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HPV Vaccine Reminders at the Point of Service: Efficacy and Missed Opportunities. A Claims Based Study within One Health Plan

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Abstract

Introduction: Our objective is to assess HPV vaccine series completion rates, whether on-screen Point of Service reminders (POS) make a difference, and missed opportunities for reminders to have an effect.

Methods: Retrospective, claims-based study of females aged 9-26 receiving an initial dose of HPV vaccine during 2 periods: before (period 1) and after (period 2) implementation of a POS reminder system in 1("Change Group") of 2 physician groups using EHRs for both periods. Completion rates, and missed opportunities during eligible periods were calculated for those with continuous enrollment in the health plan investigated.

Results: Completion rates within 1 year of the 1st dose were Period 1: 47% Change Group vs. 46% Control Group (p=0.847). Period 2: 50% Change group vs. 57% Control Group (p=0.158). No significant improvement occurred between the 2 periods in either group. Differences in 1 year completion rates by specialty of initiating provider or age group (<18 or ≥18) were not significant.

During period 2, among those with continuous insurance plan enrollment in the Change Group, 43 patients received 1 dose and 46 received 2 doses. Of those receiving 1 dose, 30 (70%) had a visit to the same group within an eligible time period (median # visits: 2, range 1-20); of those completing 2 doses, 4 (9%) had a visit to the same group within an eligible period (median # visits: 1, range: 1-3). Among those receiving 1 dose, 25 (58%) had a visit to the same group

and same specialty as the initial dose (median # visits: 1, range 1-8); for those having received 2 doses, 3 (6%) had a subsequent visit to same group and specialty (median # visits: 1, range 1-3).

Conclusion: POS reminder systems was not associated with improved completion rates. POS reminders are limited by infrequent visits among non-completers in an eligible period.

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Introduction:

In the United States only about 50% of recommended preventive health care is carried out[1,2]. In this study, we examine human papilloma virus (HPV) vaccine administration in order to address the more general problem of effective health services delivery, particularly those entailing multistep processes. The HPV vaccines (2 were available during the study period) are given in a series of 3 shots over 6 months. Both are currently approved for males and females aged 9 to 26[3,4]. Studies have shown that, among those who start the series, completion rates are about 50%[5-9]. A multitude of reasons may be behind failures. How often do patients fail to complete a course that they had originally agreed to? How often are they seen in their provider group at a time when a dose could have been administered but it was not?

On-screen, point of service (POS) reminders would seem an opportunity to improve implementation in cases in which patients may be seen for other reasons. Indeed, the Office of the National Coordinator's "meaningful use" criteria for certification of electronic health records has required this capability. But evidence regarding the effectiveness of these reminders is weak at best with a Cochrane review noting only about a 5% improvement in process when used in other circumstances [10].

In this study, we take advantage of a natural experiment to assess whether implementation of these reminders made a difference in improving completion rates, and to look at how often vaccine initiators were seen in eligible intervals - i.e. times where the POS reminder had an opportunity to facilitate improved vaccine completion rates. We utilized claims data from a single health plan to track this process.

Materials and Methods

This is a retrospective, claims-based, observational study of cohort of female patients enrolled in a single health plan who began the HPV vaccine series. Patients who received an initial dose of HPV vaccine in 2010 (period 1) or during the year from June 2012- May 2013 (period 2) were included. This takes advantage of a natural experiment in which one provider group implemented POS reminders in their electronic health record (EHR) in May of 2012 (Change Group), compared to other groups (Control Group), with EHRs, that had not implemented these reminders for the HPV vaccine.

At the time of first HPV vaccine dose, the process in the Change Group involved making a follow-up appointment, calling to remind patients before the next appointment, and calling or sending a letter to those who missed an appointment. In the Control Groups, patients made a follow-up appointment at the time of the first HPV vaccination, were not regularly contacted before the upcoming visit, and were not routinely contacted if the appointment was missed. These routines were not changed between the two observation periods. Both the Change group and the 2 physician groups in the Control Group were multispecialty groups of >100 physicians. Both had implemented EHRs before the study periods. All groups acknowledged that during the second observation period a greater emphasis was placed on the providers educating patients and their parents, and on offering the HPV vaccine. Between the two periods, providers in both groups became more willing to give doses beyond the recommended intervals, feeling that this was better than abandoning the immunization series. The on-screen reminder in the Change Group consisted of a tab that listed overdue Health Maintenance testing on the home screen for

the patient that would appear each time the patient was seen within the multispecialty group. Clicking the appropriate item would lead to placing an order.

Using health plan data, we looked at vaccine completion rates for female patients between the ages of 9 and 26 who had a claim for an initial HPV vaccine dose during period 1 (2010) or period 2 (6/2012-5/2013); period 2 was after the implementation of an on-screen reminder system in the Change Group. The HPV vaccine is ideally given in a series of 3 IM injections over a 6 month period. The second injection should be given two months after the first one, and the third injection should be given six months after the initial one. Claims were based on CPT code 90649 (Quadrivalent Human Papillomavirus [Types 6, 11, 16, 18] Recombinant Vaccine (Gardasil, Merck) which was responsible for >99% of claims) or CPT code 90650(Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant (CERVARIX, GlaxoSmithKline Biologicals)).

In order to assure that the first dose during either period 1 or 2 was, in fact, the patient's first dose, we performed a one year look-back and dropped all patients having received a dose prior to each start period. We also collected claims data for 1 year after each period to capture completion rates for those who began later in the observation year. Patients whose initial doses were given during the 1 year look forward period were excluded. *Patients who did not have continuous enrollment during the 1 year look back, the observation period and the 1 year look forward period were excluded from analysis since we could not be sure about either completion rates or missed opportunities.*

A patient was considered to have an "on-time" complete vaccine course if an initial dose was administered within either period 1 or 2 and a total of 3 doses were received within one year. The 1 year look forward time span was chosen since research has shown that, although a routine course should be completed in 6 months, times up to 1 year are considered adequate[11,12]. Completion rates were calculated by totaling the number of patients with a complete course, divided by the number of patients who had continuous enrollment in the health plan with at least an initial dose.

We determined the number of doses for each subject, and the intervals between doses. For those without 3 documented vaccine doses in the Change Group in period 2 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 and thus 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 was calculated. We also 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).

Additional collected data included year of birth, dates of vaccine administration, provider specialty, provider group, continuous or sporadic enrollment for 2009, 2010, 2011 (period 1), or 2011, 2012, 2013, 2014 (for period 2).

Comparisons were made regarding completion rates between the two periods, as well as the frequency of missed opportunities in the POS reminder period for the Change group.

Comparisons were made regarding completion rates by specialty of initial provider as well as age group (youth (<18 years old at initial dose) and adult (≥18 years old at first dose).

We also performed a secondary analysis utilizing data from the look forward year to capture late completions that occurred greater than a year from the first dose. Because of the nature of the data collection these "late completions" could range from 1 day to 365 days beyond the one year period.

Confidence intervals and p values for comparisons were calculated using Stata/MP 14.1 (StataCorp 2015. Stata Statistical Software: Release 14 College Station, TX). Percentages are rounded to the nearest 1%. P-values <0.05 are considered significant.

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

Results

During period 1, 596 HPV vaccine doses were given in the Change Group of which 297 patients had continuous enrollment during the full period including look back and look forward and 111

in the Control Group with 65 having continuous enrollment. During period 2 (2012-13) 562 first doses were given in the Change Group of which 297 were continuously enrolled and used for analysis, and in the Control Group 277 first doses were given of which 140 were continuously enrolled and used for analysis.

The rates of continuous enrollment did not differ between the Control Group and the Change Group for either period, nor did they change significantly between the periods. In both groups the majority of first doses were given to youth, both groups trended up for youth from period 1 to period 2 but the change was only significant in the Change Group (Change Group: 65% to 82%, $p<0.0001$; Control Group: 66% to 77%, $p=0.0976$). First doses were mostly given by pediatricians with others spread over 6-7 other specialties. From period 1 to period 2 a greater percentage were administered by pediatrics, the trend being significant only in the Change Group (Change Group: 54% to 88%, $p<0.0001$; Control Group: 59% to 66%, $p=0.3331$). See Table 1 for details.

The period 1 completion rate within a year of initial dose for the Change Group was 47%, using a denominator of those in continuous enrollment. For the Control Group it was 46% (between group $p=0.847$). The period 2 completion rate within a year of initial dose was 50% in the Change Group and 57% in the Control Group ($p=0.158$). Between the two periods the rates of on time completion did not improve significantly. For the Change Group: 47% to 50% ($p=0.575$) and for the Control Group 46% to 57% ($p=0.142$).

For the secondary analysis using data extending beyond the 1 year period: the overall completion rates in period 1was 59% in the Change Group and 51% in the Control Group (p=0.874). During period 2 the overall completion rates, again, were not significantly different (68% Change group versus 71% Control Group, p=0.523), but both significantly improved from the group's earlier performance. The proportion of late completers in the Change group went from 8% to 26% (p=<0.001) and in the Control Group from 9% to 19% (p=0.178). See Figure 1 & Table 2 for details.

Looking at on-time completion rates by specialty we found that the on-time completion rates for pediatricians and "other specialties" did not show significant improvement over the two periods in either group (Pediatrics: Change Group: 44%-53%, p=0.0772; Control Group: 50%-54%, p=0.6784; Other specialties: Change Group: 51%-39%, p=0.2170; Control Group: 44%-64%, p=0.0969).

Looking at on-time completion rates by age group we found that the on-time completion rates for youth and adults did not show significant improvement over the two periods in either group (Youth: Change Group: 48%-54%, p=0.2228; Control Group: 54-63%, p=0.3090; Adults: Change Group: 46%-39%, p=0.4098; Control Group: 36%-38%, p=0.8823).

In the Change Group in period 2, among those with continuous medical insurance enrollment, 89 patients received only 1 or 2 doses and 34 (38%) had a visit within the same group within an eligible period. Forty three patients received only 1 dose and 30 (70%, 95% CI: 53-82) had a visit with the same group practice within their eligibility period. Twenty five (58%; 95% CI: 42-

73) had a visit with the same group *and same specialty* as the initial dose within an eligible period. Forty six received only 2 doses and 4 (9%; 95% CI: 2-21) had a visit at the same group practice, within their vaccine administration eligibility period and 3 (6%; 95% CI: 1-18) had a visit with the same group *and same specialty*. See Table 3 for details.

Discussion

The point of this study was to use the multistep HPV vaccine process to probe whether or not on-screen reminders in an electronic health record led to significant improvement and to see just how often patients who had not completed their course returned at a time when the reminder could have made a difference. After implementation of a point of service (POS) reminder system in the Change group, the 1 year HPV vaccination on-time completion did not improve. During these observation periods both groups trended upward in completion rates, though. Interestingly, there was also a trend towards a greater prevalence of completions beyond the recommended 1 year, especially in the Change group and especially among pediatricians. Both the Change and Control groups saw a greater percentage of doses going to youth, which makes sense since adult dosing of this vaccine was viewed as a "catch up" to bridge the period to when we could rely on administration in youth.

Much of this lack of effect of on-screen point of service reminders likely relates to the fact that so many non-completers (62%) did not return to the group that initiated their series within an eligible period of time. For those with only 1 dose, visits to the same group occurred in about 70% of cases, for those with 2 doses, it occurred in only about 9% of cases. Visits to the office with the same group and same specialty as the initial dose occurred in 58% and 6% of cases,

respectively. Thus, the potential for an effect from this intervention was limited. Although the raw numbers for these rates were small, this does support the notion that there are significant limits on the potential impact for POS reminders. Even so, there were individuals who had as many as 20 encounters with the same group and 8 encounters with the same specialty office within that group during an eligible interval- pointing to the possibility of alarm fatigue, ineffective interface design, or the possibility that some patients changed their mind about this vaccine.

Although the study was not designed to assess dosing beyond 1 year from the first dose, we decided to use this information for a sub-analysis. The data for this is incomplete since the range of dosing beyond a year could span 1 day to 365 days. Thus, the percentage of 3 dose regimens that extended into the post 1 year time span was an underestimate. The effectiveness of courses completed late is unclear, but emerging data suggests a level of effectiveness even with two doses[13]. Since nearly a quarter of completed courses in this extended sample were completed beyond the manufacturer's recommended time period, and there was a trend, especially among pediatricians to extend the eligible period beyond the recommended 1 year, it is worthwhile to monitor the literature on the effectiveness of late dosing of this costly vaccine.

It should be noted that about 17% of patients receiving an initial HPV vaccination dose in the first year of the change period dropped out of the insurance plan studied by the second year. It is possible that some of these patients changed insurance plans but could still be seen in the same provider office; however due to the nature of this claims data, we would not have detected their vaccine series completion which could underestimate completion rates as presented here. By

restricting analysis to those with continuous enrollment we attempted to correct for this in calculating rates. Patients dropping off the studied insurance plan may have dropped out of the health care system altogether during the period. This could occur in situations of housing and job insecurity, or transient arrangements related to educational pursuits, which may be more common in the adult age group, particularly as they leave secondary school. This may have also contributed to the poorer rates of completion even among continuously enrolled adults. Thus, patient mobility (moving among plans, providers and even communities) likely plays a major role in failures related to this multistep vaccine administration process. This also limits the ability of managed care plans to take on the reminder function and to track completion rate outcomes, especially since there is no systematic transfer of immunization data among the different plans in our area. As centrally located vaccine registries are more broadly implemented and accessed by EHRs, this may open opportunities for tracking and completion.

From a workflow point of view, patients were scheduled for their next visit as they left the visit for the initial dose. The groups had essentially the same process of scheduling the next visit but differed in follow up for missed appointments. The Change Group routinely contacted patients who had missed appointments and the Control Group offered this inconsistently, although it would seem that this process difference would make a difference, it did not in this dataset. Going forward, both groups are planning on incorporating text messaging for both reminders and follow up.

The results of this study regarding improvement in process completion are in agreement with other studies regarding Point of Service Reminders, including a Cochrane review in which only a

modest improvement (~5%) in process measures was achieved[10]. If patients are not returning, patient outreach would seem to be the next logical step, although, as noted above, it did not make a difference in this study. Literature on patient outreach has also had modest results. Kharbanda, et al[14] used text messages to parents as a means of reminding them about next doses of HPV vaccine with an increase of ~15% in compliance when compared to those who did not sign up for the program and when compared with historical controls. Matheson, et al[15] also utilized text message reminders and achieved ~15% improvement in completion rates in a population in which virtually none of those in the control group completed the series. Messages were sent 7 days prior, day of and 7 days post (if the patient had not kept the appointment). Patel, et al[16] offered reminders via text, phone call, private Facebook page message or letter and were unable to improve HPV vaccine completion rates. Szilagyi et al[17] used calls and letters from a managed care plan to try to increase overall vaccine (TDaP, MCV4 (meningococcal vaccine), and HPV) completion for adolescents aged 10-17. The number of reminders yielding an additional patient with a completed series was 14 for letters and 25 for calls, resulting in an additional cost of $464 for letters and $715 for calls. Clearly, results using a variety of reminder interventions are, at best, modest.

In looking for missed opportunities we chose to use a time period of no more than one year from the initial dose and 4 months after the second dose. There may have been instances in which the second dose was given later and a third could have been given twelve weeks after the second in cases of late second doses. For technical reasons this was not included in our analysis and we do not feel that it significantly affected the conclusions although it may have resulted in a few more missed opportunities. Additionally, it is unlikely that those who were enrolled got their doses

outside of insurance since doses cost in excess of $120 each at the time of this study. We were not able to look at medical records to see if follow up was obtained by those who were not continuously enrolled. Today, in Massachusetts, doses for youth are covered by the state Department of Public Health and can be administered by a patient's personal physician, rendering the coding query for this study obsolete.

By far, the greatest limitation of this study was getting significant numbers of patients to study. We obtained a complete dataset for the periods involved from one of the largest managed care insurers in this area. However, because of significant turnover in the plans that patients enroll in, we lost about 50% of our sample by specifying continuous enrollment. Thus, particularly in the Control group (which included two large multispecialty organizations with hundreds of providers) we ended up with samples that lacked the power to reveal trends. Within the Change group, in looking for missed opportunities, a data set of outpatient visits consisting of over 66,000 individual visits dwindled to single digits when we specified the Change Group, continuous enrollment, incomplete dosing, an eligible period and linked to an individual patient. Clearly, this study would have been much more powerful if using an all payer claims database. Since this study was undertaken, this has become available in Massachusetts, although access has significant restrictions.

Given the design of this study, we could not survey the reasons why patients did not complete their course. Completion rates for youth were better than for adults. It stands to reason that the adolescent group is more likely to have a parent who is responsible for getting them to the medical office.

We quantified efforts to improve HPV vaccination series completion rates upon initiation of an onscreen point of service reminder system housed within an EMR. No significant improvement was noted. Clearly there is no simple fix for the high percentage of discontinuity or incomplete HPV vaccine series after initiation. Issues are multifactorial including failure to make and keep appointments, potential discontinuity with insurance plans and discontinuity with providers. Point of Service reminders, which may have reached a percentage of those who have not completed their regimen, did not significantly improve outcomes. This may be generalizable to other multi-step processes in outpatient health care.

	Control Group	**Continuous Enrollment**	**Change Group**	p value
Period 1	65/111 (59%)		297/596 (50%)	0.08
Period 2	140/277 (51%)		275/562 (49%)	0.5861
p value	0.1540		0.7338	
		Youth (<18yo)		
Period 1	42/65 (66%)		**192/297 (65%)**	0.8783
Period 2	108/140 (77%)		**224/275 (82%)**	0.2264
p value	0.0976		**<0.0001**	
		Initial Dose by Pediatrician		
Period 1	38/65 (59%)		**160/297 (54%)**	.4665
Period 2	**93/140 (66%)**		**242/275 (88%)**	**<.0001**
p value	0.3331		**<0.0001**	

Table 1. Population Characteristics. Areas of significant difference in bold.

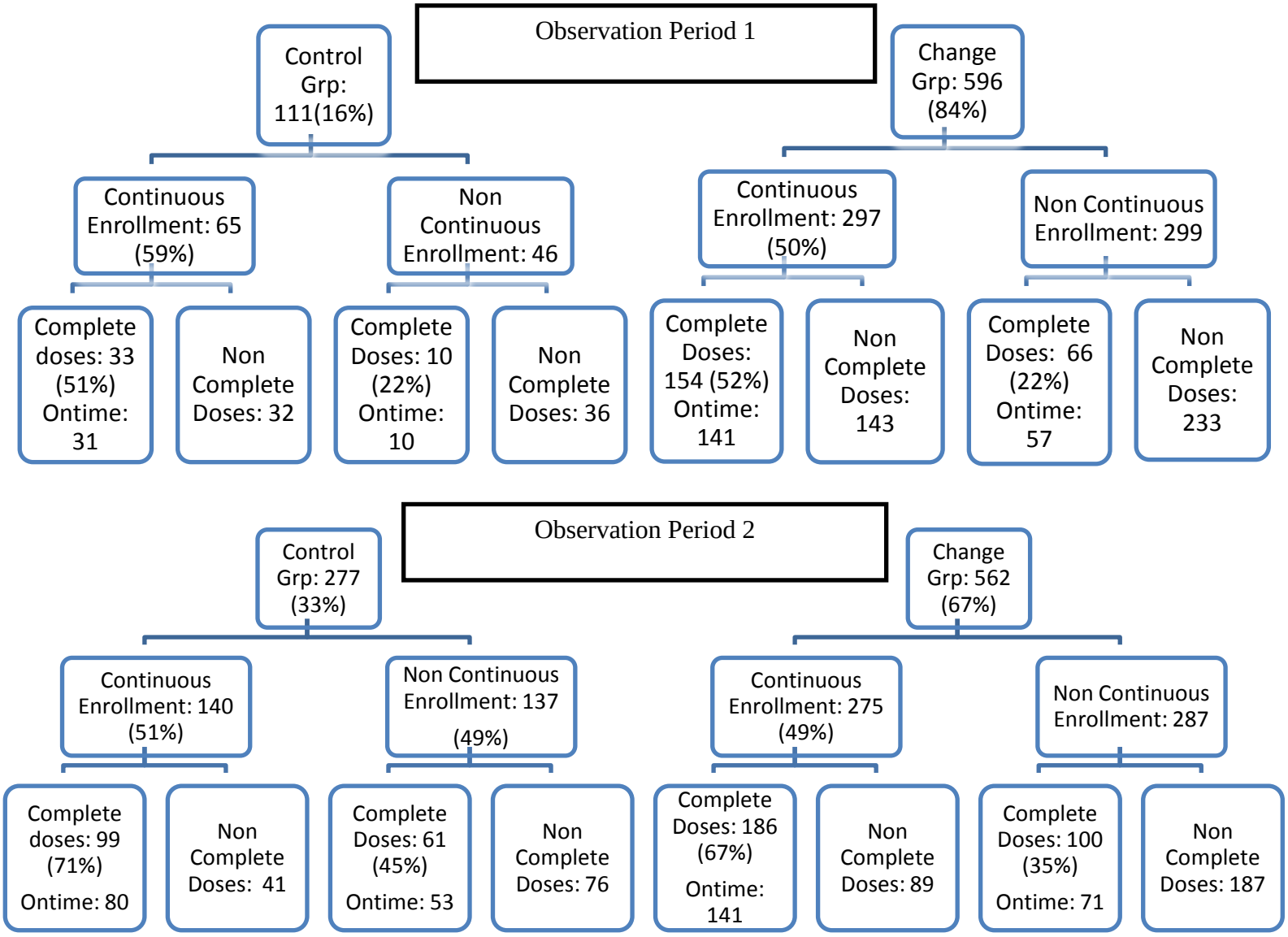

Figure 1. Population receiving first doses of HPV vaccine in pre (2010 – Period 1) and post change periods (6/2012-5/2013 – Period 2).

	Period 1 sample	Period 2 sample	p-value
Change Group, within 1 year of 1st dose	141/297 (47%)	137/275(50%)	0.575
Control Group, within 1 year of 1st dose	30/65 (46%)	80/140 (57%)	0.142
p-value for Change vs. Control	0.847	0.158	
Change Group (includes late completers)	154/297 (59%)	186/275 (68%)	**<0.001**
Control Group (includes late completers)	33/65 (51%)	99/140 (71%)	**0.006**
p-value for Change vs. Control	0.874	0.523	
Change Group % of completes completing >1 year	13/154 (8%)	49/186(26%)	**<0.001**
Control Group % of completes completing >1 year	3/33 (9%)	19/99(19%)	**0.178**
p-value for Change vs. Control	**0.904**	0.177	

Table 2. Completion Rates within 1 year of 1st dose and Completion Rates >1 yr from 1st dose (incomplete sample). Denominator = total continuously enrolled during eligible period.

	Same Specialty/Same Group	Any Specialty/Same Group
1 Dose Completed (43)	25 (25/43=58%) (1; 1-8)	30 (30/43=70%) (2; 1-20)
2 Doses Completed (46)	3 (3/46=6%) (1; 1-3)	4 (4/46=9%) (1; 1-3)

Table 3. Missed Opportunities in Change Group 2012-13 Sample
(Percentages are percent of those who did not complete and had an eligible visit, median, range. Eligible visit is between 2 months and 1 year after the 1st dose for 1 dose completed. Eligible visit is between 4 months after the 2nd dose and with 1 year of the first dose for 2 doses completed)

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