

Report Concerning Survey of Adverse Events Following Inoculations with Gardasil

©2010 Emily Tarsell, LCPC and James Garrett, PhD

February 18, 2010

Abstract

Background The Food and Drug Administration (FDA) concluded that the rates of Adverse Events Following Injections (AEFIs) for the human papillomavirus recombinant vaccine (qHPV) Gardasil were not greater than background rates. They also acknowledge limitations in the reporting system that could compromise this conclusion. On record as of 1/31/2010 were 15,829 AEFI reports including 49 deaths.

Methodology 39 respondents who experienced AEFIs following Gardasil injections self-selected to complete an on-line National Vaccine Information Center (NVIC) questionnaire. Respondents checked symptoms experienced prior to and following consecutive qHPV injections. Additional data were gathered and analyzed and an exact test was performed regarding 6 cases of death.

Principal Findings The data reflect a two to four fold increase in occurrence, type and severity of symptoms with additional exposure to Gardasil for all respondents. Chronic fatigue and headache or dizziness were pervasive and compounded over time. Additional concurrent symptoms and frequency reported were: numbness, muscle pain, nausea and muscle weakness, 60–70%; joint pain, chest pain, skin disorders and concentration problems, more than 50%; menstrual problems, 40%; post-vaccine heart disorders, 33%; seizures, 13%–20%. Time intervals from inoculation to onset of symptoms were mostly within 30 days. Cause of death was undetermined for five cases; one autopsy is pending. Five of the six deaths occurred after the third injection. This diverges from expectations if the deaths were coincidental. There was statistical evidence at the 5% level, with a p-value of 0.0434, that the hypothesis that Gardasil is not related to any of the reported deaths is not tenable.

Conclusion Data analyzed suggest a dose-response and temporal relationship to Gardasil. Data may be biased toward reports of severe adverse reactions. However, a vaccine can have a low rate of AEFIs while still indicating strong evidence that the small numbers of events that do occur are related to the vaccine.

1 Introduction

The quadrivalent human papillomavirus recombinant vaccine, (qHPV) Gardasil, (Merck and Co., Inc., Whitehouse Station, New Jersey) was approved by the Food and Drug Administration (FDA) in June, 2006 to address human papillomavirus (HPV) types 6, 11, 16, and 18 [1]. The viruses HPV-16 and HPV-18 cause some types of cervical cancer. The viruses HPV-6 and HPV-11 can cause genital warts [1]. Following licensure, the Advisory Committee on Immunization Practices (ACIP) recommended routine vaccination of females aged 11 to 26 years with 3 doses of Gardasil on a schedule of 0, 2 and 6 months, respectively [1]. As of December 31, 2008, about 23 million doses of the HPV Vaccine had been distributed in the United States [1].

Adverse events following immunization (AEFIs) are voluntarily reported to the Vaccine Adverse Event Reporting System (VAERS) which is operated jointly by the FDA and the Centers for Disease

Control (CDC) [1]. From June 1, 2006 through December 31, 2008, VAERS received 12,424 reports of AEFIs, including 32 deaths [2]. An analysis of these AEFIs was published by the FDA on August 19, 2009 [2]. In their report, the FDA explained that 68% of the AEFIs were submitted by the manufacturer and 89% of the manufacturer reports had insufficient information to permit clinical follow up [2]. The FDA also acknowledged that the number of AEFIs may be underreported because VAERS is a passive reporting system [2]. Regardless of these significant barriers to data collection, the FDA divided the number of reported AEFIs by the number of doses of vaccine distributed (not the number of doses actually administered) to obtain an AEFI rate [2]. Except for syncope and venous thromboembolic events, they determined that the AEFI rates were not greater than expected background rates [2]. Other limitations of VAERS that are identified by the FDA include incomplete reporting, inconsistent quality of reports, lack of standard case definitions and coding, and an inability to establish causality [2].

This study was undertaken to report AEFI data gathered from utilizing a detailed questionnaire which queried those experiencing Gardasil related AEFIs in a standardized manner. The reporting method allowed for pre and post injection comparisons of symptoms by dose over time and was conducive to identifying patterns in the responses.

2 Methods

Data regarding adverse events were obtained from 39 female respondents who voluntarily, self-selected to complete a detailed National Vaccine Information Center (NVIC) questionnaire which was available on line [3]. The questionnaire included a disclosure statement regarding confidentiality.

The ten page questionnaire consists of matching lists of thirty two symptoms in each of four conditions: *Pre-Injection*; *Injection 1*; *Injection 2*; and *Injection 3*. Respondents were asked to check any symptoms that existed prior to inoculations of Gardasil and symptoms that occurred after each of the injections. The *Pre-Injection* checklist served as a baseline for measuring change. The data were tabulated and graphed according to occurrence, type and frequency of symptoms. The results for these thirty two symptoms were tallied on the graphs as “Total Symptoms in Section 1” (Figures 1, 2, 3, 4, 5, 8, 9 and 10).

Respondents were also queried about additional symptoms following the inoculations. This data were tabulated and graphed in addition to the 32 previously mentioned symptoms as “Total Symptoms in Sections 1 & 2” (Figures 1, 2, 3, 4, 5, 8, 9 and 10). Since these additional symptoms, which included dizziness, muscle pain and nausea, were not listed among the *Pre-Injection* symptoms, they were tabulated and graphed separately. The patterns that emerged were consistent for both Section 1 alone or Section 1 and 2 Data combined.

Additional information requested included age of participant, dates of inoculations and onset of symptoms, lot numbers, duration and severity of symptoms, other medications or inoculations administered concomitantly, family history and outcome.

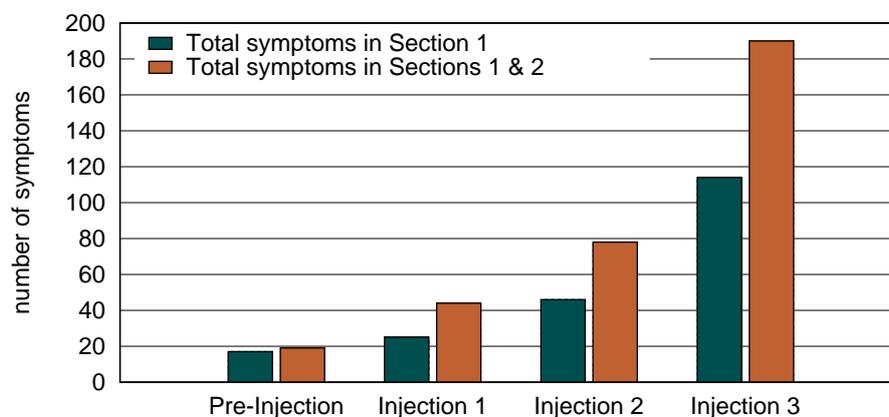
In order to see if there was a difference in types of symptoms reported between those who became ill and those who died, the data for each of these events were recorded separately. The embedded graphs depict the data for each of these conditions. Therefore we have separate graphs for the respondents who became ill, and stopped after *One Injection – Illness*, or *Two Injections – Illness*, as well as those who completed all three doses, *Three Injections – Illness*. Similarly, for those who died, we have separate graphs to reflect the number of injections prior to death: *Two Injections – Death*, or *Three Injections – Death*. We did not have data for any deaths that occurred after one injection.

The respondents were all females ranging in age from 10 to 26 years. A summary of the number of respondents by age is given in Table 1. The majority of respondents were between 15 and 18 years of age with the mode being the 17–18 years old group. For minors and females who had died, the questionnaires were completed by parents.

Table 1: Respondents grouped by age

Age group (years)	Number
11–12	4
13–14	5
15–16	6
17–18	14
19–20	6
21–23	3
24–26	1
Total	39

Figure 1: Number of symptoms by time interval in the *Three Injections – Illness* group (15 cases)



Although one respondent had a sore throat at the time of an injection, overall, respondents reported they were in good health prior to inoculations with Gardasil. This is supported by the low number of reported *Pre-Injection* symptoms. In addition to indicating that they were in good health at the time of the first injection, many of the respondents noted that they were also athletes and good students academically. After inoculations, however, there was a significant increase in the number of symptoms and reported deterioration in physical and academic performance.

3 Results

Of the thirty-two symptoms listed in Section 1 for the fifteen respondents in the *Three Injections – Illness* group (Figure 1), four symptoms were checked on both the pre- and post-inoculation lists. Otherwise the symptoms that appeared after inoculations were all new symptoms not previously experienced. In addition, the new symptoms reappeared or worsened after subsequent shots, and/or additional symptoms developed. As is evident in the total symptoms for Section 1, following the first, second and third vaccine inoculations, respectively, 25, 46 and 114 symptoms were identified. For the fifteen respondents in this group, that is an average of 1.5 new symptoms after the first injection, 2.5 new or reoccurring symptoms after the second injection, and 6.6 new or reoccurring symptoms after the third injection. To summarize, the symptoms almost doubled after the second injection and more than quadrupled after the third one.

For the nine respondents in the *Two Injections – Illness* group, there were also four symptoms

Figure 2: Number of symptoms by time interval in the *Two Injections – Illness* group (9 cases)

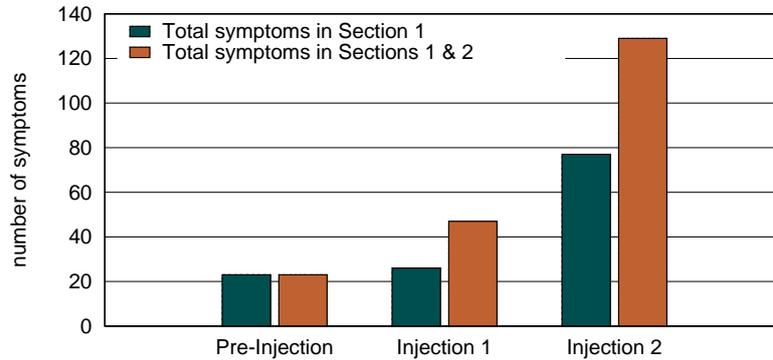
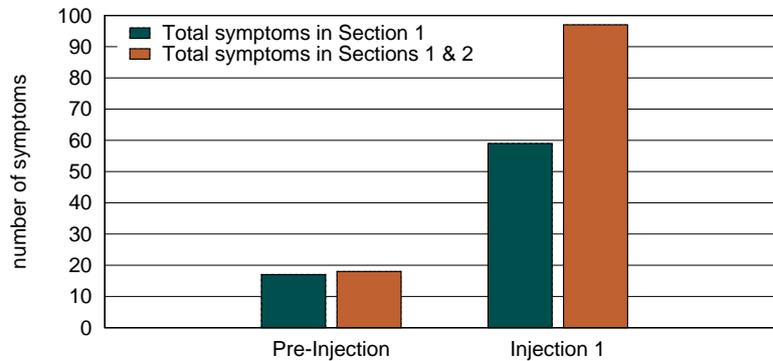


Figure 3: Number of symptoms by time interval in the *One Injection – Illness* group (9 cases)



that appeared in Section 1 on both the pre and post inoculation lists (Figure 2). Therefore, the 26 symptoms reported by this group after the first dose and 77 symptoms reported after the second dose were predominantly new symptoms that did not exist prior to receiving the vaccine. For the nine respondents in this group, that is an average of 2.4 new symptoms after the first injection. This almost quadrupled to an average of 8.3 new or worsening symptoms per person after the second injection. These respondents did not get a third inoculation.

There were nine respondents in the *One Injection – Illness* group (Figure 3). For them, there were 7 symptoms in Section 1 which appear as both pre and post-vaccine symptoms. Therefore of the 59 symptoms reported after the first injection, 52 of them were not pre-existing. That is an average of 5.8 new symptoms per respondent following one dose of Gardasil. These respondents declined further doses of the vaccine.

With regard to deaths, there were five respondents in the *Three Injections – Death* group (Figure 4). One symptom in Section 1 was checked on both the pre and post-vaccine lists. Otherwise, the 7, 16, and 26 post-vaccine symptoms following injections one, two and three, respectively, were only present after the injections. For the five respondents in this group, that is an average of 1.4 new symptoms after the first inoculation, 3.2 new or worsening symptoms after the second injection and 5.2 new or worsening symptoms after the third injection. The pattern is rather similar to that of the respondents who became ill after three injections in that symptoms which did not pre-exist, doubled and quadrupled after subsequent inoculations.

Figure 4: Number of symptoms by time interval in the *Three Injections – Death* group (5 cases)

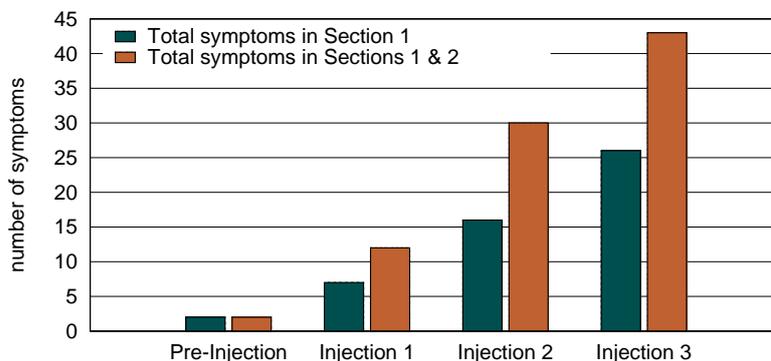
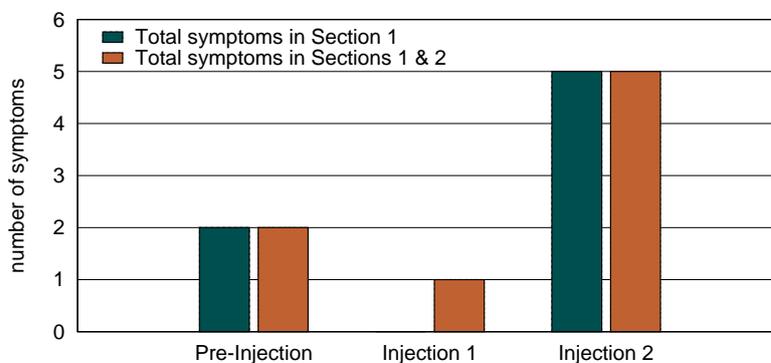


Figure 5: Number of symptoms by time interval in the *Two Injections – Death* group (1 case)

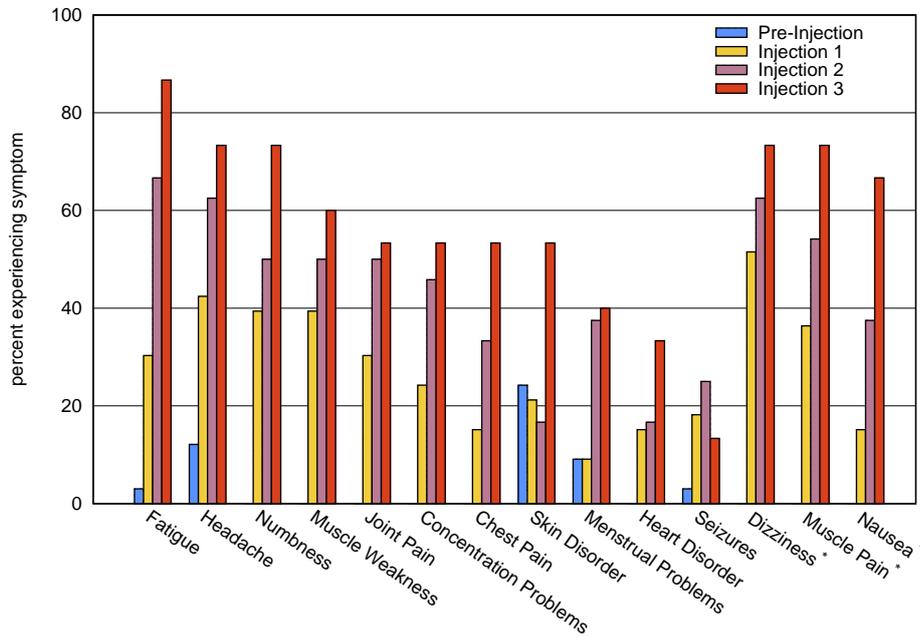


In the one case of the respondent in the *Two Injections – Death* group (Figure 5), there were no pre-existing symptoms in Section 1 that overlapped with post-vaccine symptoms. This respondent experienced no symptoms after the first injection and 5 symptoms after the second dose of vaccine. She therefore experienced a five-fold increase in new symptoms prior to her death, shortly after the second injection.

To summarize, it appears that in all conditions, on average, there is the occurrence per respondent of one to two new, previously non-existing symptoms following one injection of Gardasil. These symptoms then at least doubled after the second injection and roughly quadrupled if there was a third injection. By self report these symptoms, non-existent prior to the inoculations, became worse with subsequent injections and coincided with a deterioration in functioning and/or death. Among these respondents, there were no instances in which new symptoms improved following subsequent doses of the vaccine.

Other than reflecting the frequency and severity of adverse events following increased exposure to doses of Gardasil, the data also reflect some consistency in the types of symptoms reported. By charting the data according to the 14 most frequently reported symptoms following injections, we see that for respondents who became ill (Figure 6) there were three symptoms reported by almost all respondents. Foremost on the list are dizziness or headache and extreme fatigue. Of the 33 respondents who became ill, there were 43 reports of dizziness, 40 for headache and 39 for chronic fatigue. According to the respondents, the headaches or dizziness did not usually come on immediately, but rather hours or days later. The headaches and dizziness were reported to reappear intermittently and became worse

Figure 6: Dose Response by Symptom to Injections from Gardasil (33 cases – Illness)



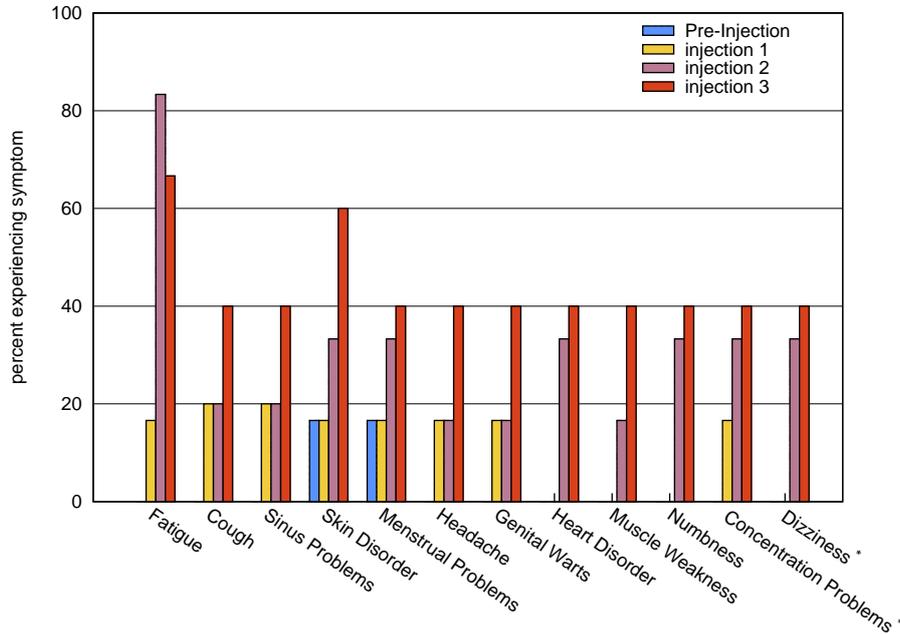
following subsequent injections. These events were often very debilitating and continued, along with other symptoms, for months. The CDC has dismissed headaches and dizziness as minor, temporary reactions [4]. They convey the impression that if such a reaction occurs, it will happen immediately after injection. Therefore they recommend that the patient should have a fifteen minute post-injection resting period to stabilize before departing [5]. However, the participants in this study describe an experience in which the headaches or dizziness and extreme fatigue often persisted intermittently for months in combination with other symptoms, and that they were very debilitating at times.

In addition, the data reflect a high incidence of neuromuscular problems among the respondents who became ill, which did not exist prior to vaccination. For these 33 respondents, there are 36 reports of muscle pain, 36 reports of numbness and 34 of muscle weakness. These are reported in combination with the previously mentioned symptoms and others.

Other symptoms frequently reported as non-existent prior to injection were joint pain, concentration problems, nausea, chest pain, depression, blurred vision, menstrual problems, bowel problems, heart disorders like intermittently racing heart or irregular heartbeat, seizures, personality changes and skin problems. These post-inoculation skin problems were described as warts and rashes. They differed from those reported prior to injections which tended to be things like acne. The only symptom that was reported less frequently by the third injection was seizure. Several respondents who experienced seizures after the second inoculation refused further injections. This may explain the decline in reported incidences of seizure following the third injection.

For the six respondents who died following injections of Gardasil, chronic fatigue, dizziness or headache and skin disorders were high among the top twelve most frequently reported symptoms (Figure 7). These were also not short-lived experiences but continued intermittently over time in combination with other symptoms. Five respondents received 3 injections, while one respondent died after receiving only two injections. Forty percent of these six cases experienced neuromuscular problems like numbness and muscle weakness, or post-vaccine respiratory inflammation, cough, and post-vaccine

Figure 7: Dose Response by Symptom to Injections from Gardasil (6 cases – Death)



cardiovascular symptoms. One respondent reported seizures. No cause of death could be determined by autopsy for five of the deaths herein reported. The sixth autopsy report is pending. Where cause of death was noted as undetermined, autopsy findings included organ inflammation, cardiovascular inflammation and hemorrhages.

Other symptoms frequently reported by this group were menstrual problems, concentration problems, depression, skin disorders like rashes and warts, personality change and heart disorders like irregular heartbeat. Respondents indicated that these symptoms did not exist prior to inoculation.

The types of symptoms recorded in Figure 6 and Figure 7 are consistent with symptoms associated with autoimmune abnormalities described in literature by the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) [6]. AANEM reported that in 54 cases of patients who had symptoms of autoimmune disorders, 57% of them had at least one vaccine, and many had more. The symptoms associated with these autoimmune abnormalities include respiratory problems, gastrointestinal problems, muscle weakness, tingling and interference with regulation of heart rate, blood pressure & breathing. Other symptoms include fatigue, feeling faint or passing out (syncope), headache, stroke and cognitive impairment. It is striking that these are the types of adverse symptoms reported by participants in this study.

A case study documented in *Dermatology Times* [7] suggests a possible link between the HPV vaccine, Gardasil and a case of cutaneous polyarteritis nodosa (PAN). The article also references five reports of vasculitis associated with inoculations of Gardasil.

Another case study printed in the *Journal of Neurology, Neurosurgery, and Psychiatry* [8] documents a case of severe vasculitic neuropathy following influenza vaccination. Three other papers cited in this article associate Guillain-Barre syndrome and systemic vasculitis with influenza vaccination.

A report in *Multiple Sclerosis* [9] describes five cases of multifocal or atypical demyelinating syndromes that are temporally associated with Gardasil immunizations.

A paper presented by Dr. Catherine Lomen-Hoerth at the American Neurological Association

meeting [10] in 2009 reported a verified case of autoimmune initiated motor neuron disease. Gardasil was temporally associated with the autoimmune attacks on the neurological system in this case.

While the cause of immune system abnormalities is unknown, the possibility that in some individuals they are triggered by a vaccine such as Gardasil appears to be a possibility.

Table 2: Time until onset of symptoms following injections with Gardasil.

Time interval	Group		
	1 Injection – Illness	2 Injections – Illness	3 Injections – Illness
Immediately	1	3	2
Within 24 hours	1		
Within 72 hours	1		2
Within 7 days	2	2	2
Within 14 days	1	1	4
Within 30 days	3	2	4
After 30 days		1	
Unknown			1
Total	9	9	15

Table 3: Among those who died, time from final injection until onset of symptoms and time until death.

Time until onset of symptoms	Final injection number	Time until death
Immediate	2	7 days
Immediate	3	6 months
1 day	3	2 days
1 day	3	4 months
2 days	3	4 months
3 days	3	18 days

Data regarding the onset of first symptoms in relation to the last injection of Gardasil were recorded in Table 2. For this report, the time between the last injection and the first noted symptom was used as the date of onset of symptoms. Time intervals are approximations. Following any of the three injections for those who became ill, the onset of symptoms was usually within 30 days. About a third of these were within two weeks and another third were in a week or less.

Regarding cases in which respondents died (Table 3), onset of first symptoms was within 3 days of an inoculation. The interval of time between the third injection and death for each of five cases was two days, eighteen days, four months, four months and six months, respectively. For the one case in which the respondent died after two injections of Gardasil, the onset of symptoms was immediate, and death occurred seven days after the second dose.

The pattern of death timings relative to inoculations diverges from what one would expect if the reported deaths were coincidental towards what one would expect if a cumulative vaccine effect were present. Coincidental deaths should be uniformly distributed in time, hence one would expect deaths to fall within the three periods between first and second injection, between second and third, and

Table 4: Medications and/or vaccines received concomitantly with injections of Gardasil (17 total respondents).

Number of Respondents	Other vaccines	Medicines
1	antibiotic	
3	DPT, Menactra	
7		birth control pills
1	Depo-Provera	birth control pills
1	Depo-Provera	
1		acne medication
1		antibiotic
2		anti-depressant

within six months of the third injection in proportions $1/7$, $3/7$, and $3/7$, respectively. Six deaths were reported in our data, so under the null hypothesis of time uniformity the allocation of these deaths to the three periods would follow a multinomial distribution with 6 trials and the probability vector $(1/7, 3/7, 3/7)$. Under this distribution, the probability of a set of death-period allocations as or more extreme (in the direction of a cumulative effect) than the one observed is 0.0434. That is, 0.0434 is the p-value for a hypothesis test in which the null hypothesis is time uniformity of deaths and the alternative hypothesis is a cumulative effect. This indicates that, even with a small number of deaths, there is substantial evidence of a cumulative effect.

4 Discussion

A confounding element in this study is the fact that some of the respondents were on medications at the time of the injections or they may have received more than one vaccine concurrently. Table 4 summarizes the reported seventeen instances when respondents concomitantly received another vaccine and/or were on medications.

If these 17 participants were dropped from the 39 girls in the study, Figures 8, 9, and 10 graph the resulting data. None of the respondents who died after three injections of Gardasil concurrently received another vaccine or medication with any of the injections, although one respondent did receive injections of Depo-Provera in months prior to Gardasil injections. The graph for the one respondent who died after two inoculations would drop out and the others would be modified in terms of numbers. However, the trend whereby there appears to be a dose-response increase in symptoms in relation to additional exposure to the vaccine remains unchanged.

Viewed from another perspective, the inclusion of these respondents in the data is a truer reflection of what is happening in the population of females who receive HPV vaccines. Candidates for Gardasil injections are not screened based on whether or not they are taking medication. Doctors are not advised to defer from giving a concurrent vaccine at the time of administering Gardasil. Merck did not test for interactions between Gardasil and birth control pills, other medications, or other vaccines like Menactra, Depo-Provera or DPT that might be given simultaneously [11]. It is unknown if one's risks for adverse outcomes increases when one has concomitant vaccinations or medications with injections of Gardasil.

A limitation of the study is its size, comprising only 39 reports. Those 39 cases might also reflect selection bias in that only those who experienced serious adverse events responded. While these cases may not be representative of all of those who received inoculations of Gardasil, they may be representative of those who reported serious adverse events to VAERS. In any case, the consistency and specificity in the frequency and types of symptoms in this small subset, the apparent dose-response

Figure 8: Number of symptoms for the *Three Injections – Illness* group, excluding those with other vaccines or medications (6 cases included).

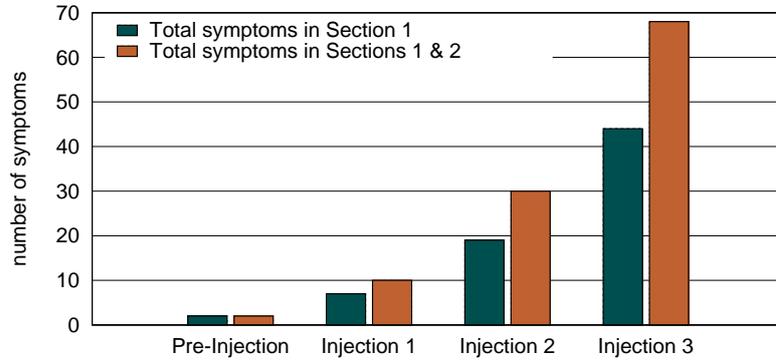


Figure 9: Number of symptoms by time interval in the *Two Injections – Illness* group, excluding those with other vaccines or medications (6 cases included).

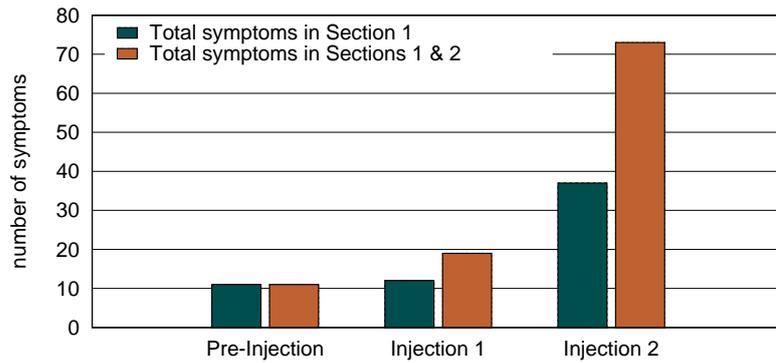
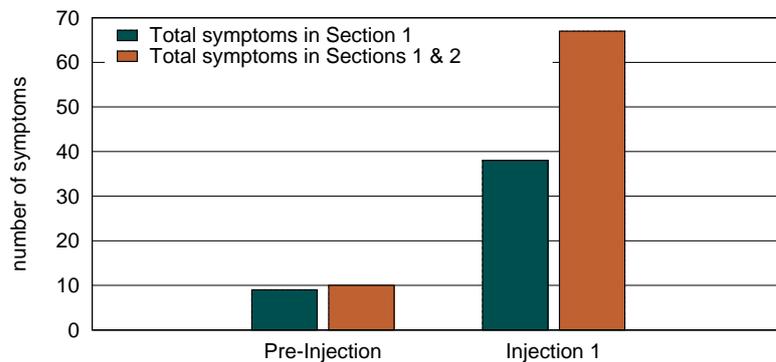


Figure 10: Number of symptoms by time interval in the *One Injection – Illness* group, excluding those with other vaccines or medications (5 cases included).



relationship, and temporal associations suggest the need for further investigation.

In addition, the questionnaires document symptoms that existed prior to inoculation. Two-thirds of the pre-injection symptoms concerned allergies to pollen, seasonal changes, foods and medications. Thus another focus of investigation might be to explore if consumers with predispositions to allergies are more susceptible to severe adverse responses to the HPV vaccine.

With regard to the temporal findings for the six cases of death, it is possible that the divergence from time uniformity, in the direction of cumulative effect, is due not to a cumulative effect but to selection bias, caused by families being more likely to report deaths that conform to an apparent cumulative vaccine effect. However, the opposite could just as easily be the case: families of those dying after three shots could be *less* likely to report their cases: if their loved one survived two shots, why suspect the vaccine after the third shot? One might just as easily expect family members to be more likely to report deaths after the first shot than the second or third.

At any rate, no analysis of self-reported data can wholly and confidently erase the taint of possible selection bias; only a controlled clinical trial or experiment can do that. Nevertheless, although surveillance data cannot meet the inferential standard of the controlled study, FDA has used it on occasion to remove drugs from market. Presumably the question is not whether the analysis is free of any possible bias, but whether the causative hypothesis is sufficiently more plausible than other possible explanations.

There are no other studies known to these authors that gather detailed data regarding symptoms in relation to each dose of Gardasil over time. VAERS does not track and evaluate symptoms in relation to increasing doses of vaccine and pre-existing health. Consumers are not interviewed or consulted by the CDC about their adverse events and there is no detailed, uniform questionnaire that queries all reporters in the same manner. The reporting system is passive and many consumers and medical practitioners do not know to report. There also is no standardized symptoms checklist by which to record and compare responses. Revisions in the VAERS reporting system might overcome some of the current limitations, thereby resulting in better surveillance of vaccine safety.

5 Conclusion

The data in this report evidence patterns in the type of post-injection symptoms experienced by respondents as well as an increase in the occurrence, number and severity of symptoms with additional exposure to the HPV. The temporal relationships between inoculation and onset of symptoms fall within the realm of biological possibility. For the 6 deaths reported there is statistically detectable evidence that the hypothesis that Gardasil is not related to any of them is not tenable.

Analysts who have assessed post-approval surveillance of the Gardasil vaccine have concluded that Gardasil is safe, based primarily on comparing rates of adverse events to background rates. However, a vaccine can have a low rate of adverse events while still indicating strong evidence that the small number of events that do occur are related to the vaccine. It is not a contradiction that the frequency of adverse events including death associated with Gardasil may be small, yet the evidence for an association may be strong. This would constitute strong evidence of a small yet real association.

One practical consequence of these findings might be that those who choose to receive Gardasil should be informed that if they experience certain adverse post-injection symptoms, it might be an indication that they should abort the inoculation protocol.

6 Acknowledgments

We would like to acknowledge the girls and young ladies who have experienced adverse events including death, following injections of Gardasil. We thank them and their families for contributing the data

and hope there is some comfort in knowing the shared information may be of benefit to others.

We also wish to thank Dr. Vicky DeBold and Barbara Loe Fisher for producing the questionnaire and NVIC for providing a forum to promote vaccine education and consumer advocacy.

Sincere appreciation is also extended to Kenneth Corson for his invaluable technical support.

Thank you also to Dr. William Reichel and to Dr. Jay Silkworth for advisory support.

References

- [1] Available from World Wide Web: www.fda.gov/BiologicsBloodVaccines/SafetyAvailability.vaccinesafety/umc179549.htm. Accessed February 5, 2010.
- [2] B. A. Slade, L. Leidel, C. Vellozzi, E. J. Woo, W. Hua, A. Sutherland, H. S. A. Izurieta, R. Ball, N. Miller, N. M. Braun, L. E. Markowitz, and J. Iskander. Postlicensure safety surveillance for quadrivalent human papillomavirus recombinant vaccine. *The Journal of the American Medical Association*, 302(7):750–757, 2009.
- [3] Available from World Wide Web: www.NVIC.org/vaccines-and-diseases/HPV/questionnaire.aspx. Accessed April 3, 2010.
- [4] Available from World Wide Web: www.cdc.gov/vaccines/news/news/trs/lmwrks/2009/06-11-09_spec_imwks2009.htm. Accessed December 20, 2009.
- [5] Available from World Wide Web: www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111263.pdf. Accessed February 5, 2010.
- [6] Symptoms associated with autoimmune abnormalities reported in literature by the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM). Available from World Wide Web: www.newswise.com/articles/view524115/-23k. Accessed November 15, 2009.
- [7] J. Jesitus. HPV vaccine possibly linked to cutaneous PAN. *Dermatology Times*, August 2009. Available from World Wide Web: <http://dermatologytimes.modernmedicine.com/dermatologytimes/author.authorDetail.jsp?5or1=null&pageNo=5&start=36&id=913>. Accessed November 15, 2009.
- [8] J. H. K. Hull, S. H. Mead, O. J. Foster, and H. Modarres-Sadeghi. Severe vasculitic neuropathy following influenza vaccination. *Journal of Neurology, Neurosurgery, and Psychiatry*, 75:507–508, 2004.
- [9] I. Sutton, R. Lahoria, Il. Tan, P. Clouston, and M.H. Barnett. CNS demyelination and quadrivalent HPV vaccination. *Muscular Sclerosis*, 00:1–4, 2008.
- [10] *Report of motor neuron disease after HPV vaccine*, 2009. Available from World Wide Web: www.medscape.com/viewarticle/711461. Paper presented at the American Neurological Association (ANA) 134th Annual Meeting. Accessed February 5, 2010.
- [11] Merck and Co. *Gardasil, Publication 9883611*. Whitehouse Station, NJ 08889, USA, 2008.