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B. Dale Magee
University of Massachusetts Medical School

Et al.

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Authors:

1. B. Dale MAGEE, MD, MS, Dept. of OB-Gyn, University of Massachusetts Medical School, Worcester, MA

Corresponding author: 555 Main St; Shrewsbury, MA 01545; 508-842-2010, Fax: 508-842-8790; dalemagee@gmail.com

2. AuTumn S. DAVIDSON, MD**,** Dept. of OB-Gyn, University of Massachusetts Medical School, Worcester, MA

3. Ms L. REGH, MBA, Fallon Community Health Plan, Worcester, MA

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Abstract (Word Count 244)

Objective: To use the 3 dose HPV vaccine administration (given at 0, 1-2 and 6 months) to quantify opportunities to improve efficacy in the delivery of preventive health services.

Methods: This was a retrospective, claims-based analysis using data provided by a single managed care plan. Female patients aged 9-26 who were continuously enrolled between 2009 through 2011 and received ≥ dose of the HPV vaccine during 2010 were analyzed. The proportion of initiators who did and did not completed the vaccine series, the timing and location of doses, and the number of outpatient visits during which the vaccine could have been given to non-completers were determined.

Results: 1,830 patients were analyzed in the 2010 sample. 843 (46%) were continuously enrolled during the three-year observation period. 500 (59%) completed 3 doses. Among completers, the interval range between doses 1 and 2 was 27-619 days (median 96 days). The interval range between doses 2 and 3 was 32-621 days (median 127 days). 261 (52%) completers received dose 2, and 139 (28%) received does 3 over 1 month late. Among the 343 non-completers, 137 (40%), and 206 (60%) completed 1 and 2 doses, respectively. 63% of single-dose recipients and 17% of 2-dose recipients had at least 1 visit within the eligible time period for administration.

Conclusion: Nearly half of HPV vaccine initiators do not complete the vaccine series. Of those who do, a large percentage complete it late. This example quantifies the potential for reminders, registries and outreach to improve on-time dosage and completion.

Level of Evidence: II

Key Words: Human Papilloma Virus; Vaccine; Quality of Care; Efficacy; Medication Adherence; Guideline Adherence; Missed Opportunities; Health Care Cost, Access & Evaluation

Introduction: Today in the U.S. about 50% of the recommended preventive health care is carried out[1]. In this study, we examine experience with the administration of the HPV vaccine in order to address a more generalized problem of effective delivery of preventive health services. The vaccines (2 are available) are given in a series of 3 shots over 6 months. Both are currently approved for males and females aged 9 to 26[2,3]. Studies have shown that, among those who start the series, completion rates are about 50%[4-8].

This pilot study quantifies opportunities for improvement in vaccine completion rates. We analyzed claims of a single health plan who received at least 1 dose of the HPV vaccine. We assess the potential impact of registries, reminders and outreach and consider what level it should be carried out, should it be at the level of the individual office, the health care delivery organization, the health plan, or the regional Department of Public Health? How much redundancy in the system is healthy?

Materials and Methods

This is a retrospective, claims-based, observational study of patients enrolled in a single health plan during 2010. All claims for female patients between the ages of 9 and 26 who had a claim for HPV vaccine in 2010 were obtained from the health plan. Claims were based on CPT code of 90649: Quadrivalent Human Papillomavirus [Types 6, 11, 16, 18] Recombinant Vaccine (Gardasil, Merck) or 90650: Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant (CERVARIX, GlaxoSmithKline Biologicals). Since the 6 month series could easily cross over into adjacent year (and the maximum interval for administration is listed as 1 year by the manufacturer) we focused on the subgroup with continuous enrollment for 2009-11.

Collected data included year of birth, dates of vaccine administration, specialty of provider, provider group, continuous or sporadic enrollment for 2009, 2010, 2011, and, for those with fewer than 3 doses, interval visit dates and provider specialties and groups.

We determined the number of doses for each participant, and the intervals between the doses. For those without 3 documented vaccine doses we analyzed evaluation and management (E&M) codes for office visits (CPT codes 992XX and 993XX) to determine whether or not these patients were seen during a dosing interval when they would have been eligible for completion of the vaccine course. For those who had only 1 dose we looked for visits occurring between 60 and 365 days after that dose. For those receiving 2 doses, we looked for visits occurring between 120 days after dose 2 and 365 days after dose 1. The range in the number of visits and median number of visits among those with interval visits were calculated. We calculated visits that occurred with the same specialty and same group for those with eligible visits (specific provider identifiers were not made available for privacy reasons).

Confidence intervals and p values for comparisons were calculated using STATA version 9 (STATACorp LP, College Station, TX). Percentages are rounded to the nearest 1%.

The study was approved by the University of Massachusetts Medical Institutional Review Board and the Fallon Community Health Plan and MassHealth (Massachusetts' Medicaid Program).

Results

The total number of female patients aged 9-26 for whom at least 1 HPV vaccine claim was submitted during 2010 was 1,830. The median age was 16. Of the total, 840 (46%) were 9 to 15 years of age and 990 (54%) were 16 to 26 years of age in 2010. 843 (46%, 95% CI 44-48%) were continuously enrolled for all 3 years (Figure 1). Among these, 49% were 9-15yo and 44% of those who were 16-26yo ($p<0.05$).

Five hundred of the 843 (59%, 95% CI: 56-63%) who were continuously enrolled for 3 years completed the HPV vaccination series Enrollees under 16 completed the series 66% of the time, while those 16 and over completed it 53% of the time ($p<.05$). Among completers, the interval range between dose 1 and dose 2 was 27-619 days (median of 96 days). The interval range between dose 2 and dose 3 was 32-621days (median of 127 days). Among completers, 261 (52%, 95% CI: 48-57%) received dose 2, and 139 (28%, 95% CI 24-32%) received dose 3 over 1 month late. (Table 1).

Among the 343 enrollees who were continuously enrolled and did not complete the three-dose course, 137 received only 1 dose (40%, 95% CI: 35-45%) and 206 received 2 doses (60%, 95% CI: 55-65%). Among these non-completers, , 223 (65%, 95% CI: 60-70%) did not have a visit with a provider in the year post dose. Among non-completers with one dose, 86 of 137 (63%, 95% CI: 54-71%) had a visit in the eligible interval, and 55 of the 137 (40%, 95% CI: 32-49%, median 2, range 1-21) had at least one visit with the same group and the same specialty. Thirty-four of 206 with 2 doses (17%, 95% CI: 12-22%) had a visit in an eligible interval and, of these, 23 (11%) had at least 1 visit with the same group and same specialty (11%, 95% CI: 7-16%, median 2, range 1-7). The range in number of eligible visits for those receiving 1 dose was 1-21

visits with a median of 2 (95% CI: 1-2) and for those receiving two doses the range was 1-7 with a median of 1 (95% CI: 1-2) (Figures 1 and 2). By age group, older non-completers were more likely than younger ones to have had an interval visit within the time period they were eligible for vaccination: 41% vs 26% for those older than 15 and younger than 15, respectively ($p < 0.05$).

Comment:

This study used completion rates for the HPV vaccine as a model to look for opportunities to improve care in a multi-step treatment plan that spans several months. Clearly no one approach has the potential to markedly improve completion rates. Movement of patients out of the health plan was common; 54% of those who received at least 1 dose not having continuous coverage during the observation period. This limits the ability of plans to track and remind patients unless care data is exchanged among plans at enrollment. This does, however, point to a potential target for public health registries which can track individuals regardless of their insurance status.. Failure to complete the vaccine course was common , even among those who were continuously enrolled in insurance and had no co-pays (41%),. In 1/3 of the cases (36%) non-completers were seen at a provider's office in interval time period in which vaccine administration would have been appropriate. It is possible they did not receive the vaccine because in half of these cases, the enrollee was seen by a different provider than the one who had initially administered the vaccine. These missed opportunities could be decreased by incorporating provider reminders at the point of service. Such point of service reminders would, at most, improve compliance by 36% and would require reminders at visits throughout the medical group, not just the initial provider's office. Finally, for the sixty-five percent of cases that were continuously enrolled but not seen in an appropriate interval, outreach at the level of plan, organization or office may be

effective. An informal survey of the largest providers in this study revealed that none were conducting outreach for missed doses of this vaccine at the time of this study.

Another issue relates to late dosing. Although dose 2 should be given in the 1 to 2 month interval and dose 3 at about 4 months from dose 2, we found that late dosing was common. Among completers, late dosing occurred in 52% and 28% of those receiving dose 2 and 3, respectively. One month was chosen to quantify lateness since it was felt that this was a reasonable interval to exclude those who may have simply had to reschedule a visit and identify those who may have needed outreach.

Several studies have shown that patient outreach can be successful in increasing vaccine compliance. While automated calls have not shown success, personal telephone calls, text messaging[10-12], e-mails[13], and letters[14,15] have. These have been tried both as reminders pre-visit[16] and outreach after missed visits. Reminders to both the parent and the adolescent have been tried[17]. All have been met with modest success with odds ratios of 1.1 to 2[18,19] . Obtaining accurate patient contact information is challenging, especially in the adolescent population. [20]. Results have been mixed with Stockwell, dealing with a lower socioeconomic population, realizing a less than 5% increase[21] to an absolute increase of over 40% in attendance rates by Prasad[11].

Studies on the effectiveness of reminders at the point of service have shown mixed results[22-25]. This may relate to complex interfaces and high false alarm rates that lead to alerts being ignored. Nonetheless, some results have been very encouraging with Riley showing a 40% absolute increase in guideline compliance with point of service reminders[23].

A certain level of redundancy will be desirable in maximizing response rates. With practices integrating, registries and reminders may be appropriate at the group level- with pop-ups occurring wherever the patient and group are in contact. Further down the line, when statewide vaccination registries and regional Health Information Exchanges are functional, even broader opportunities will become available for tracking and outreach. This is especially relevant for the patients who may change providers or plans.

One strength of this study is the fact that all contacts with the health care system were obtained with claims data (it is unlikely that patients would opt to get the vaccine at ~$120/dose on their own) and it looked at continuously insured patients who had no co-pay for the vaccine administration.

A weakness of this study was that the population of Central Massachusetts encompassed in this study is, by census, primarily Caucasian, with less than 20% Hispanic and less than 10% black. This does not mirror the population of other urban centers and, since health care behaviors may vary among these groups, different results may be expected elsewhere. In addition, being a claims based study we were not able to determine how often failure to continue the vaccine course was intentional. Although the numbers in this study are relatively small for a claims-based analysis, they are well above the threshold for finding clinically significant observations.

This study has shown that there are multiple opportunities to address missed and late vaccine doses and that none can be expected to fully address the issue.

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