An Analysis by the National Vaccine Information Center of
Gardasil & Menactra Adverse Event Reports to the
Vaccine Adverse Events Reporting System (VAERS)
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The centralized federal Vaccine Adverse Events Reporting System (VAERS) was created under the National Childhood Vaccine Injury Act of 1986 [1] and became operational in 1990. Although there was a mandate in the 1986 law for vaccine providers to report serious health problems, hospitalizations, injuries and deaths to VAERS, there were no sanctions for failure to report.

It is estimated that only between 1 and 10 percent of all adverse health outcomes which occur following vaccination are reported to VAERS. [2] [3] [4] The following information was produced from analyzing VAERS data published by CDC and FDA and made available on the www.NVIC.org website through the MedAlerts searchable VAERS database at www.MedAlerts.org

Gardasil vs. Menactra VAERS Reports

(through November 30, 2008)

Menactra (meningococcal) vaccine was licensed by the FDA on January 14, 2005 for children and adults aged 11 to 55 years. [5] One dose is recommended by the CDC for boys and girls 11-12 years old [6]and many high schools and colleges are requiring it for attendance. Menactra is routinely administered by pediatricians and family practice physicians to grade school, high school and college students. Between 1,000 and 2,600 cases of meningococcal disease occurs in the U.S. every year and Menactra contains four of the most common strains of meningococcal.

Gardasil (Human Papillomavirus Quadrivalent) vaccine was licensed by the FDA on June 8, 2006 for girls and women aged 9 to 26 years. [7] Three doses are recommended by the CDC for universal use in girls 11-12 years old [8] and Gardasil is routinely administered by pediatricians, obstetrician/gynecologists and family practice physicians to grade school, high school and college students. Chronic human papillamovirus infection is associated with the development of cervical cancer and Gardasil contains four HPV types associated with this sexually transmitted infection.

What follows is a comparison of some of the more serious Gardasil and Menactra adverse event reports submitted to VAERS.

SUMMARY STATISTICS | Gardasil (HPV) Reports | Comment on Gardasil Reports | Menactra Reports | Comment on Menactra Reports

Total Reports	10,151		4,436	
Life Threatening	152		57	(18 with HPV)
Emergency Room	5,021		1,667	
Hospitalization	458		268	
Did Not Recover	2,017		393	
Disabled	261		29	(13 with HPV)
Died	**29**	(***25 HPV alone***)	6	(none with HPV)
SYMPTOM STATISTICS				
Alopecia	51	(*41 HPV alone*)	12	(8 with HPV)
Arrhythmia	18	(*14 HPV alone*)	4	(1 with HPV)
Arthralgia	276		119	
Arthritis	68	(*57 HPV alone*)	18	(6 with HPV)
Blindness	36	(*31 HPV alone*)	10	(2 with HPV)
Blood clot	**23**	(***all HPV alone***)	**0**	
Cardiac arrest	**9**	(***all HPV alone***)	2	(none with HPV)
Chest pain	123		63	(16 with HPV)
Collapse	44	(*29 HPV alone*)	18	(7 with HPV)
Deafness	17	(*11 HPV alone*)	5	(4 with HPV)
Demyelination	12	(*10 HPV alone*)	10	(1 with HPV)
Dizziness	1,320		589	
Encephalomyelitis	8	(5 *HPV alone*)	9	(1 with HPV)
Fainting	278		41	(28 with HPV)
Hair Loss	36	(*30 HPV alone*)	8	(5 with HPV)
Hemorrhage	**9**	(***7 HPV alone***)	**2**	**(2 with HPV)**
Joint pain	126		37	(7 with HPV)
Lupus	**28**	(***27 HPV alone***)	6	(1 with HPV)
Migraine	159		36	(9 with HPV)
Multiple sclerosis	16	(*12 HPV alone*)	7	(2 with HPV)
Numbness	351		149	
Pain	2,422		1,320	
Paralysis	70	(*54 HPV alone*)	26	(6 with HPV)
Rash	963		473	
Rheumatoid arthritis	31	(*25 HPV alone*)	6	(4 with HPV)
Seizures	**544**		**158**	**(73 with HPV)**
Stroke	**16**	(***all HPV alone***)	1	(none with HPV)
Syncope	1,643		427	
Thrombosis	**34**	(***all HPV alone***)	1	(none with HPV)
Tingling	278		132	
Vasculitis	**11**	(***all HPV alone***)	2	(none with HPV)
Rechallenge	**275**		**8**	**(7 with HPV)**

RED FLAGS:

VAERS is a sentinel reporting system, designed to raise "red flags" for unusual numbers of serious adverse events following receipt of a newly licensed vaccine. In 2005, the FDA responsibly issued a public advisory to physicians and parents after five (5) cases of Guillain Barre Syndrome (GBS) following receipt of Menactra by 17 and 18 year old girls occurred.[9] A rough comparison of Gardasil and Menactra adverse event reports to VAERS through November 30, 2008 reveals that:

- Compared to Menactra, receipt of Gardasil is associated with at least **twice as many Emergency Room** visit reports; **4 times more Death** reports**; 5 times more "Did Not Recover"** reports**;** and **7 times more "Disabled"** reports.

- Compared to Menactra, receipt of Gardasil is associated with **all of the reports of Blood Clots.** All 23 reports of Blood Clots following Gardasil occurred when Gardasil was given alone without any other vaccines.

- Compared to Menactra, receipt of Gardasil is associated with at least **4 times as many Cardiac Arrest** reports. All 9 reports of Cardiac Arrest following Gardasil occurred when Gardasil was given alone without any other vaccines.

- Compared to Menactra, receipt of Gardasil is associated with at least **6 times as many Fainting** reports and at least 3 times as many Syncope reports.

- Compared to Menactra, receipt of Gardasil is associated with at least **4 times as many Lupus** reports. 27 reports of Lupus following Gardasil occurred when Gardasil was given alone

- Compared to Menactra, receipt of Gardasil is associated with at least **15 times as many Stroke** reports. 16 reports of Stroke following Gardasil occurred when Gardasil was given alone.

- Compared to Menactra, receipt of Gardasil is associated with at least **3 times as many Syncope** reports.

- Compared to Menactra, receipt of Gardasil is associated with at least **33 times as many Thrombosis** reports. 34 reports of Thrombosis following Gardasil occurred when Gardasil was given alone.

- Compared to Menactra, receipt of Gardasil is associated with at least **5 times as many Vasculitis** reports. 11 reports of Vasculitis following Gardasil occurred when Gardasiil was given alone.

- Compared to Menactra, receipt of Gardasil is associated with at least **30 times as many Rechallenge** reports, which involve a worsening of symptoms experienced after previous receipt of Gardasil.

CONCLUSION:

In 2007, the National Vaccine Information Center issued three analyses of VAERS reports following receipt of Gardasil. [10] [1112] In these reports, we warned

that Gardasil appeared to be associated with an unusually high number of reports of atypical collapse (fainting and syncope) and other symptoms of brain and immune system dysfunction.

A rough analysis of adverse events reported to VAERS following receipt of Gardasil and/or Menactra vaccines through November 30, 2008 indicate that Gardasil is involved in a much higher number of serious adverse health events than Menactra.

Although Gardasil is given in a three-shot series and only one dose of Menactra is given, Menactra is given to both boys and girls while Gardasil is given only to girls. It is unusual for there to be such a big discrepancy between two vaccines used in similar populations involving serious and relatively rare life threatening adverse events and autoimmune disorders such as death, blood clots, cardiac arrest, lupus, thrombosis, stroke, and vasculitis.

Fainting, which has been attributed by doctors and health officials as “fear” of needles in teenage girls is reported six times as often (and Syncope is reported three times as often) after receipt of Gardasil than Menactra even though Menactra is also given to girls in the same age group.

In pre-licensure clinical trials, Gardasil was only tested in fewer than 1200 girls 16 years and younger. [13] [1415] Through November 30, 2008, in girls 16 or younger, there were reports of 9 deaths; 3 blood clots; 4 cardiac arrests; 9 cases of lupus; 6 strokes; and 2 cases of vasculitis developing after receipt of Gardasil.

This VAERS analysis gives compelling evidence for the need for action to be taken by the FDA, CDC and Congress:

- the FDA should further investigate reports of serious health problems and deaths following Gardasil vaccination; review the accuracy of information about adverse events contained in product manufacturer inserts; and inform physicians and parents about <u>all</u> serious health problems that have been reported to VAERS after Gardasil vaccination;

- the CDC should re-investigate VAERS reports of serious health problems and deaths after Gardasil vaccination; consider the need to withdraw the recommendation that all girls between the ages of 9 and 26 should receive Gardasil vaccine; and issue a warning that, when a serious adverse event occurs after Gardasil vaccination, no further Gardasil shots should be given;

- physicians in the fields of pediatrics and obstetrics/gynecology should fully inform patients and parents about all reported Gardasil adverse events and refrain from re-vaccinating those who experience serious health problems following Gardasil vaccination;

- Merck and the NIH should separately conduct studies into the biological mechanisms for Gardasil vaccine injury and death and define them for physicians and the public so: (a) biological high risk factors can be identified to facilitate informed medical decisionmaking; (b) pathological profiles can be developed to confirm Gardasil-induced brain and immune system dysfunction and death; (c) healing therapies to moderate Gardasil-induced brain and immune system dysfunction can be developed; and (d) Merck can improve the safety of Gardasil;

- Congress should investigate the fast-tracking of Gardasil vaccine without adequate long-term safety studies in American pre-adolescent and teenage girls between ages 9 and16 and the safety and effectiveness of Gardasil vaccine in all age groups.

Vaccines which are licensed and recommended by the government for universal use by children and young adults, should adhere to the highest standards with regard to proof of safety and efficacy. In October 2008, the government issued a report maintaining that receipt of Gardasil is not associated with more serious health problems, hospitalizations, injuries and deaths among young girls and women than are experienced by those young girls and women who do not receive Gardasil.[16] This analysis comparing adverse events reports to VAERS following receipt of Gardasil and Menactra appears to contradict that assertion.

Immediate action should be taken now by federal health agencies to protect recipients of Gardasil from injury and death.

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