Assessing Quality Of And Implementing Improvements In HPV Vaccination Delivery At A Family Medicine Residency Clinic.

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Abstract

HPV-associated diseases are common and burdensome. Over 7 years of use, HPV-vaccines have been found to be effective and safe; however, uptake of said vaccines is lagging. The purpose of this study was to assess the quality of and implement improvements in HPV vaccination delivery at a family medicine residency clinic. Electronic chart review was conducted before and after implementation of interventions including: strengthened HPV-vaccine recommendations with increased education for parents, providers and patients; scheduling 2nd and 3rd dose follow-up visits at time of 1st dose; patient-reminder cards and appointment-reminder calls. No significant changes in HPV vaccinations rates were seen following 4 months of implementation. Also, some significant disparities were seen in receipt of vaccine with females being vaccinated more than males and blacks more than whites. Despite this, interventions were easy and inexpensive to implement and the normal HPV vaccine course extends a minimum of 6 months, well beyond the 4-month implementation. Given this and burden of diseases in question, an extended trial of 1-2 years with added focus on above disparities seems warranted to truly assess effectiveness.

Introduction

In 2008 there was an estimated 14,100,100 new HPV infections in the United states bringing the 2008 total of HPV infected individuals in the country to 79,100,000. [1] The burden of disease for HPV ranges from genital warts and Recurrent Respiratory Papillomatosis to cancers of the cervix, anus, oropharynx, vulva, vagina and penis. In 2009, incidence of new HPV-associated cancers in the United States was 34,788 with 21,342 of those cases in women (53.4% cervical) and 13,446 in men (78.2% oropharyngeal).[2] The annual cost of these HPV-associated diseases is estimated at 8.0 billion dollars. [3]

The quadrivalent HPV vaccine was licensed in 2006 for females (and in 2009 for males), covering HPV types 6, 11, 16 and 18. [4] The bivalent vaccine was licensed in 2009 for females covering only types 16 and 18, which are the types most often associated with HPV-attributable cancers. [4] There are three vaccine administrations and, currently, their schedule from date of first vaccination is 0, 1-2, and 6 months. The quadrivalent and bivalent vaccines are recommended for females aged 9-26 years old. This is similar for males except that only the quadrivalent is licensed for use and MSM or immunocompromised males aged 21 or older who have not received the full course are especially recommended for vaccination. [4] Since the inception of their use, Vaccine Safety Datalink has been monitoring patient's receiving these vaccines and have found them to be safe with no significant increased risk for any of the pre-specified adverse events (GBS, seizures, anaphylaxis, etc.) [5]

According to the CDC, HPV vaccination rates leveled off between 2011 and 2012. [6] Eighty-four percent of these girls unvaccinated for HPV received other vaccines and, if an HPV vaccine had been administered at these times, coverage for 1 dose or greater of HPV vaccine could be an estimated 93% rather than its current 54%. Worse, the current 3-dose HPV vaccine coverage rate is only 33%. The CDC found that for each year the 3-dose HPV vaccine series remains at this current level an additional 4,400 women will be diagnosed with cervical cancer and 1,400 cancer-attributable deaths will occur in the future. [7]

All of these serves to illustrate that: HPV is a common and burdensome disease and that the HPV vaccines are effective and safe. Despite this, HPV vaccination rates are leveling off. Fortunately, many of the barriers to HPV vaccination are surmountable with simple interventions geared towards patient, parent and physician education. The purpose of this study was to assess the quality of and implement improvements in HPV vaccination delivery at a family medicine residency clinic.

Methods

This was a prospective interventional cohort study. The study took part in three stages. First, baseline data was collected from our residency's Family Medicine clinic by electronic chart review. This served to identify current vaccination rates (single, double and triple dose) for eligible patients aged 9-26 male and female. Information pulled from the chart included: gender, age, insurance coverage, and vaccination history. A Business Intelligence Architect from our hospital system's Analytics and Performance department was supplied this data extraction sheet and analyzed the charts of the population of interest. She populated a data sheet with the requested information and then de-identified this information before supplying the data to the statistician and myself, the primary investigator, to be analyzed. Before beginning, this study was submitted to IRB for review and was subsequently given expedited IRB approval.

Following this, interventions were implemented at the clinic to increase HPV vaccination rates. These included a verbal recommendation from both nursing staff and physician for the HPV vaccination at every visit when it's administration would be appropriate. Follow-up visits were scheduled at the time of the first and second dose for the second and third dose respectively. Patients and parents were supplied with a business-card sized piece of paper, which showed the date of their first vaccination and subsequent scheduled appointment dates for their second and third vaccines. Telephone call reminders were made the morning of scheduled vaccine administration days. After four months of the implementation of these new interventions, a chart review was conducted once again to identify any improvements and illustrate areas in need of further intervention.

Chi square test was performed to compare the difference for categorical variables. Frequency and percentages were reported for these variables. T test or equivalent nonparametric modes were used based on the data distributions. Multiple logistic regressions were conducted to assess the specialty effect on the all three doses of HPV vaccine rate, adjusted for appropriate covariates such as gender, race and insurance coverage. The two-tailed P values were calculated for all tests and $p<0.05$ was considered for statistical significance. All statistical analyses were conducted using SAS 9.2(SAS Institute Inc., Cary, NC).

Results

The sample size was 2175 patients with 1840 in the pre-implementation group and 335 in the post-implementation group. We excluded 582 subjects from the data analysis since those subjects were present in both the pre and post data sets. We further narrowed our analysis to patients 13-17 years old as this was the age range studied in the National Immunization Survey. This brought the sample size to 414 patients with 353 in the pre-implementation group and 61 in the post-implementation group.

Pre-implementation, the rates in patient's 13-17 years old for HPV vaccination were: 42 % with zero doses, 58% with at least one dose, 37% with at least two doses, and 25% with all three doses. Post-implementation rates were: 48 % with zero doses, 52% with at least one dose (p: 0.4374), 34% with at least two doses (p: 0.7507), and 20% with all three doses (p:04004). P-values are for Chi-square analysis of pre versus post-implementation rates with no significant differences seen.

Analyzing the pre-implementation data among those 13-17 years old, we looked at the different demographic groups' receipt of 1 or more doses with the following results. Comparing genders, 68% of females received at least one dose versus 51% of males (p: 0.0002). Comparing ethnicity, 65% of blacks and 55% of whites received at least one dose (p: 0.0275). Finally, 62% of those patients with public insurance versus 55% with private insurance received at least one dose (p: 0.2367). We checked the interaction effects between these demographic characteristics using logistic regression

models with the post-implementation data and found the post-implementation group had the same rate difference seen in the pre-implementation data.

Conclusions

No significant change was seen in HPV vaccine rates following implementation of stated interventions. Further, significant disparities were seen in receipt of the vaccine with females being vaccinated more than males and blacks more than whites. Despite insignificant effect, the interventions were, anecdotally, easy and inexpensive to implement and maintain.

This study had many limitations. It had a component of retrospective chart review, weakening its strength. Most importantly, the study was originally intended to run for 1 full year of implementation but was truncated to 4 months due to a change in EMRs at this 4-month interval. Maintaining the year course would have created too great a variation in comparing pre and post-implementation data from two different EMRs. This shortened 4 -month timeline is significant in studying a vaccine course that is at a minimum at least 6 months and has no maximum intervals between doses. These 4 months also extended from January through April, no longer including the high-vaccine-period of the late summer and fall when the age group in question comes to clinic for school physicals.

Despite no significant changes in vaccination rates, the ease and low-cost of interventions coupled with heavy burden of HPV-associated diseases warrants further study and testing. An extended trial of 1-2 years with added focus on above disparities is recommended to truly assess the effectiveness of these interventions.

Resources

1. http://www.cdc.gov/std/stats/STI-Estimates-Fact-Sheet-Feb-2013.pdf

2. Ahmedin Jemal, Edgar P. Simard, Christina Dorell, Anne-Michelle Noone, Lauri E. Markowitz, Betsy Kohler, Christie Eheman, Mona Saraiya, Priti Bandi, Debbie Saslow,Kathleen A. Cronin, Meg Watson, Mark Schiffman, S. Jane Henley, Maria J. Schymura,Robert N. Anderson, David Yankey, and Brenda K. Edwards. Annual Report to the Nation on the Status of Cancer, 1975–2009, Featuring the Burden and Trends in Human Papillomavirus (HPV)–Associated Cancers and HPV Vaccination Coverage Levels. JNCI J Natl Cancer Inst (2013) 105 (3): 175-201 first published online January 7, 2013doi:10.1093/jnci/djs491

3. Chesson H et al. Vaccine 2012;30: 6016-19?

4. http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm172678.html

5. Gee J et al. Vaccine 2011;29:8279-84

6. 2012 National Immunization Survey-Teen (NIS-Teen)

7. http://www.cdc.gov/media/releases/2013/p0725-HPV-vaccine.html