Human Papillomavirus (HPV)

Quadrivalent & Bivalent Vaccines

Global Parental Concerns Regarding Safety and Efficacy of Gardasil & Cervarix

FDA WEBINAR

March 12, 2010

THE TRUTH ABOUT GARDASIL

Our daughters are in danger

We are a group of six women including a mother whose daughter died after receiving the Gardasil vaccine and another whose daughter suffered adverse reactions. Over the last three to four years we have offered our time to research, educate and communicate the potential dangers of the HPV vaccines. We represent a growing global community of parents, journalists, and researchers who are dedicating energy, time and knowledge to assist those families desperate to understand what happened to their daughters, and to bring out the truth about Gardasil and Cervarix so there will be "one less" instead of "one more" innocent victim.

We speak on behalf of families around the world to bring justice to the thousands of adversely injured girls and the estimated hundreds of girls who have died from Gardasil and Cervarix.

United States	United Kingdom	Netherlands	India
Australia	Germany	New Zealand	Argentina
France	Canada	Spain	Finland
		Sweden	

THE TRUTH ABOUT GARDASIL

Our daughters are in danger

Webinar Researchers & Participants

Karen Maynor	New Mexico	mother of deceased daughter	Political Activist
Rosemary Mathis	North Carolina	mother of injured daughter	VAERS Data
Freda Birrell	Scotland	political lobbyist	Global Reports
Janny Stokvis	Netherlands	research analyst	VAERS Data
Cynthia Janak	Illinois	research journalist	Histamine and IgE Research, VAERS Data
Leslie C. Botha	Colorado	women's health activist broadcast journalist	Menstrual Cycle Evaluation

Global Parental Concerns

There are thousands of concerned parents with tens of thousands of questions
Seven are addressed in this presentation and are substantiated with research and data.

I. My daughter is now sick after the HPV vaccination and has warts on her hands and feet. Is HPV really only an STD?

II. My daughter has received an irregular pap test two years after the vaccinations. I thought the vaccine was supposed to prevent this?

III. Why is my daughter so ill now when she was always so healthy before the vaccination?

IV. After reporting my daughters reactions to VAERS (Vaccine Adverse Event Reporting System) I became curious to see how many other girls are like my daughter. There are so many I am now afraid my daughter will not get better.

V. I am 18 and my friends and I got the shots. Why did I get an autoimmune disorder and they did not?

VI. How does the side effects my daughter is experiencing compare with other children?

VII. Why did my daughter die?

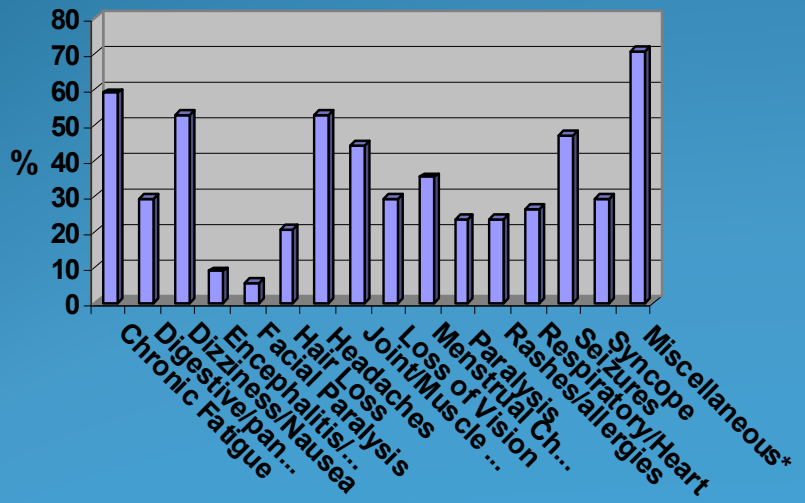
Global Parental Concerns

The international stories, spreadsheet and graphs that have been prepared represent a sample of the injuries occurring to adolescent girls globally.

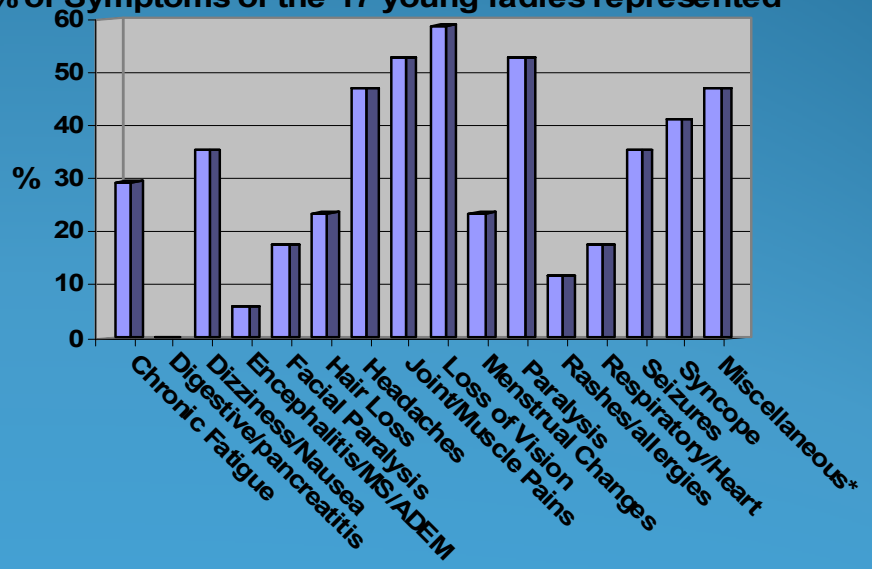
When reading the many reports of girls adversely affected it becomes quickly evident that the symptoms they are experiencing are part of a pattern of events that are similar wherever the HPV vaccines are administered around the world.

The handouts and in particular the graphs demonstrate this very point.

Graph 3
United States of America
% of Symptoms of the 34 young ladies represented



Graph 4
Spain
% of Symptoms of the 17 young ladies represented



Gardasil and Cervarix Synopsis

Gardasil

Cervical cancer is an important public health problem in the United States, with 9,710 new cervical cancer cases and 3,700 deaths due to cervical cancer projected for 2006[1]. Cervical cancer has been associated with human papillomavirus (HPV) infection. Merck, Inc., began a clinical development program in 1997 with a recombinant HPV virus-like particle (VLP) vaccine for the **prevention of cervical cancer.** pg.8

Reviewer's Comment: In all analyses, there is a positive impact in prevention of these dysplasias in those who have not been exposed to the relevant HPV type … pg. 29

(Clinical Review of Biologics License Application Supplement for Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant (Gardasil®) to extend indication for prevention of vaginal and vulvar cancers related to HPV types 16 and 18. 2008 09 11,)

1. Jemal A et al. Cancer Statistics, 2006. *CA: A Cancer Journal for Clinicians 2006;56:106-30.*

Gardasil and Cervarix Synopsis

Cervarix

Cervarix is intended for the vaccination of girls and women 10-25 years of age for the **prevention of the following diseases** caused by HPV types 16 and 18 included in the vaccine:

- Cervical cancer
- Cervical intraepithelial neoplasia (CIN) grade 2 or worse and adenocarcinoma *in situ*
- Cervical intraepithelial neoplasia (CIN) grade 1, pg.14

Biological changes in the cervix around the time of puberty render young girls particularly susceptible to HPV infection [Moscicki, 2005]. This period coincides with the initiation of sexual activity, which is considered an important factor in the acquisition of oncogenic HPV infection. To achieve the maximum benefit from a prophylactic vaccine, vaccination should occur before sexual debut. Pg. 42

(Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant, Vaccines and Related Biological Products Advisory Committee (VRBPAC), Briefing Document, September 9, 2009,)

Post Vaccine
Global Parental Concerns

I. My daughter is now sick after the HPV vaccination and has warts on her hands and feet.
Is HPV really only an STD?

HPV Transmission in Infants and Children

Studies regarding HPV Contact

Cadernos De Saude Publica, Rio deJaniero, 21(4): 1006-1015, jul-ago, 2005
http://www.scielo.br/pdf/csp/v21n4/03.pdf

Although epidemiological trials suggest the possibility of non-sexual transmission, there is evidence of vertical transmission, presumably occurring during passage of the fetus through an infected birth canal. The virus could also be transmitted by ascending infection, principally after premature rupture of membranes. Pg. 1006

Acta Microbiologica et Immunologica Hungarica 48(3-4) pp 511-517 (2001)
http://www.akademiai.com/content/h32q968j22183585/

Introduction of the polymerase chain reaction (PCR) revealed that HPV infections are much more common among young asymptomatic women than it had been previously suspected. The side-specificity of genital HPVs led to the assumption that HPVs were primarily transmitted by sexual contact. However, since HPVs have been detected in virgins, infants/children and juvenile laryngeal papillomatosis was shown to be caused by these viruses, it became acknowledged that HPVs may be transmitted by other – non-sexual – routes as well. Pg. 511

HPV Transmission in Infants and Children

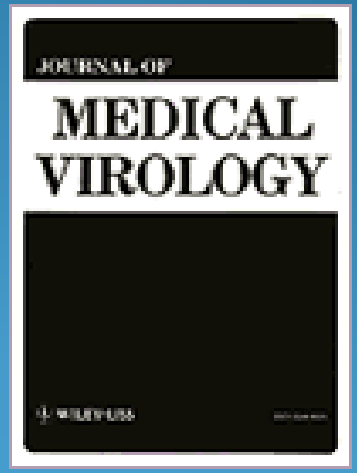
Studies regarding HPV Contact

Journal of Clinical Microbiology, January 2005, p. 376-381, Vol. 43, No. 1
http://jcm.asm.org/cgi/reprint/43/1/376

... nonsexual modes of HPV transmission also have to be considered. These include vertical transmission from parents to infants, horizontal transmission from other family members and those in close contact with the child, autoinoculation from one site to another, and possibly indirect transmission via fomites.

Journal of Medical Virology, Vol 61 issue 1, pp 70-75 (2000)
http://cat.inist.fr/?aModele=afficheN&cpsidt=1403036

Before immunisation programmes can be designed, however, it is necessary to know the age of acquisition and all routes of infection for these viruses. Sexual transmission is well documented and vertical transmission has also been demonstrated, although the frequency of transmission remains controversial. We previously showed that vertical transmission frequently results in persistent infection, and now present data on the prevalence of HPV-16 DNA (the most prevalent high-risk HPV type) in healthy children.



Journal of Medical Virology, Vol 71 issue 4, pages 593-598 (2003)
http://www3.interscience.wiley.com/journal/106056791/abstract

It is concluded that HPV-16 DNA in the oral cavities of children is a transient event and is most probably acquired from their peers.

Post Vaccine
Global Parental Concerns

II. My daughter has received an irregular pap test two years after the vaccination series. I thought the vaccine was supposed to prevent this?

By sledmom | **Reply** | (2) replies | Private Message me

January 2th
2009
8:20 AM
A good friend of mine, a person I have known for 30 years, told me yesterday that her son's girlfriend, a college student, had surgery over the Christmas break for cervical cancer. This is her second surgery, and both surgeries were paid for by the manufacturer of Guardasil. By paying for these surgeries, it seems clear that the company is accepting responsibility for what happened to her. Apparently, because this girl had a weak immune system, Guardasil actually caused the very thing it was intended to prevent--cervical cancer.
Neither my friend nor I had never heard anything like this before, and I am wondering if others know of girls who have actually gotten cervical cancer after receiving Guardasil.

According to the National Vaccine Information Center there are **272 events with Vaccine that is HPV or HPV4 and Symptom is Smear cervix abnormal**
http://www. medalerts.org

HPV Vaccines - Are They Safe for Seropositive Females?

VRBPAC Background Document
Gardasil™ HPV Quadrivalent Vaccine
May 18, 2006 VRBPAC Meeting

Table 17. Study 013: Applicant's analysis of efficacy against vaccine-relevant HPV types CIN 2/3 or worse among subjects who were PCR positive and seropositive for relevant HPV types at day 1. [From original BLA, study 013 CSR, Table 11-88, p. 636]

	Gardasil™ N=2717				Placebo N=2725					
Endpoint	N (subgroup)	Number of cases	PY at risk	Incidence Rate per 100 person years at risk	N (subgroup)	Number of cases	PY at risk	Incidence Rate per 100 person years at risk	Observed Efficacy	95% CI
HPV 6/11/16/18 CIN 2/3 or worse	156	**31**	278.9	11.1	137	**19**	247.1	7.7	-44.6%	<0.0, 8.5%

HPV Vaccines - Are They Safe for Seropositive Females?

VRBPAC Background Document
Gardasil™ HPV Quadrivalent Vaccine
May 18, 2006 VRBPAC Meeting

Table 19. Study 013: Analysis of efficacy against vaccine-relevant HPV types CIN 2/3 or worse among subjects who were PCR positive and/or seropositive for the relevant HPV type at day 1. [From additional efficacy analyses requested by CBER and submitted March 15, 2006, table 1e-2, p. 13.]

	Gardasil™ N=2717				Placebo N=2725					
Endpoint	N (subgroup)	Number of cases	PY at risk	Incidence Rate per 100 person years at risk	N (subgroup)	Number of cases	PY at risk	Incidence Rate per 100 person years at risk	Observed Efficacy	95% CI
HPV 6/11/16/18 CIN 2/3 or worse	685	**48**	1385.6	3.5	664	**35**	1350.3	2.6	-33.7%	<0.0, 15.3%

HPV Vaccines - Are They Safe for Seropositive Females?

CERVARIX
Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant
Vaccines and Related Biological Products Advisory Committee (VRBPAC)
Briefing Document
September 9, 2009

Table 15 Study HPV-008: overview of vaccine efficacy against histological lesions associated with HPV-16/18 (by PCR) in HPV DNA positive subjects at baseline (TVC-1)

Endpoint	*Cervarix*		Control		Vaccine Efficacy		
	N	Cases	N	Cases	%	96.1% CI	P-value
HPV DNA positive subjects at baseline, irrespective of initial serostatus							
CIN2+	617	62	567	58	0.5	-47.7, 32.9	0.9235
CIN1+	617	72	567	76	13.0	-23.8, 38.9	0.3801
HPV DNA positive and seronegative subjects at baseline							
CIN2+	303	18	285	27	37.8	-20.9,68.8	0.1216
CIN1+	303	27	285	36	30.5	-20.9,60.5	0.1819
HPV DNA positive and seropositive subjects at baseline							
CIN2+	315	43	290	31	-32.5	-123.1,20.4	0.3205
CIN1+	315	44	290	40	-3.0	-66.0,35.9	1.0000

As expected, the vaccine did not show a therapeutic effect in subjects HPV DNA positive at baseline for the type considered in the evaluation (Table 15). Pg 62

HPV Vaccines - Are They Safe for Seropositive Females?

Does HPV screening take place before vaccination?

No screening takes place prior vaccination with either of the HPV vaccines!

"In June 2009, representatives from the Society, ACOG (American College of Obstetricians and Gynecologists), and approximately 25 other organizations met to discuss cervical screening and management for adolescents. There was general consensus that new screening guidelines should **recommend against adolescent screening and that screening should begin at age 21**," said Saslow. "The Society will formally review the evidence and update our cervical cancer screening recommendations in the coming year." *

When does screening take place?

- United States 25 years old
- Scotland 20 years old
- England/Wales 25 years old

ACOG Revises Cervical Cancer Screening Guidelines, **Article date: 2009/11/20,**
http://www.cancer.org/docroot/NWS/content/NWS_1_1x_ACOG_Revises_Cervical_Cancer_Screening_Guidelines.asp

HPV Vaccines are They Safe for Seropositive Females?

HPV screenings do not take place prior to vaccination with either Gardasil or Cervarix

The Problem

1. An infant can contract HPV at birth
2. A child can contract HPV by lateral transmission
3. Young girls and women are having intercourse at an earlier age
4. New pap recommendations will push initial screenings back to age 25

Post Vaccine
Global Parental Concerns

III. Why is my daughter so sick now when she was always so healthy before the vaccination?

Gardasil "New Medical Conditions"

Clinical Review of Biologics License Application Supplement September 11, 2008

TABLE 79
New Medical Conditions After Day 1 in Studies HPV-007, -013, -015, -016, -018 in the Safety Population (Final Close-out data)

Event	Gardasil N=11778	Placebo N=9686
Subjects with new medical history	8628 (73.3%)	7390 (76.3%)

VRBPAC Background Document
Gardasil™ HPV Quadrivalent Vaccine
May 18, 2006 VRBPAC Meeting

Table 32. Detailed Safety Population: Number (%) of subjects who reported systemic adverse reactions of 2% or greater in the 15 days following receipt of study vaccine.
[From original BLA, safety summary, Table 2.7.4:14.]

Systemic adverse reaction	**Gardasil™ N=6160**	**Placebo N=4064**
Subjects reporting systemic adverse reaction	3591 (59.2%)	2414 (60.4%)

Cervarix - Solicited Adverse Events

CERVARIX
Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant
Vaccines and Related Biological Products Advisory Committee (VRBPAC)
Briefing Document
September 9, 2009

Table 28 Pooled safety analysis: percentage of doses (overall/dose) followed by solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period (Total Vaccinated Cohort, 10-25 year olds)

Symptom	Type	HPV group	HAV720 group	HAV360 group	Placebo group
General					
No. of doses		18544	8748	3058	1565
Fatigue	Any	35.5	35.3	24.6	31.7
	Grade 3	1.7	1.3	1.1	2.0
Fever	≥ 99.5°F	5.3	4.6	6.8	5.5
	> 102.2°F	0.2	0.1	0.6	0.4
GI	Any	13.9	14.0	11.3	15.9
	Grade 3	0.8	0.7	0.8	0.5
Headache	Any	31.3	30.8	25.4	36.5
	Grade 3	1.8	1.4	1.6	2.1
Rash	Any	4.2	3.6	2.6	4.2
	Grade 3	0.1	0.1	0.1	0.0
Other General*					
No. of doses		16964	8748	3058	-
Arthralgia	Any	10.4	8.6	9.3	-
	Grade 3	0.4	0.3	0.2	-
Myalgia	Any	31.0	26.5	17.1	-
	Grade 3	1.6	0.6	0.5	-
Urticaria	Any	3.3	3.7	2.1	-
	Grade 3	0.2	0.4	0.2	-

HPV group: 10-25 years, HAV720 group: 15-25 years, HAV360 group: 10-14 years, Placebo group: 15-25 years
GI = Gastrointestinal, including nausea, vomiting, diarrhea, and/or abdominal pain.

Comparison of Gardasil and Cervarix VAERS Reported Adverse Reactions

Adverse Event	Gardasil	Cervarix
Fatigue	2.6%	35.5%
Fever*	8.8%	5.5%
GI**	5.6%	13.9%
Headache	26.4%	31.3%
Rash/Skin disorder	3.5%	4.2%
Arthralgia	1.2%	10.4%
Myalgia	2.0%	31.0%
Urticaria	n/a	3.3%

Gardasil numbers are taken from table 322 of May 18, 2006 VRBPAC Meeting Background Document
Cervarix numbers are taken from Table 28 of the VRBPAC Briefing Document, September 9, 2009
* Computation of table 323 of May 18, 2006 VRBPAC Background Document
** Computation of gastrointestinal including nausea, vomiting, diarrhea, and/or abdominal pain.

Analysis of CDC numbers of administered HPV vaccine.

National, State, and Local Area Vaccination Coverage Among Adolescents Aged 13--17 Years --- United States, 2008

For HPV4, 37.2% of adolescent females had initiated the vaccination series (≥1 dose) in 2008, compared with 25.1% in 2007, and 17.9% of females had received ≥3 doses. Among adolescent females who initiated the HPV4 series, 79.4% had received their first dose at least 24 weeks before the interview date (the minimum period in which to complete the series); of these, 59.6% (95% confidence interval [CI] = 55.5--63.5) had received ≥3 doses.

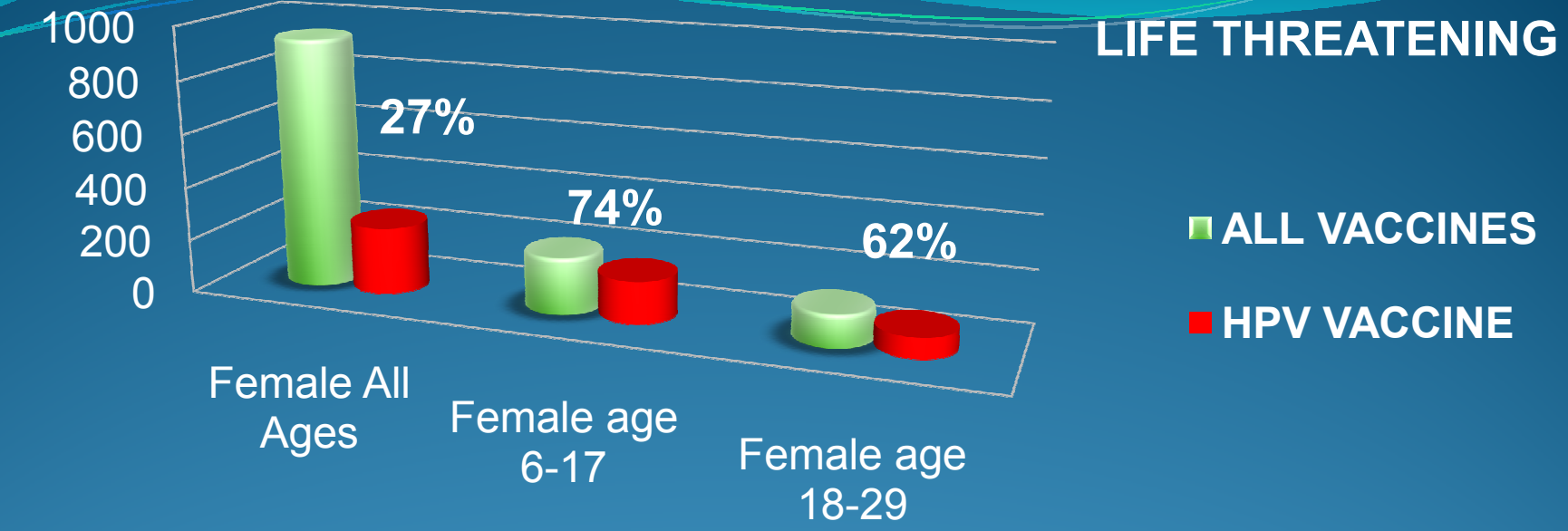
Census data years			2008	2007		
15 to 19 years			10,487,094	10,466,821		
CDC estimates						
13 - 17 years old						
≥ 1 dose						
	2007	25.1%		2,632,261		
	2008	37.2%	3,901,199			
total				6,533,460		
≥ 3 doses		1,169,489				
2007 & 2008		17.9%	1,877,190			
Difference			4,656,270	28.7%	71.3%	

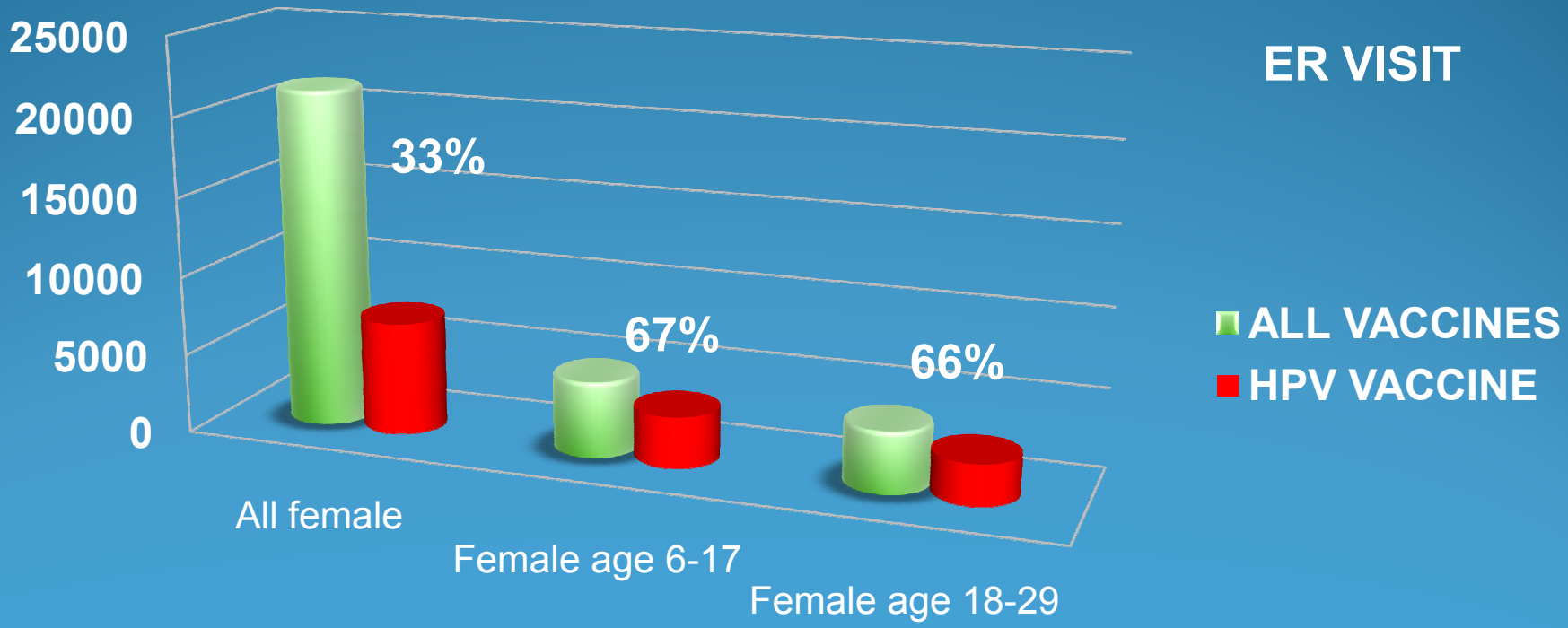
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5836a2.htm **September 18, 2009 / 58(36);997-1001**

Post Vaccine
Global Parental Concerns

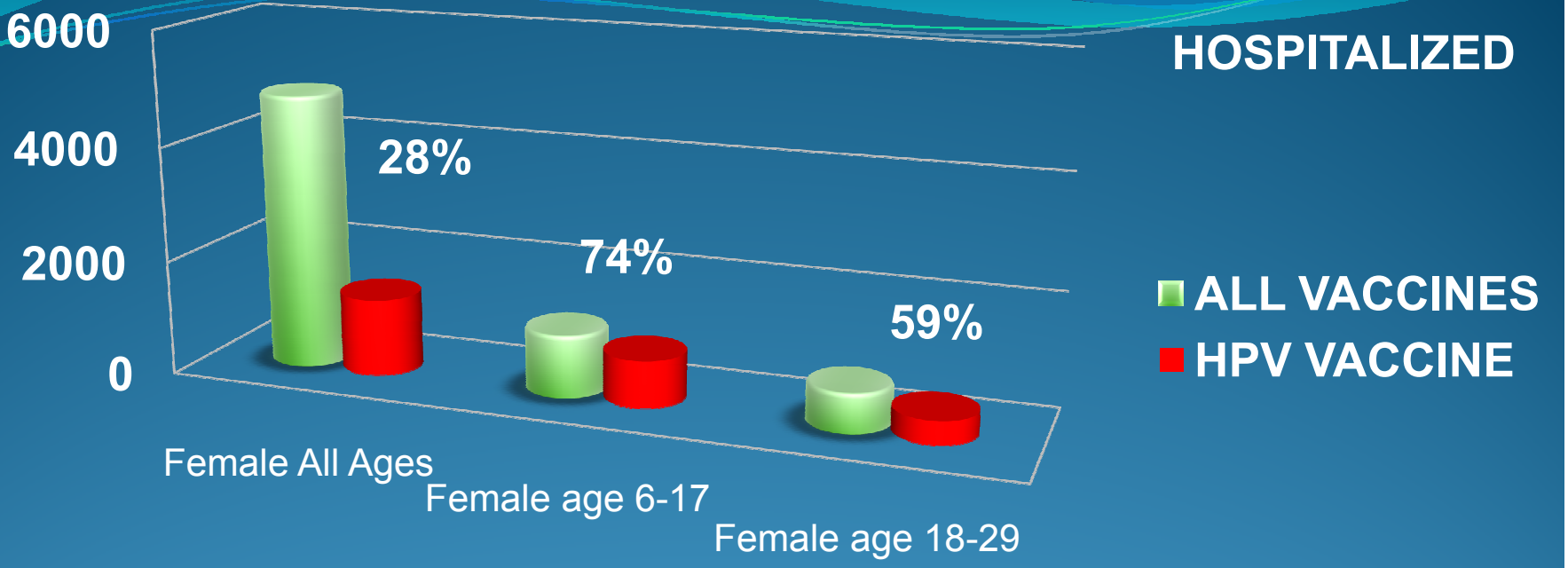
IV. After reporting my daughters reactions to VAERS (Vaccine Adverse Event Reporting System) I became curious to see how many other girls are like my daughter.
There are so many I am now afraid my daughter will not get better.

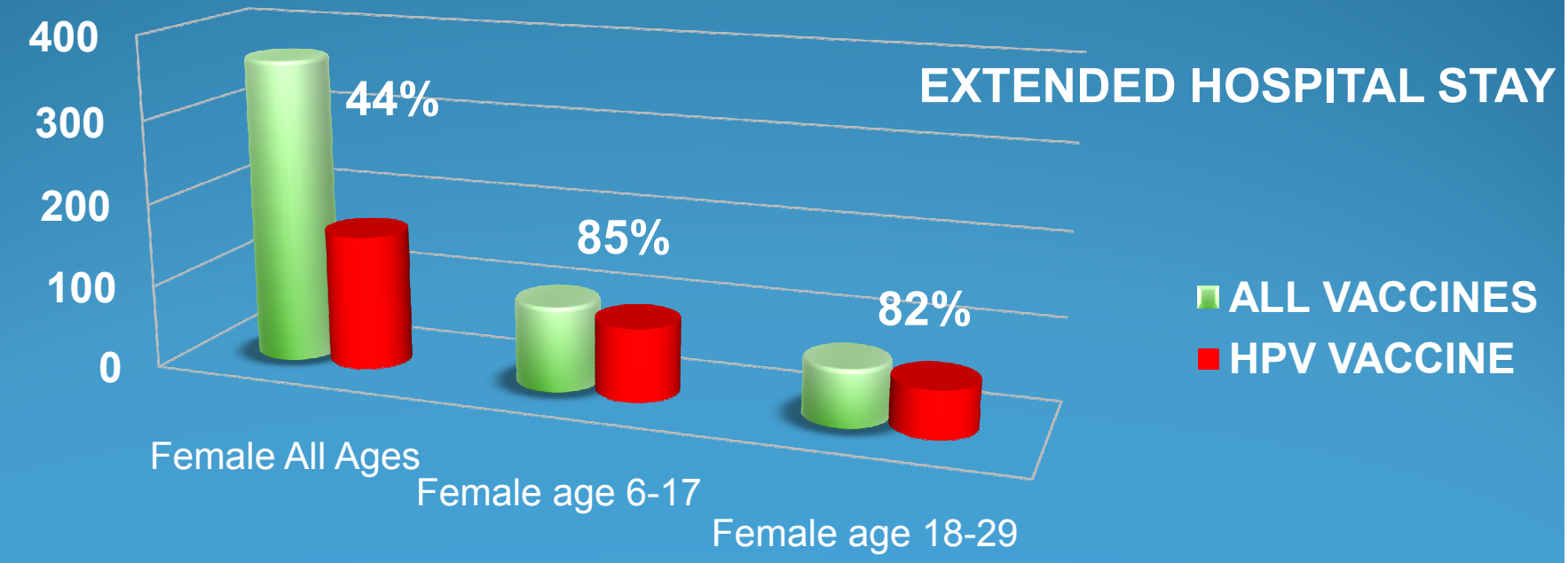
HPV vaccine trend of injury by classification



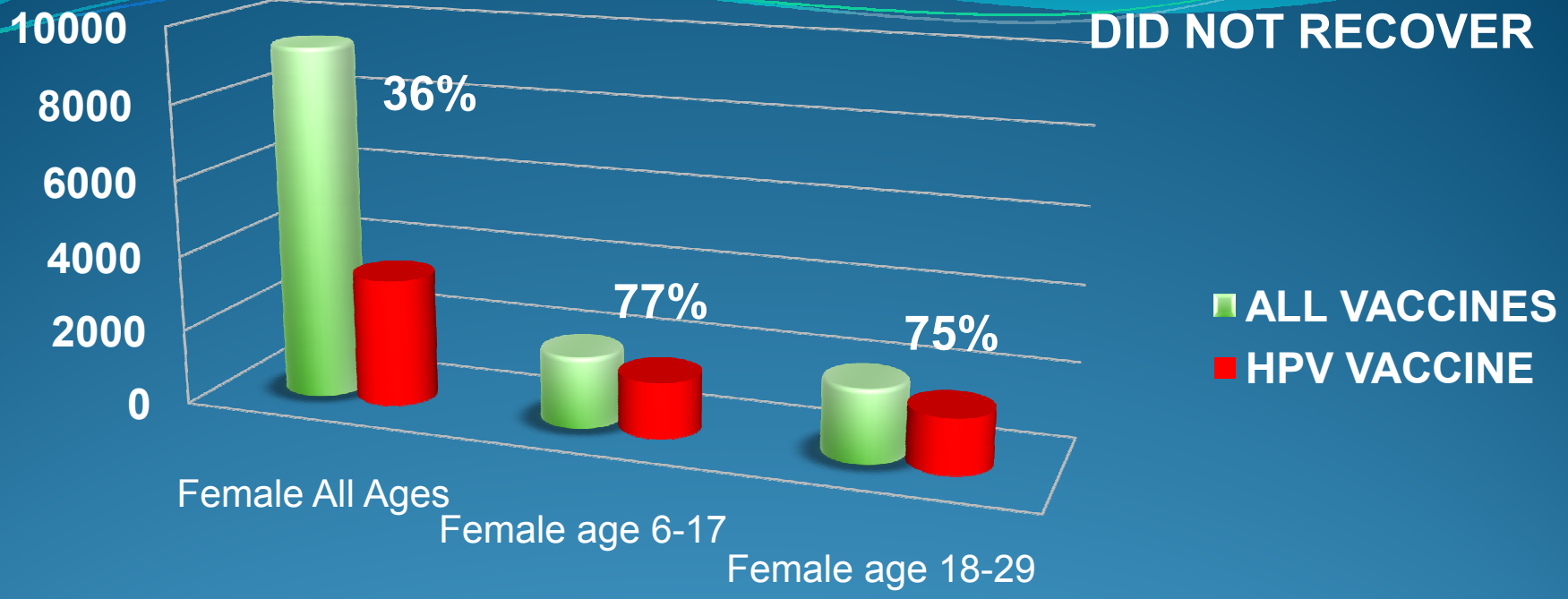


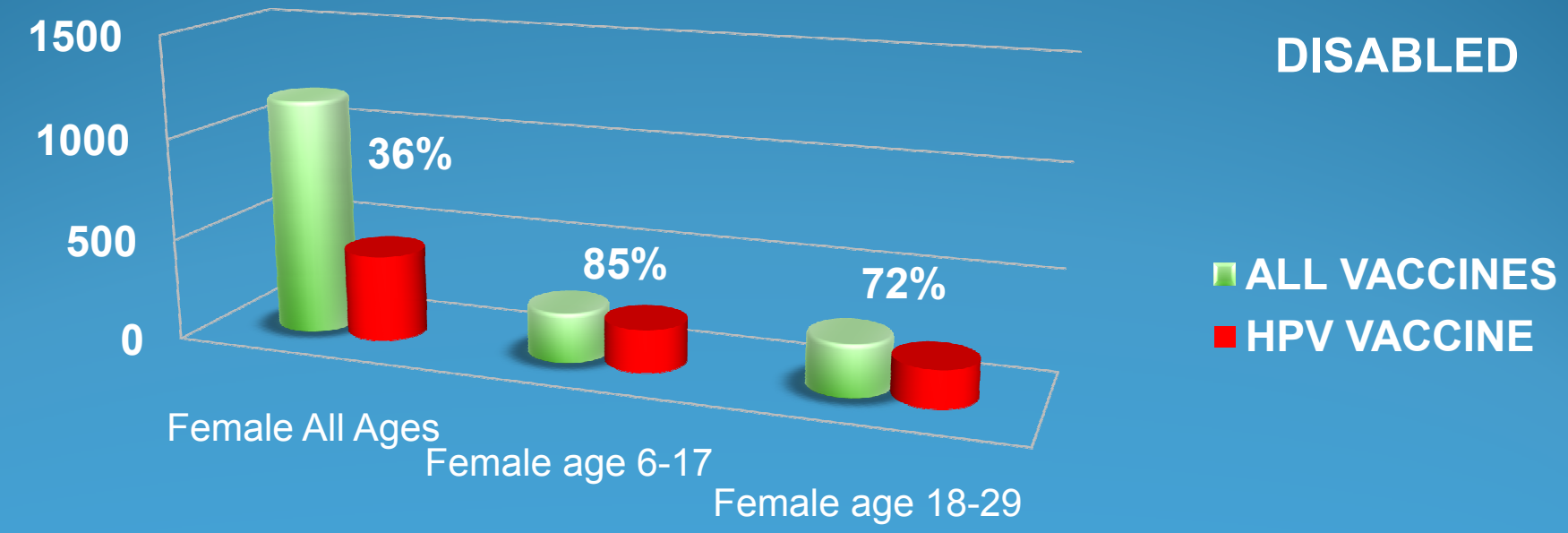
HPV vaccine trend of injury by classification



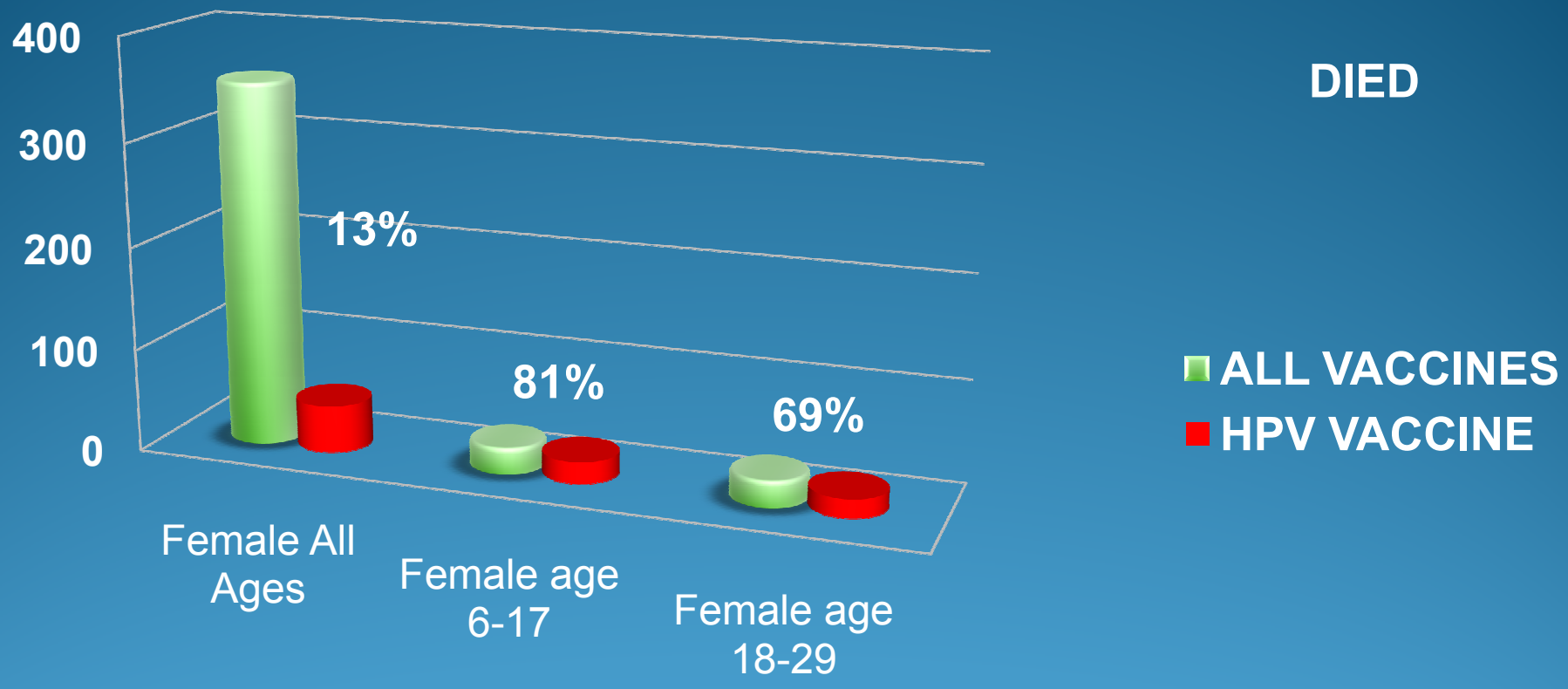


HPV vaccine trend of injury by classification

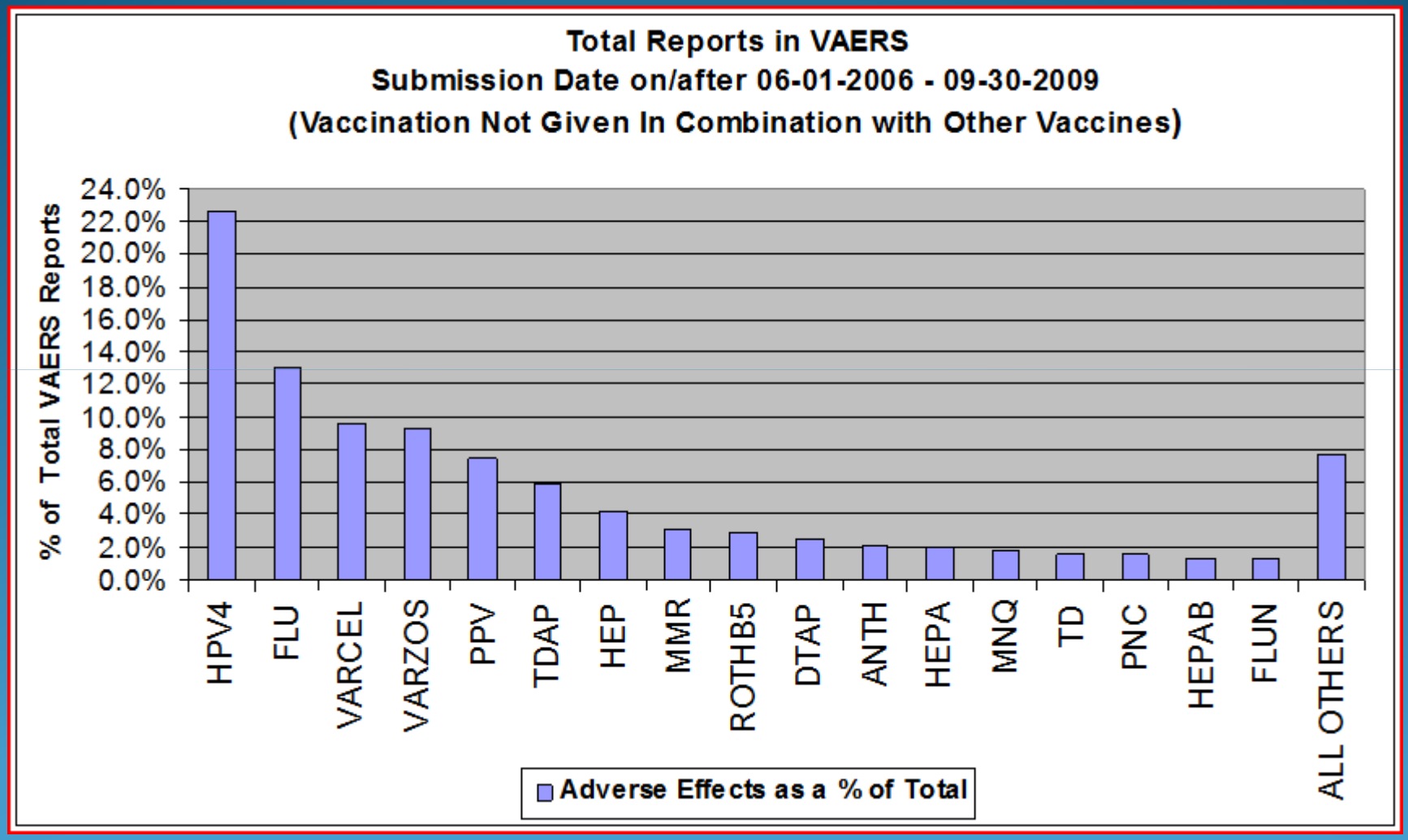




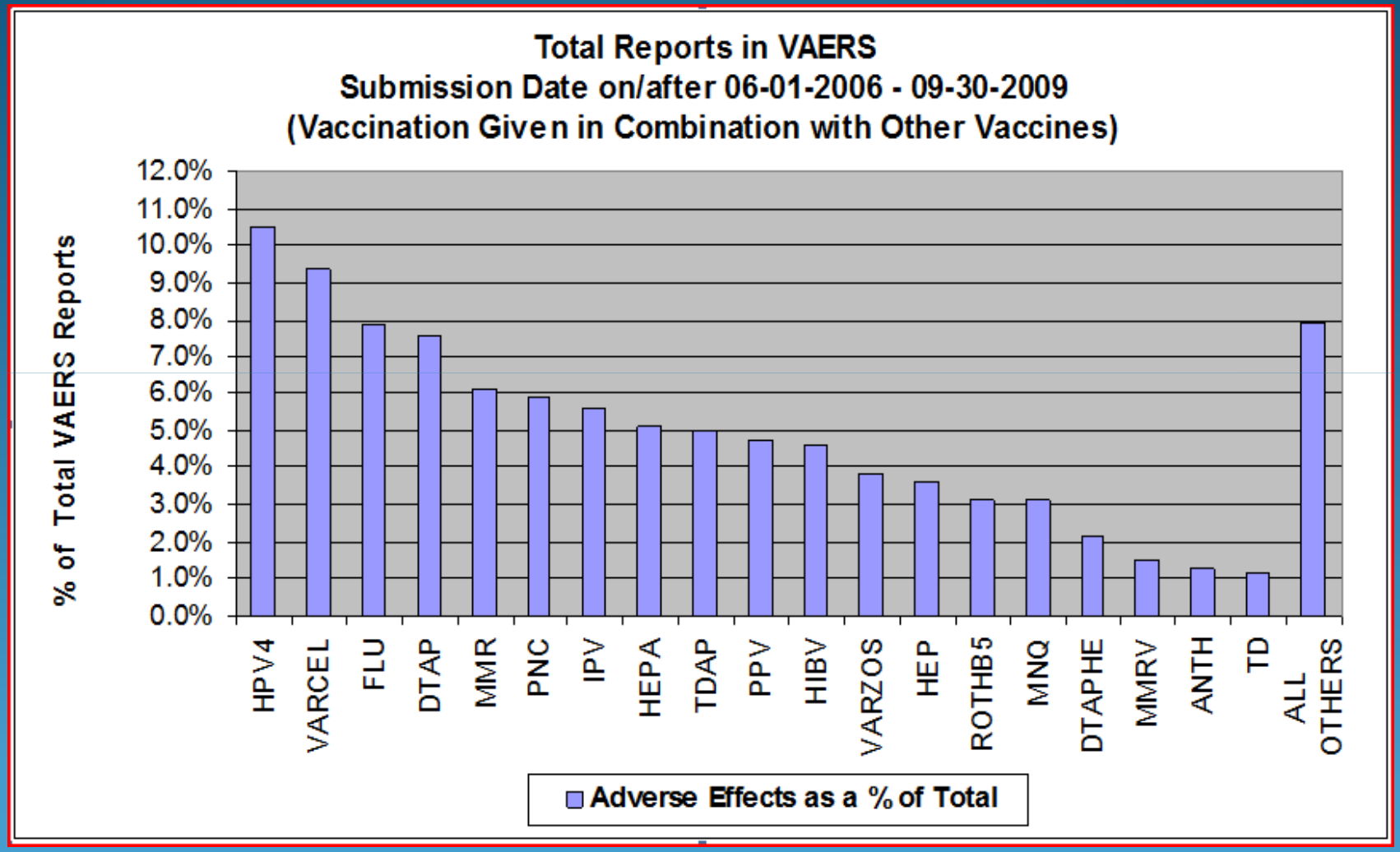
HPV vaccine trend of injury by classification



VAERS Reported Vaccine Injuries



VAERS Reported Vaccine Injuries for Multiple Vaccinations



VAERS Comprehensive Analysis

	Submission date on/before 05/31/06		05/31/06 Difference	%	Submission Date on/after 06/01/06		06/01/06 Difference	%
	male	female			male	female		
0 - 2 year olds	35216	30719	4497	14.6%	9382	8091	1291	16.0%
3 - 5 year olds	12868	11679	1189	10.2%	3945	3687	258	7.0%
6 - 10 year olds	3990	3743	247	6.6%	1937	2308	371	16.1%
11 - 13 year olds	2980	3099	119	3.8%	1987	3592	1605	44.7%
14 - 16 year olds	1858	2587	729	28.2%	940	4746	3806	80.2%
17-19 year olds	1589	2665	1076	40.4%	782	4097	3315	80.9%
20 - 26 year olds	3617	6496	2879	44.3%	1315	5238	3923	74.9%
27 - 30 year olds	2059	4569	2510	54.9%	596	1415	819	57.9%

*Note: the numbers for 06/01/06 reflect reporting through October of 2009.

VAERS Comprehensive Analysis

	2005 female	%	2006 female	%	2007 female	%	2008 female	%	2009 female	%
0 - 2 yr olds	2022	8.2%	2245	12.4%	2476	16.8%	2662	13.4%	1462	15.0%
3 - 5 yr olds	616	21.8%	638	17.1%	745	5.0%	772	5.6%	577	6.1%
6 - 10 yr olds	316	10.4%	325	6.2%	637	11.9%	697	13.9%	335	19.1%
11 - 13 yr olds	138	23.9%	210	11.4%	812	41.5%	943	38.1%	627	34.3%
14 - 16 yr olds	124	4.8%	216	36.6%	1001	76.5%	1327	82.8%	719	78.9%
17 - 19 yr olds	218	41.7%	237	37.6%	1140	84.5%	1366	83.5%	619	80.6%
20 - 26 yr olds	384	31.0%	494	49.6%	1592	74.6%	1915	78.5%	933	71.3%
27 - 30 yr olds	183	42.1%	245	57.6%	366	55.2%	411	58.9%	231	55.8%

*Note: the numbers for 2009 reflect reporting through October of 2009.

Post Vaccine
Global Parental Concerns

V. I am 18 and my friends and I received the Gardasil series. Why do I have an autoimmune disorder and they do not?

Demographics of Girls Affected by Adverse Reactions

- Athletic
- Overweight
- Vaccination during Paramenstrum

Demographics of Girls Affected by Adverse Reactions

Studies of Female Athletes

Diurnal Profiles of Testosterone and Pituitary Hormones Suggest Different Mechanisms for Menstrual Disturbances in Endurance Athletes

We found that 24-h profiles of testosterone, LH, and PRL were positively correlated and cortisol negatively correlated with the number of menstruations during the last year in these athletes. However, the endocrine profiles in amenorrheic and oligomenorrheic athletes were apparently different. Amenorrehic athletes displayed a hormonal pattern in agreement with hypothalamic inhibition. **In contrast, oligomenorrheic athletes had higher 24-h secretion of testosterone than all other groups.**

The Journal of Clinical Endocrinology & Metabolism 89(2):702–707

doi: 10.1210/jc.2003-030306

Demographics of Girls Affected by Adverse Reactions

Studies of Female Athletes

THE IMPORTANCE OF HORMONES IN FEMALE ATHLETIC COMPETITION*

The pre-event rise in males averages nine percent whereas in **females it increases by twenty-four percent. During the competition itself women increase their testosterone production by forty-nine percent** while in males it increases on average fifteen percent.

"We are not sure why women's testosterone elevation prior to competition is so much greater than it is in men. It is probably due to the fact that every day levels of testosterone are four times higher in men than they are in women. To effectively meet the challenge a higher production rate may be necessary," explains Dr. Alan Booth, Distinguished Professor of Sociology, Human Development and Family Studies, and Demography at Pennsylvania State University.

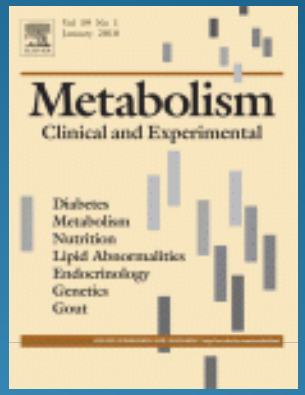
"Among women, pre-game testosterone increases were significantly correlated with reports of being focused just prior to the game, just as it is associated with arousal in men," Booth says. "Unlike pre-game increases in men, the pre-game increase among women was unrelated to the perceptions of how easy or difficult the opponent was thought to be prior to the game. Men seem to adjust their pre-game rise to the perceived strength of the opponent."

* http://www.collegesportsscholarships.com/steroids-testosterone-women.htm "College Sports Scholarships"

Demographics of Girls Affected by Adverse Reactions

Studies of Overweight Females

Link Between Polycystic Ovary Syndrome and Obesity Involves Insulin *



Hyperinsulinemia also **stimulates the ovaries to make more male hormones (testosterone and androstenedione)** and lowers the liver's ability to clear these hormones from the blood. Higher blood levels of male hormones contribute to PCOS symptoms including **acne, male-pattern hair growth (on face or body) or balding, and lack of ovulation**.

Testosterone Concentrations in Women Aged 25–50 Years: Associations with Lifestyle, Body Composition, and Ovarian Status **

The greater circulating levels of testosterone with obese women and smokers suggest that testosterone may be an important contribution to those disease conditions where obesity and smoking are risk factors, including cardiovascular disease.

* http://win.niddk.nih.gov/notes/summer04/winnotes_summer04.htm The full report, "Pathogenesis of polycystic ovary syndrome: What is the role of obesity?" appears in *Metabolism* (2004;53:358-376).

** http://aje.oxfordjournals.org/cgi/reprint/153/3/256 American Journal of Epidemiology, Copyright © 2001 by The Johns Hopkins University School of Hygiene and Public Health, Vol. 153, No. 3, *Printed in U.S.A.*

"It's All In Your Head"

Endocrine-disrupting chemicals
can undermine neurological and behavioral development

My daughter had 2 Gardasil vaccines and approximately a year later has tested positive for high-risk HPV. We also believe that her HPV is the result of the vaccines because: she did not have HPV when she received the vaccines; she suffered SEVERE side effects from them which incapacitated her for 2 1/2 months; and she continues to experience menstrual problems even though it has been over a year. Now the news that she has precancerous, high-risk HPV.

"

Polycystic Ovarian Syndrome – Infertility - Occurrence of Cervical Lesions – Hair Loss

New evidence is especially worrisome because it underscores the exquisite sensitivity of the developing nervous system to chemical perturbations that result in functional abnormalities. Moreover, the consequences of these perturbations depend upon the stage of development during which exposure occurs and are expressed in different ways at different times in life, from birth through to advanced age.

Because the endocrine system is sensitive to perturbation, it is a likely target for disturbance. In contrast to natural hormones found in animals and plants, some of the components and by-products of many manufactured organic compounds that interfere with the endocrine system are persistent and undergo biomagnification in the food web, which makes them of greater concern as endocrine disruptors.

Statement from the work session on environmental endocrine disrupting chemicals: neural, endocrine and behavioral effects.
Erice,Sicily November 1995.

Demographics of Girls Affected by Adverse Reactions

Studies on Menstrual Cycle Evaluation

Annovulatory, Oligomenorrheal and Dysmenorrheal Cycles

Impact of stress, gender and menstrual cycle on immune system: possible role of nitric oxide

http://www.ncbi.nlm.nih.gov/pubmed/11935378

Stress is a factor found to be involved in the etiology of many diseases. Gender and menstrual cycle phases are other factors affecting the predisposition of individuals for certain diseases. Results from animal and human studies suggest that the distribution of immune system cells may change at different phases of the menstrual cycle.

Sex Differences in Stress Response Circuitry Activation Dependent on Female Hormonal Cycle

http://www.jneurosci.org/cgi/content/abstract/30/2/431

Understanding sex differences in stress regulation has important implications for understanding basic physiological differences in the male and female brain and their impact on vulnerability to sex differences in chronic medical disorders associated with stress response circuitry.

Influence of menstrual cycle on NK activity

http://www.journals.elsevierhealth.com/periodicals/jri/article/PIIS0165037800000917/abstract

Natural killer (NK) cells* are CD3- CD56+ and/or CD16+ cytotoxic lymphocytes that mediate first-line defense against various types of target cells without prior immunization.... results showed that (1) NK cytotoxicity was higher in the follicular than in the luteal phase of the menstrual cycle

Demographics of Girls Affected by Adverse Reactions

Menstrual Cycle Evaluation Studies

Testosterone levels and cognitive functioning in women with polycystic ovary syndrome and in healthy young women
http://www.ncbi.nlm.nih.gov/pubmed/17433328
Women with PCOS had significantly higher levels of free T (estimated by the free androgen index) and demonstrated significantly worse performance on tests of verbal fluency, verbal memory, manual dexterity, and visuospatial working memory than the healthy control women.

Hair Loss
http://mayoclinic.com/health/hair-loss/DS00278/DSECTION=causes
Due to hormonal changes, irritation or damage, some hair follicles have a shorter growth phase and produce thinner, shorter hair shafts.

Alopecia areata. This is classified as an autoimmune disease, but the cause is unknown. People who develop alopecia areata are generally in good health. A few people may have other autoimmune disorders, including thyroid disease. Some scientists believe that some people are genetically predisposed to develop alopecia areata and that a trigger, such as a virus or something else in the environment, sets off the condition.

Demographics of Girls Affected by Adverse Reactions

Studies on Menstrual Cycle Evaluation

Luteinizing hormone provides a causal mechanism for mercury associated disease
http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6WN2-4XP3C11-2&_user=10&_coverDate=11%2F13%2F2009&_rdoc=1&_fmt=high&_orig=search&_sort=d&_docanchor=&view=c&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=088cbd4b1b6837e023db2ef62e4df6ba#cor1
Previous studies have demonstrated that the pituitary is a main target for inorganic mercury (I-Hg) deposition and accumulation within the brain. My recent study of the US population (1999–2006) has uncovered a significant, inverse relationship between chronic mercury exposure and levels of luteinizing hormone (LH). This association with LH signifies more than its presumed role as bioindicator for pituitary neurosecretion and function.

Brief Assessment of Aluminum Exposure and Endocrine System
http://www.safeminds.org/mercury/docs/Brief%20Assessment%20of%20Aluminum%20Exposure%20and%20Endocrine%20Disruption.pdf
It is thought that inflammation resulting from aluminum exposure may induce learning and memory deficits [39]. Certainly, targeted effects on the endocrine system may affect immune-modulation and produce a pro-inflammatory cascade that responds to targeted aluminum deposition in the hippocampus with resultant neurotoxicity.

Heavy Metals and Fertility
http://www.informaworld.com/smpp/content~content=a713851573&db=all
Thus, the hypothalamic-pituitary-ovarian axis can be affected by heavy metals either directly or indirectly through modifications of the secretion of prolactin, adrenocortical steroidsor thyroid hormones. In the ovary itself, accumulation of heavy metals impairs the production of estradiol and progesterone.

Demographics of Girls Affected by Adverse Reactions

Menstrual Cycle Evaluation Studies

Hormone Allergy

http://onlineallergycenter.com/folder/research_abstracts/Hormone_Allergy_AJRI_3_10_06.pdf

Many disorders have been associated with menstrual cycle influences, including acne, asthma, hereditary angioedema, apthous ulcers, Behc¸et syndrome, porphyria, epilepsy, myasthenia gravis, allergic rhinitis and migraines.1–10 A recent review of autoimmune progesterone dermatitis11 describes an allergic reaction to progesterone that can lead to severe dermatitis and anaphylaxis. Geber12 described the first documented case of cyclic urticaria associated withthe menstrual cycle in 1921. He suggested a terminology of hormone allergy after demonstrating a flare in the disease by administering the patient's own pre-menstrual serum.1

Immunological Adjuvants and Vaccines

http://www.amazon.com/Immunological-Adjuvants-Vaccines-Nato-Science/dp/0306433869

...it has now been revealed that it is the *aluminum* which is put into vaccines as an adjuvant which causes production of IgE...the antibody of allergy and anaphylactic shock.

Histamine Metabolism During the Menstrual Cycle

http://www.ncbi.nlm.nih.gov/pubmed/973560

At mid cycle an increase in the urinary excretion of histamine metabolites was sometimes evident and a statistically significant correlation could be established between MeHi and estrogen in urine. These results may support previous findings of histamine release by estrogens in uterine tissue but may also reflect an elevated histamine formation. The allergic woman excreted constantly increased amounts of histamine and its metabolites, especially when her allergic symptoms became aggravated premenstrually.

Post Vaccine
Global Parental Concerns

VI. How do the side effects my daughter is experiencing compare with other children?

Gardasil Girls give the Silent Faces of Autism a Voice

Vaccinations, cytokine storms, and autism
http://www.generationrescue.org/binstock/090711-autism-by-cytokine-storms.htm

The CDC's list of vaccination side-effects (3) seems based upon individual vaccines. As reported by many parents of autistic children who regressed after vaccination episode, the mild, moderate, and supposedly "rare" side effects of vaccinations resemble post-vaccinal symptoms manifested by their child.

Apparently not addressed by the CDC's list of adverse effects of individual vaccinations is whether or not a child who is injected with multiple vaccines during one incident is more likely (a) to experience one or more of the side effects, (b) to develop a more severe reaction (eg, fever related to seizures), or (c) to develop symptoms consistent with vascular pathology or brain damage. Examining specific vaccine's side effects (4) offers clues regarding what might be more likely to occur in some individuals when, for instance, the DTaP, MMR, and another "routine" vaccine are injected during the same incident.

Reported Adverse Reactions Partial Summary

Gardasil and Cervarix

Auto immune disorders
Paralysis
Guillane Barre Syndrome
Seizures
Migraines
Blindness or temporary disruption of vision
Hearing Loss (predominate with Cervarix VAERS reports)
Memory Loss, inability to concentrate, brain fog

Chemical Menopause Symptoms
facial hair, disruption of menses, drastic mood swings (hormone imbalance), painful menses, poly cystic ovarian syndrome*
Circulation Issues
heart palpitations, numbness in extremities, fainting, drops in blood pressure, pain in chest

http://pcos.about.com/od/normalmenstrualcycle/f/androgens.htm

Post Vaccine
Global Parental Concerns

VII. Why did my daughter die?

One less daughter, one less sister, one less aunt, one less niece, one less student, one less future wife, one less future mother; one less woman who will make a difference.

64 deaths reported in VAERS
17,400 adverse affects
ONE LESS! .....
-Shanna Jojola, sister of Megan

Not a day goes by that our family does not mourn the loss of our beautiful daughter, Megan Hild. My oldest daughter, Shanna is traumatized by the fact that she encouraged Megan to get Gardasil.

I will not live with a cause of death unknown on her autopsy report. I will not tolerate the "expert's" who told me that Megan was ready to leave this life. I spoke with my daughter two hours before she died. She was vibrant, beautiful, healthy and embraced her life, her future – her family and her boyfriend.

Do not forget the guilt, grief and loss that the families are left with. They are the ones who carry the burden of a life unnecessarily taken or a daughter damaged from the HPV vaccines.

-Karen Maynor

U.S. HPV Vaccine VAERS Reported Deaths

Presently there are 46 deaths referencing heart issues in the VAERS reports in regards to the HPV vaccination.

3	Myocarditis -
1	Sudden Cardiac Death
7	Pulmonary Embolism/Blood Clots
5	Cardiac Arrest
1	Pulmonary Thromboembolus
1	Arrhythmia Due to Cardiomyopathy
1	“Viral insult to the heart”
1	Cardiovascular Collapse
1	Hypertrophic Cardiomyopathy
1	Acute Cardiac Arrhythmia
1	Cardiomegaly
6	Sudden Death
2	“Died in her Sleep”
15	Unknown

U.S. HPV Vaccine VAERS Reported Deaths

Autopsy Report – 18 year old female

1. "There was biventricular cardiomegaly"
2. "There was transmural replacement of myocytes by fibro-fatty tissue in the right ventricular wall"
3. "There was also diffuse variable myocyte hypertrophy"

ARVD – Arrhymogenic Right Ventricular Dysplasia*

1. Is a cardiomyopathy (a disease of the cardiac muscle cells)
2. Affects about 1/5000 people
3. Is a known cause of sudden cardiac death in young people
4. Many cases of death occur in the home during sedentary activities
5. Symptoms - Abdominal pain, Decreased exercise tolerance, Dizziness, Dyspnea 'difficulty breathing' (especially with exertion), Fatigue, Mental confusion, Palpitations, Syncope or fainting

The Problem

"Because of the extensive tissue degeneration that had occurred prior to autopsy, some of these diagnostic findings could not be definitively identified."
"Other main diagnostic criteria **can only be assessed in living patients.**"

*Arrhythmogenic Right Ventricular Dysplasia, ERIC L. ANDERSON, LT, MC (FS), USNR, Naval Air Station Jacksonville, Jacksonville, Florida, American Family Physician, Vol. 73/No. 8 (April 15, 2006) http://www.aafp.org/afp/2006/0415/p1391.html

Global HPV Vaccine Reported Deaths

19 year old female - NZ

September 2008 - First HPV vaccination
"Developed hand warts"

November 2008 - Second HPV vaccination
"Warts returned. There were some warts under her nails which were really painful."

March 2009 - Third HPV vaccination,
"Became more agitated", "complained every so often about a weak arm and tiredness", "arm pain continued and she used to get pins and needles and tingling in her hands for no reason", "started dropping things",

April 2009 – Adverse Reaction
"Night sweats", "feeling clumsy", "knocking things over", "dropping things at work", "where in the past she'd just do it, she didn't seem to know how. It was like re-teaching a child.", "where is her decision making gone? Why can't she do simple things any more?"

July 2009 – Adverse Reaction
"Intermittently complained of chest pain and a racing heart.", "sore achy back and abdominal pain", "the warts returned"

August 2009 – Adverse Reaction
"Cold never got better", "had quite a few headaches", "skin changed...a lot more pimples than normal", "hair lanky"

September 2009 – Died in her sleep.

L-histidine , Histamine and the Heart

L-Histidine is an amino acid from which Histamine is derived. L-Histidine is an amino acid that the human body **cannot** manufacture, hence, it must be obtained from your diet. When released from mast cells, **histamine causes vasodilation** (relaxation or dilation of the blood vessel walls).

"Dr. Levi adds that it is important to put the relationship between arrhythmia and histamine in perspective. Severe arrhythmias can also result from the release of large amounts of histamine that occurs when there is a massive allergic reaction, such as anaphylaxis. This is because too much histamine stimulates the heart's H2-receptors, which tends to cause arrhythmia. In most myocardial ischemia, only a small amount of histamine is released in the heart"(1)

"In 1959, Prinzmetal et al described a syndrome of chest pain at rest secondary to myocardial ischemia associated with ST-segment elevation.[1] Exercise tolerance was characteristically normal in these individuals, who experienced a cyclical pain pattern with most episodes occurring in the early morning hours. This syndrome, known as Prinzmetal or variant angina, is due to focal coronary artery vasospasm and may be associated with acute myocardial infarction (MI), serious ventricular arrhythmias, and sudden death." (2)

(1) Weill Cornell Scientists Reveal Action of a Histamine Receptor That May Lead to New Therapies for Heart Attacks Studies with Human Cell Lines Show that Activation of the H3-Receptor Limits the Release of Arrhythmia-Causing Noradrenaline, New York-Presbyterian, NEW YORK (Dec 20, 2001) http://nyp.org/news/hospital/histamine-receptor-activation.html

(2) **Coronary Artery Vasospasm**

Author: Andrew P Selwyn, MD, MA, FACC, FRCP, Professor of Medicine, Harvard Medical School; Senior Physician and Cardiologist, Associate Chief of the Cardiovascular Division(Academic Affairs), Brigham and Women's Hospital

Coauthor(s): James L Orford, MBChB, Clinical and Research Fellow in Cardiovascular Diseases, Department of Internal Medicine, Brigham and Women's Hospital, Harvard Medical School, http://emedicine.medscape.com/article/153943-overview

Myocardial Ischemia

Myocardial ischemia develops when coronary blood flow becomes inadequate to meet myocardial oxygen demand. This causes myocardial cells to switch from aerobic to anaerobic metabolism, with a progressive impairment of metabolic, mechanical, and electrical functions. Angina pectoris is the most common clinical manifestation of myocardial ischemia. It is caused by chemical and mechanical stimulation of sensory afferent nerve endings in the coronary vessels and myocardium. These nerve fibers extend from the first to fourth thoracic spinal nerves, ascending via the spinal cord to the thalamus, and from there to the cerebral cortex.

Myocardial ischemia can result from (1) a reduction of coronary blood flow caused by fixed and/or dynamic epicardial coronary artery (i.e., conductive vessel) stenosis, (2) abnormal constriction or deficient relaxation of coronary microcirculation (ie, resistance vessels), or (3) reduced oxygen-carrying capacity of the blood. (1)

"Collectively, our findings emphasize the multiplicity of protective roles played by H_3R activation in the setting of myocardial ischemia. Because excess norepinephrine release can trigger severe arrhythmias and sudden cardiac death, negative modulation of norepinephrine release by H_3R agonists may offer a novel therapeutic approach to myocardial ischemia. " (2)

(1) Angina Pectoris
Author: Jamshid Alaeddini, MD, FACC, Clinical Cardiac Electrophysiologist, Inland Cardiology Associates
Coauthor(s): Jamshid Shirani, MD, FACC, FAHA, Consulting Staff, Director of Cardiovascular Fellowship Program, Department of Medicine, Division of Cardiology, Geisinger Medical Center, http://emedicine.medscape.com/article/150215-overview

(2) Decreased intracellular calcium mediates the histamine H_3-receptor-induced attenuation of norepinephrine exocytosis from cardiac sympathetic nerve endings, Randi B. Silver, Kumar S. Poonwasi, Nahid Seyedi, Sandy J. Wilson, Timothy W. Lovenberg, and Roberto Levi, Edited by Louis J. Ignarro, University of California School of Medicine, Los Angeles, CA, and approved November 1, 2001 (received for review September 25, 2001) , http://www.pnas.org/content/99/1/501.full

Immune System Reaction - IgE

•HPV protocol requires that the vaccine be administered as a series of three shots. This is called challenge and re-challenge.*
•The only immune response cell that is monitored is the IgG antibody which is the most common.
•The IgE antibody** is not monitored and is known to be the most damaging to the body.

What we do know

1. VAERS reports after June 2006 show that the HPV vaccines comprise 27% of all vaccine adverse events.
2. There are reports of auto-immune disease such as ALS, MS, etc.
3. Young girls and women are experiencing adverse events months to years after the initial vaccinations.
4. Immune response has been studied for at least 36 months with a slow decline in anti-bodies. Based on this, efficacy is expected to last 5 – 7 years.

* **Drug Injury, Liability, Analysis and Prevention, Second Edition, James T. O'Donnell, Pharm.D., M.S., FCP, ABCP, FACN, CNS, R.Ph.,** Chapter 10, Evaluation of Medical Causation, Donald H. Marks, M.D., Ph.D. , B. Riddell's criteria, Page 146 , **5. Re-challenge – Re-challenge** is the re-introduction of a treatment, which is then associated with the same or a similar AE, and is a good indication of causation. An AE that does not recur can signal a lack of causation, but it might also indicate that tolerance has developed. Because just the potential association of a treatment and an adverse reaction may pre-effect its re-introduction (re-administration of penicillin to a person with a history would be ill-advised, for example), it is not always possible to use a re-challenge test on a patient.

** IgE binds to basophils (a type of white blood cell) in the bloodstream and mast cells in tissues. When basophils or mast cells with IgE bound to them encounter allergens (antigens that cause allergic reactions), they release substances (such as histamine) that cause inflammation and damage surrounding tissues. Thus, IgE is the only class of antibody that often seems to do more harm than good.

Global Parental Concerns Resources

Acquired Immunity – "IgE binds to basophils (a type of white blood cell) in the bloodstream and mast cells in tissues. When basophils or mast cells with IgE bound to them encounter allergens (antigens that cause allergic reactions), they release substances (such as histamine) that cause inflammation and damage surrounding tissues. Thus, IgE is the only class of antibody that often seems to do more harm than good."
"These amounts are higher in people with asthma, hay fever, other allergic disorders…"
http://www.merck.com/mmhe/sec16/ch183/ch183c.html

"Cardiac ischemia happens when an artery leading to the heart becomes narrowed or blocked for a short time and oxygen-rich blood cannot reach your heart. In most cases of ischemia, this temporary blood shortage to the heart causes pain in the chest (called angina pectoris). In certain other cases, there is no pain. These cases are called silent ischemia." http://www.texasheart.org/HIC/Topics/Cond/Cardiomyopathy.cfm

NEW YORK (Dec 20, 2001)
"When a heart attack strikes, the nerve endings in the heart release excessive amounts of the neurotransmitter noradrenaline, leading to arrhythmias, or disturbances of the heartbeat, with sometimes fatal consequences. In a just-published article in *Proceedings of the National Academy of Sciences*, two scientists at Weill Cornell Medical College—Drs. Roberto Levi and Randi Silver—report on studies showing how the activation of a histamine receptor, the H3-receptor, limits this release of noradrenaline via two independent systems, based on the intracellular concentrations of calcium and sodium."
http://nyp.org/news/hospital/histamine-receptor-activation.html

"…the fact that the histamine system constitutes one of the most important brain-activating systems and that H3 receptors regulate the activity of histamine and other neurotransmitter systems. Furthermore, the H3 receptor shows functional constitutive activity, polymorphisms in humans and rodents with a differential distribution of splice variants in the CNS, and potential coupling to different intracellular signal transduction mechanisms."
http://www.ncbi.nlm.nih.gov/pubmed/15530639

British Heart Journal, 1979, 41, 426-432, Coronary artery vasospasm: the likely immediate cause of acute myocardial infarction - "Heberden, who first described angina, to consider it as spasmodic. In his Commentaries (1802), he emphasized the character of the attack, the relation to emotional factors, and the occurrence of chest pain at rest. '. . . the access and recess of the fit is sudden . . ., it is increased by disturbances of the mind .. . (and) its attacks are often after the first sleep.'" http://www.ncbi.nlm.nih.gov/pmc/articles/PMC482050/pdf/brheartj00206-0042.pdf

Possible role of histamine in pathogenesis of autoimmune diseases: Implications for immunotherapy with histamine-2 receptor antagonists, *Medical Hypotheses*, Volume 39, Issue 4, Pages 349-355, H. Nielsen, J. Hammer ,
http://linkinghub.elsevier.com/retrieve/pii/030698779290060Phttp://linkinghub.elsevier.com/retrieve/pii/030698779290060P

"Histamine is synthesized in all tissues, but is particularly abundant in skin, lung and gastrointestinal tract. Mast cells, which are present in many tissues, are a prominent source of histamine, but histamine is also secreted by a number of other immune cells. Mast cells have surface receptors that bind immunoglobulin E, and when antigen crosslinks IgE on the mast cell surface, they respond by secreting histamine, along with a variety of other bioactive mediators." http://www.vivo.colostate.edu/hbooks/pathphys/endocrine/otherendo/histamine.html

Histamine Receptors – "Histamine mediates numerous biological activities stimulated by various immunological and non-immunological stimuli, through differential expression of H_{1-4} on effectors's cells, such as mast cells and basophils. Histamine has a critical role in immunomodulation and allergic diseases. Other biological activities include cell proliferation, differentiation, hematopoiesis, embryonic development, regeneration, wound healing, aminergic neurotransmission, secretion of pituitary hormones and regulation of gastrointestinal and circulatory functions." http://www.tocris.com/pharmacologicalBrowser.php?ItemId=5011

Conclusion

There are several physiological issues that are responsible
for the dramatic increase in adverse event reports for the HPV vaccines.

During the follicular phase of the menstrual cycle, the production of estrogen releases histamine. During the luteal phase the protective effects of estradiol sharply decline, the production of progesterone increases and the immune system becomes more easily compromised; succumbing to the overdose of histamine from three sources: L-Histidine in the vaccine, increased amounts of estradiol in the body from natural production plus environmental toxins (estrogen mimickers) and the body's own natural production of histamine.

Both HPV vaccines are VLP's (virus like particles). This can be termed 'molecular mimicry' and when an antigen in a vaccine is structurally similar to an antigen in the host antibodies are produced that react with the host's normal tissue.

Allergy sufferers with moderate to severe asthma have IgE levels greater than 1,000 U/ml. Normal serum IgE levels in individuals without allergies is less than 70 U/ml. An increase in IgE means more free IgE is available for binding to the activated mast cells. More mast cell activation and degranulation may lead to an increased release of inflammatory histamine. This reaction also leads to TH2 cytokine and leukotriene secretion, resulting in systemic anaphylaxis in the form of allergy.

This proves an increased risk of injury due to an overload of histamine being released from the mast cells causing a more severe inflammatory response throughout the body. Tissue damage due to this process can cause hypertrophy of smooth muscles. Smooth muscles are evident in the heart. With the rechallenge to an already active immune response we could have more smooth muscle damage especially to the heart and Central Nervous System.

With all our research completed, due to the lack of safety testing in regards to hormone, histamine and IgE level effects due to challenge and rechallenge on the female and male physiology the risks of the HPV vaccines outweigh the benefits.

Webinar Outcome

On behalf of the parents around the world we are asking that more studies be conducted on Gardasil and Cervarix before the vaccines are administered to more healthy, innocent young women and men.

1. Safety study of participants in regards to irregular pap tests and cervical lesions 2 - 4 years post-vaccination and to be performed by independent entity

2. Review of "new medical conditions" to see if they are resolved or intensified 3 - 4 years post-vaccination and to be performed by independent entity

3. Study on fertility of individuals reporting adverse events

4. Implementation of Menstrual Cycle Evaluation and Guidelines for vaccine administration for women between menarche and menopause

5. Implementation of additional guidelines to the approval process to include hormone, IgE and histamine levels to prove safety of product

THE TRUTH ABOUT GARDASIL

Our daughters are in danger

WWW.TRUTHABOUTGARDASIL.ORG

This website was created by mothers of Gardasil victims. It is dedicated to the lives who have been lost and/or altered by this vaccine.