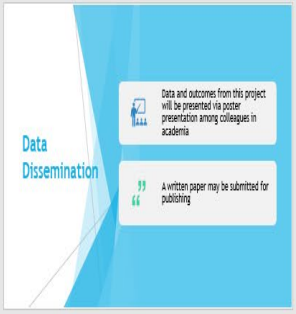

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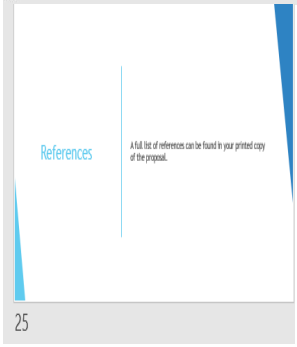

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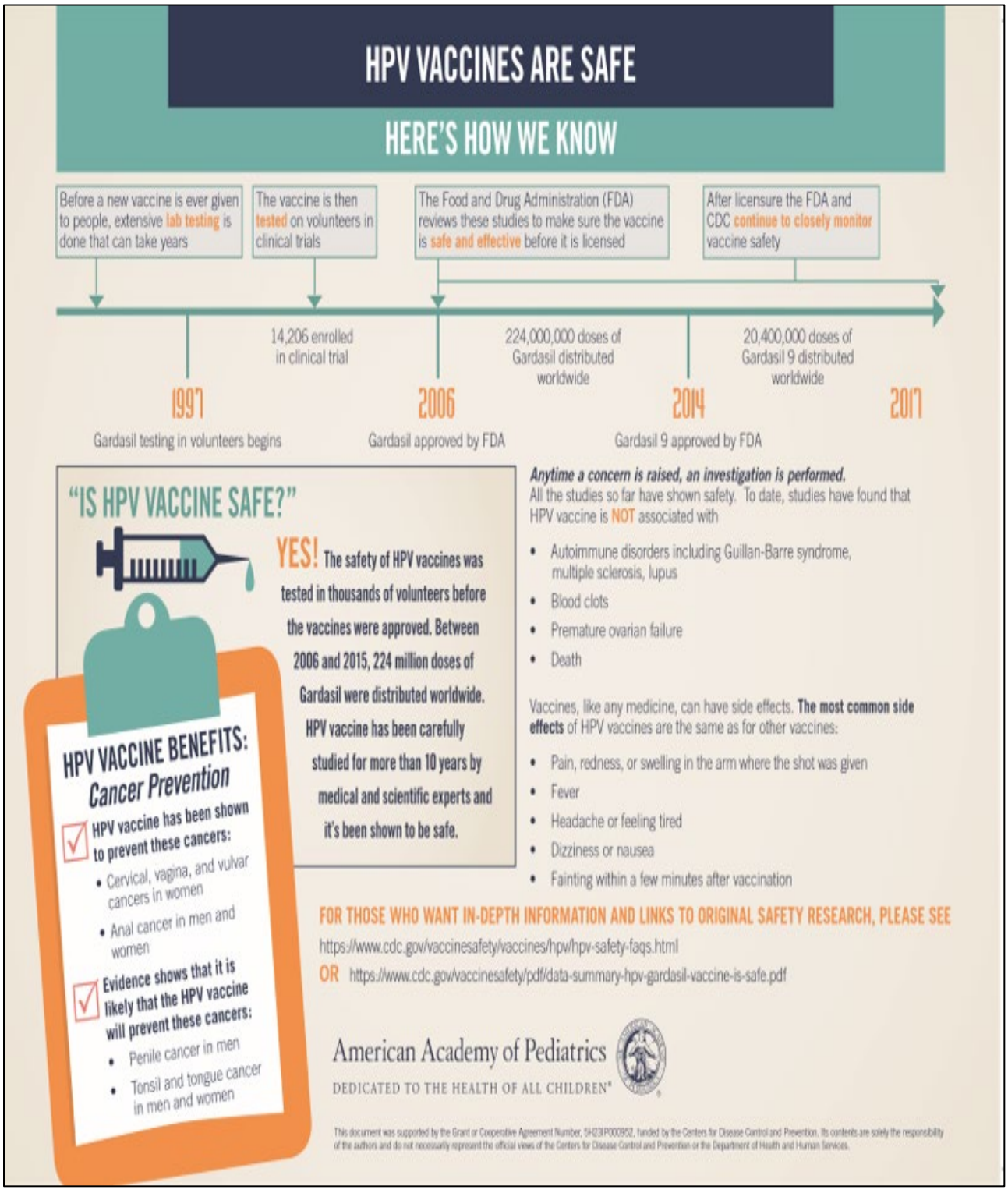
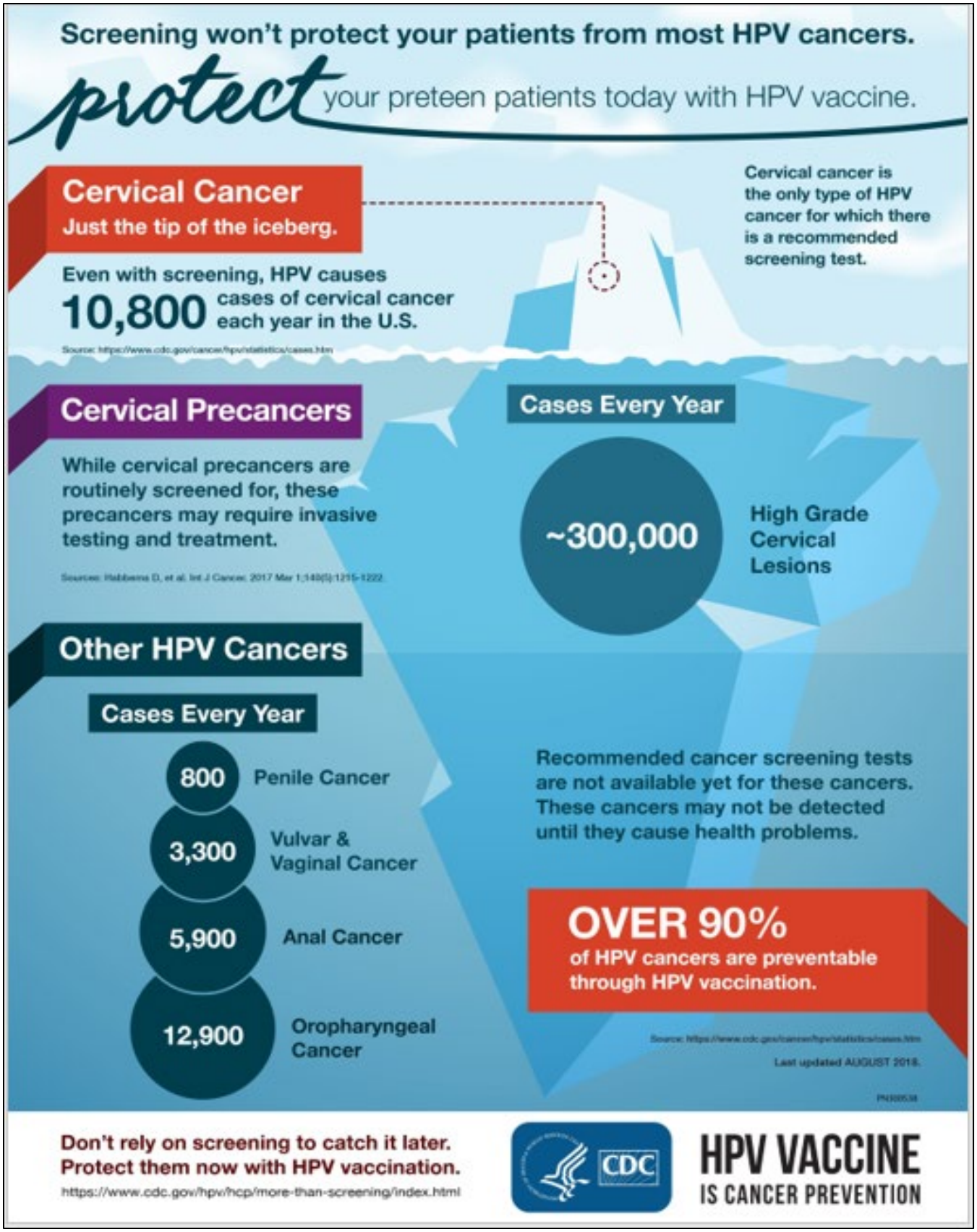
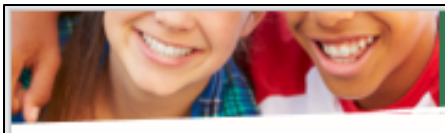
Appendix D

Educational Toolkit




Screening won't protect your patients from most HPV cancers.
protect your preteen patients today with HPV vaccine.
Cervical Cancer
Just the tip of the iceberg.
Even with screening, HPV causes
10,800 cases of cervical cancer each year in the U.S.
Source: https://www.cdc.gov/cancer/hpv/statistics/cases.htm
Cervical cancer is the only type of HPV cancer for which there is a recommended screening test.
Cervical Precancers
While cervical precancers are routinely screened for, these precancers may require invasive testing and treatment.
Sources: Habbema D, et al. Int J Cancer. 2017 Mar 1;140(5):1215-1222.
Cases Every Year
~300,000
High Grade Cervical Lesions
Other HPV Cancers
Cases Every Year
800 Penile Cancer
3,300 Vulvar & Vaginal Cancer
5,900 Anal Cancer
12,900 Oropharyngeal Cancer
Recommended cancer screening tests are not available yet for these cancers. These cancers may not be detected until they cause health problems.
OVER 90%
of HPV cancers are preventable through HPV vaccination.
Source: https://www.cdc.gov/cancer/hpv/statistics/cases.htm
Last updated AUGUST 2018.
Don't rely on screening to catch it later.
Protect them now with HPV vaccination.
https://www.cdc.gov/hpv/hcp/more-than-screening/index.html
CDC
HPV VACCINE
IS CANCER PREVENTION



IS CANCER PREVENTION

HPV Vaccine Safety and Effectiveness

HPV vaccination provides safe, effective, and long-lasting protection against cancers caused by HPV.

HPV vaccination prevents cancer

Human papillomavirus (HPV) infects about 14 million people, including teens, each year. While most HPV infections go away on their own, infections that don't go away can lead to certain types of cancer. Every year, 32,500 men and women develop a cancer caused by HPV. **HPV vaccination could prevent more than 90% of these cancers from ever developing.** The vaccine is made from one protein from the virus, and is not infectious, meaning it *cannot* cause HPV infection or cancer.

HPV vaccination is safe for boys and girls

With over 100 million doses distributed in the United States, HPV vaccine has a reassuring safety record that is backed by over 10 years of monitoring and research. All vaccines used in the United States are required to go through years of extensive safety testing before they are licensed. Once in use, public health officials continuously monitor their safety and effectiveness.

Since the Food and Drug Administration (FDA) licensed the vaccine, scientists and vaccine researchers have conducted large research studies to monitor and evaluate safety. These studies show that HPV vaccine is safe and is not associated with any serious safety concerns.

HPV vaccination works

The HPV vaccine works extremely well. Since HPV vaccination was introduced over 10 years ago, infections with HPV types that cause most HPV cancers and genital warts have dropped 71 percent among teen girls. Research has also shown that fewer women are developing cervical precancers (abnormal cells on the cervix that can lead to cancer).

HPV vaccination provides long-lasting protection

Studies suggest that the protection provided by HPV vaccine is long lasting. Studies have followed people who received HPV vaccine for about 10 years, and protection has remained high in those individuals with no evidence of the protection decreasing over time.

HPV vaccination can cause side effects

Like any vaccine or medicine, HPV vaccination can cause side effects. The most common side effects are mild and include pain, redness, or swelling in the arm where the shot is given; dizziness, fainting, nausea, and headache. Fainting after any vaccine, including HPV vaccine, is more common among adolescents. To prevent fainting and injuries related to fainting, anyone receiving HPV vaccine should be seated or lying down during vaccination and remain in that position for 15 minutes after the vaccine is given. The benefits of HPV vaccination far outweigh any potential risk of side effects.

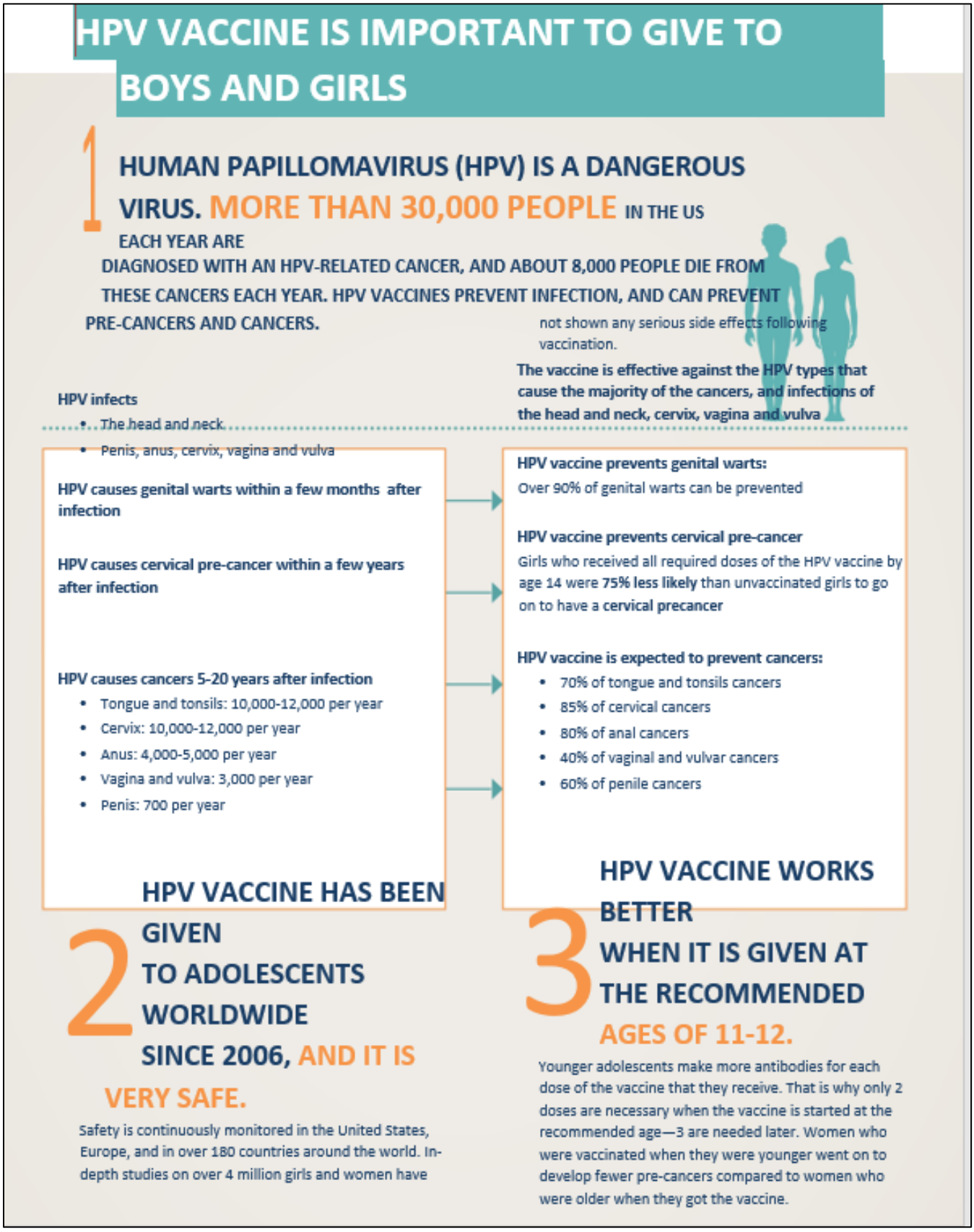
HPV vaccination doesn't negatively affect fertility

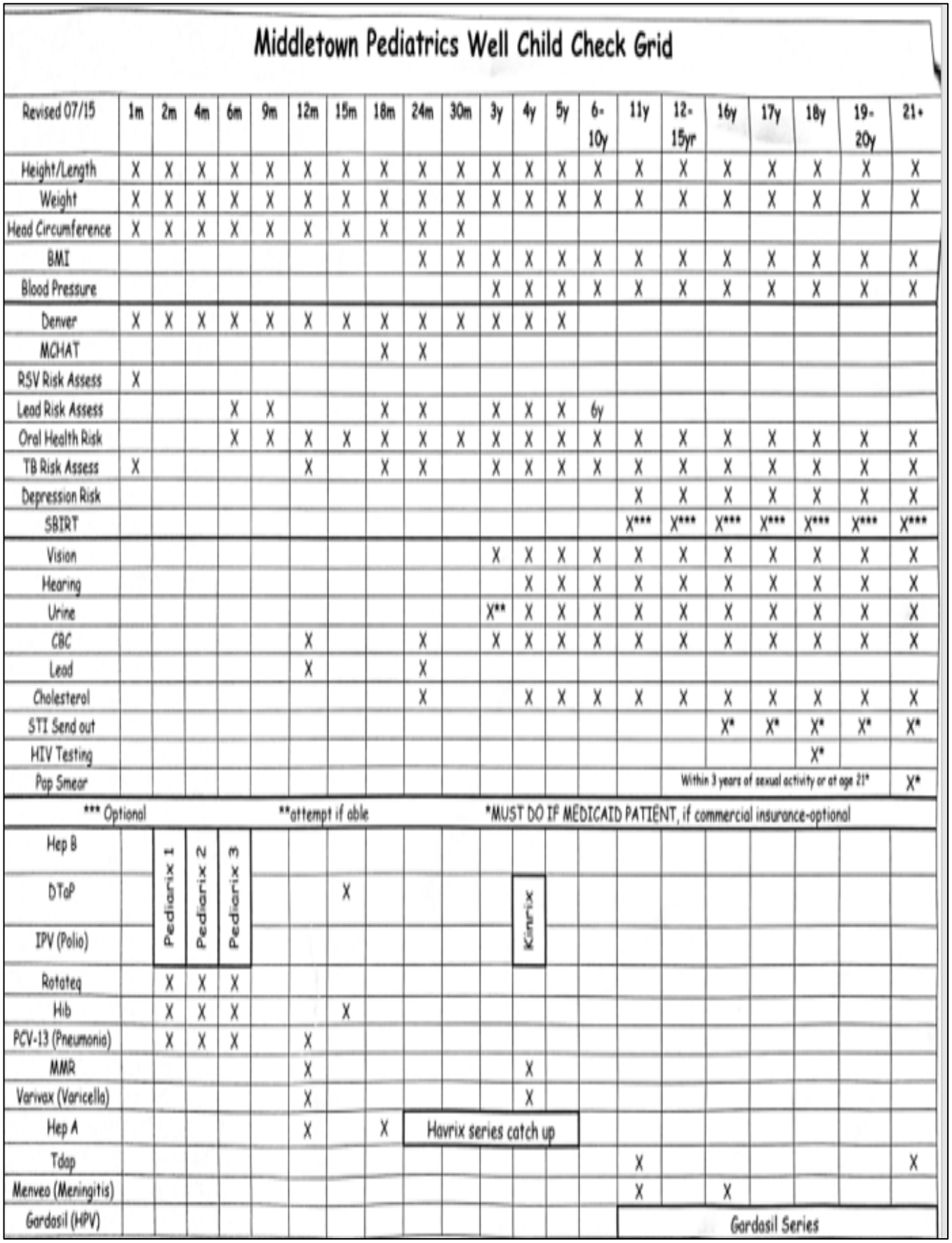
There is no evidence to suggest that HPV vaccine causes fertility problems. However, not getting HPV vaccine leaves people vulnerable to HPV cancers and precancers. Women who develop a precancer or cancer caused by HPV could require treatment that would limit their ability to have children, such as a hysterectomy, chemotherapy, or radiation. Treatment for cervical precancer could also put a woman at risk for problems with her cervix, which could cause preterm delivery.

How can I get help paying for vaccines?

The Vaccines for Children (VFC) program provides vaccines for children ages 18 years and younger, who are uninsured, Medicaid-eligible, American Indian or Alaska Native. Learn more at

www.cdc.gov/Features/VFCprogram


HPV VACCINE IS IMPORTANT TO GIVE TO BOYS AND GIRLS
1
HUMAN PAPILLOMAVIRUS (HPV) IS A DANGEROUS VIRUS. MORE THAN 30,000 PEOPLE IN THE US EACH YEAR ARE DIAGNOSED WITH AN HPV-RELATED CANCER, AND ABOUT 8,000 PEOPLE DIE FROM THESE CANCERS EACH YEAR. HPV VACCINES PREVENT INFECTION, AND CAN PREVENT PRE-CANCERS AND CANCERS.
not shown any serious side effects following vaccination.
The vaccine is effective against the HPV types that cause the majority of the cancers, and infections of the head and neck, cervix, vagina and vulva
HPV infects
The head and neck
Penis, anus, cervix, vagina and vulva
HPV causes genital warts within a few months after infection
HPV causes cervical pre-cancer within a few years after infection
HPV causes cancers 5-20 years after infection
Tongue and tonsils: 10,000-12,000 per year
Cervix: 10,000-12,000 per year
Anus: 4,000-5,000 per year
Vagina and vulva: 3,000 per year
Penis: 700 per year
HPV vaccine prevents genital warts:
Over 90% of genital warts can be prevented
HPV vaccine prevents cervical pre-cancer
Girls who received all required doses of the HPV vaccine by age 14 were 75% less likely than unvaccinated girls to go on to have a cervical precancer
HPV vaccine is expected to prevent cancers:
70% of tongue and tonsils cancers
85% of cervical cancers
80% of anal cancers
40% of vaginal and vulvar cancers
60% of penile cancers
2
HPV VACCINE HAS BEEN GIVEN TO ADOLESCENTS WORLDWIDE SINCE 2006, AND IT IS VERY SAFE.
Safety is continuously monitored in the United States, Europe, and in over 180 countries around the world. In-depth studies on over 4 million girls and women have
3
HPV VACCINE WORKS BETTER WHEN IT IS GIVEN AT THE RECOMMENDED AGES OF 11-12.
Younger adolescents make more antibodies for each dose of the vaccine that they receive. That is why only 2 doses are necessary when the vaccine is started at the recommended age—3 are needed later. Women who were vaccinated when they were younger went on to develop fewer pre-cancers compared to women who were older when they got the vaccine.



Middletown Pediatrics Well Child Check Grid

Revised 07/15	1m	2m	4m	6m	9m	12m	15m	18m	24m	30m	3y	4y	5y	6-10y	11y	12-15yr	16y	17y	18y	19-20y	21+
Height/Length	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Weight	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Head Circumference	X	X	X	X	X	X	X	X	X	X											
BMI									X	X	X	X	X	X	X	X	X	X	X	X	X
Blood Pressure											X	X	X	X	X	X	X	X	X	X	X
Denver	X	X	X	X	X	X	X	X	X	X	X	X	X								
MCHAT								X	X												
RSV Risk Assess	X																				
Lead Risk Assess				X	X			X	X		X	X	X	6y							
Oral Health Risk				X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
TB Risk Assess	X					X		X	X		X	X	X	X	X	X	X	X	X	X	X
Depression Risk															X	X	X	X	X	X	X
SBIRT															X***	X***	X***	X***	X***	X***	X***
Vision											X	X	X	X	X	X	X	X	X	X	X
Hearing												X	X	X	X	X	X	X	X	X	X
Urine											X**	X	X	X	X	X	X	X	X	X	X
CBC						X			X		X	X	X	X	X	X	X	X	X	X	X
Lead						X			X												
Cholesterol									X			X	X	X	X	X	X	X	X	X	X
STI Send out																	X*	X*	X*	X*	X*
HIV Testing																			X*		
Pap Smear																Within 3 years of sexual activity or at age 21*					X*

*** Optional **attempt if able *MUST DO IF MEDICAID PATIENT, if commercial insurance-optional

Hep B		Pediarix 1	Pediarix 2	Pediarix 3																	
DTaP							X					Kinrix									
IPV (Polio)																					
Rotateq		X	X	X																	
Hib		X	X	X			X														
PCV-13 (Pneumonia)		X	X	X		X															
MMR						X						X									
Varivax (Varicella)						X						X									
Hep A						X		X	Havrix series catch up												
Tdap															X						X
Menveo (Meningitis)															X		X				
Gardasil (HPV)															Gardasil Series						

Appendix E

Toolkit Distribution List

DNP PROJECT TOOLKIT DISTRIBUTION LIST

NAME	DATE OF SERVICE