

GLOBAL CONCERNS ABOUT HPV VACCINES FACT SHEET

- When detected, HPV infection is easily managed and rarely proceeds to cancer
- Very few women with HPV develop cervical cancer
- HPV infections are only one of several risk factors for cervical cancer
- At least 50% of sexually active men and women acquire genital HPV infection at some point in their lives 90% of the time the virus clears up on its own within two years without incident
- Centers for Disease Control and Prevention (CDC) records show 3,976 women died from cervical cancer in the U.S. in 2006.
- American Cancer Society lists cervical cancer as the 12th leading cause of carcinoma related deaths
- HPV Vaccine efficacy duration is at the maximum 5 to 6 years. Symptoms of girls adversely injured are lasting as long as the vaccine.
- Non cancerous types of HPV: 6 & 11
- Cancerous types: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 69, 73, 82
- Pap testing has reduced cervical cancer risk by 74% over the last 40 years

FACT:

The finding of HPV viral DNA integrated in most cellular genomes of cervical carcinomas supports epidemiologic data linking this agent to cervical cancer however, direct causation has not been demonstrated.

Cervical Cancer Prevention, Health Professional Version' National Cancer Institute (NCI) <u>http://www.cancer.gov/cancertopics/pdq/prevention/cervical/healthprofessional/allpages</u>

FACT:

While there are well-established cancer registries in the United States, it will take decades before the impact of vaccine on cervical cancer is observed. More proximal measures of vaccine impact include outcomes such as prevalence of HPV vaccine types, incidence of cervical pre-cancers and genital warts.

Post-licensure monitoring of HPV vaccine in the United States, Centers for Disease Control and Prevention, <u>Vaccine</u>. 2010 Jul 5;28 (30):4731-7. Epub 2010 Feb 25, <u>http://www.ncbi.nlm.nih.gov/pubmed/20188681</u>

FACT:

It is estimated that 25,000,000 women may have been previously exposed to HPV

CDC extrapolation of population figures for that age group multiplied by the percentage of infected (potentially)

FACT:

If a woman who has been exposed to vaccine-relevant HPV submits to HPV vaccination, her risk of developing precancerous lesions may increase by:

44.6% - post Gardasil® Vaccination

32.5% - post Cervarix[®] Vaccination

May 2006 VRBPAC Report -

http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4222B3.pdf

FACT:

In the September 2008, FDA Closing Statement on Gardasil it was noted that 73.3% of girls in the clinical trials developed "new medical conditions" post vaccination. 17 girls died during the clinical trials.

September 2008 FDA Closing Statement on Gardasil http://holyhormones.com/wp content/uploads/downloads/2010/11/gardasil091108.pdf

FACT:

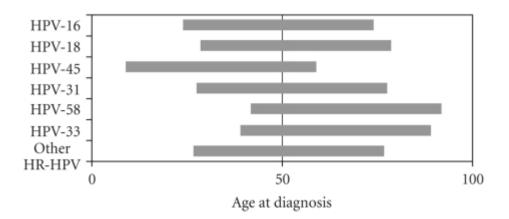
The current type-specific HPV vaccines have claimed to be almost 100% effective against infection by HPV-16 and HPV-18, and perhaps also against HPV-31 and HPV-45 infections. However, we do not know if these four HPV types are the most prevalent carcinogenic HPV genotypes in the US. According to two published reports – one by the CDC, HPV-52 not HPV-16 or HPV-18 was found to be the most prevalent "carcinogenic" genotype infecting young American women.

It is not transient HPV infections, but a persistent high-risk HPV infection that may initiate cervical cancer... Therefore, it is the persistent infection, not the virus that determines cervical cancer risk.

Dr. Sin Hang Lee -Pathologist, Milford Hospital Director, Milford Medical Laboratory, Milford, CT

FACT:

Chart below indicates that HPV 16 & 18 does not even appear in a studied population of Columbian women until their mid 20's – long after the initial efficacy of the vaccine has worn off.



HPV prevalence in Colombian women with cervical cancer: implications for vaccination in a developing country, <u>Infect Dis Obstet Gynecol.</u> 2009;2009:653598. Epub 2009 Dec 20, <u>http://www.ncbi.nlm.nih.gov/pubmed/20052389</u>

FACT:

The vaccine does not protect against infection from several other HPV subtypes, and it is no better than placebo in clearing already existing infection...

Dr. John T. Schiller Ph.D., Principal Investigator, Laboratory of Cellular Oncology, Division of Basic Sciences, National Cancer Institute, National Institutes of Health

FACT:

• **HPV Prevalence:** HPV tests currently available to American medical consumers generate both false positive and false negative reports. (See this report for verification.) Unless a test is approved for general use that uses HPV short-targeting DNA sequencing (See reliable genotyping), HPV prevalence cannot be accurately monitored to determine vaccine efficacy.

- **Precancerous lesions:** In the natural history of cervical cancer development only a small fraction of the CIN 2 lesions will progress to CIN 3 lesions; and only a small fraction of CIN 3 lesions will progress to cervical cancer. Theoretically, you cannot have cervical cancer without first having various grades of cervical intraepithelial neoplasia (CIN). However, when most of these lesions reverse on their own, it is hardly an accurate way to determine efficacy of a 'cancer' vaccine.
- **Genital Warts:** There are few reports of the rates of genital warts in the United States prior to 2000. The current statistical reports are primarily gathered from STD clinics in larger cities throughout the United States. These are then extrapolated to estimate the rates for the rest of the country. With no accurate baseline to compare to, genital warts are not an adequate judge of vaccine efficacy either.
- **Pap Tests:** There is only one proven, safe, effective method for controlling cervical cancer. Screening via regular gynecologic examinations and cytologic test (Papanicolaou smear) with treatment of precancerous abnormalities decreases the incidence and mortality of cervical cancer.

FACT:

Screening is not beneficial in detecting invasive cancer in women younger than 25 years because of the low prevalence of invasive disease, and the harms outweigh the benefits. Screening is not beneficial in women older than 60 years if they have had a history of recent negative tests.

Cervical Cancer Prevention, Health Professional Version, published by the National Cancer Institute (NCI) http://www.cancer.gov/cancertopics/pdq/prevention/cervical/healthprofessional/allpages

FACT:

GARDASIL VACCINATION: EVALUATING THE RISKS VERSUS BENEFITS

The efficacy of Gardasil in preventing cervical cancer has not been demonstrated and the marketing campaign has been misleading. The efficacy of Gardasil remains unsubstantiated since the vaccine hasn't been adequately tested on the primary age group to which it is currently given.

Merck promoted Gardasil primarily as a vaccine against cervical cancer, rather than promoting it as a vaccine against HPV infection or sexually transmitted diseases

"Most genital infections are asymptomatic and resolve spontaneously, but the virus can persist and cause precancerous lesions that can become malignant over the subsequent 20-30 years." Nature Biotechnology, 2007

"So how should a parent, physician, politician, or anyone else decide whether it is a good thing to give young girls a vaccine that partly prevents infection caused by a sexually transmitted disease (HPV infection), an infection that in a few cases will cause cancer 20 to 40 years from now?" JAMA, 2009

> Lucija Tomljenovic, PhD, University of British Columbia http://sanevax.org/news-blog/?p=1353

Vaccine Adverse Event Reporting System - VAERS HPV 4 Gardasil[®] – HPV 2 Cervarix[®] June 2006 – December 2010 -- Numbers reflect 1 to 10% of vaccinated population reporting

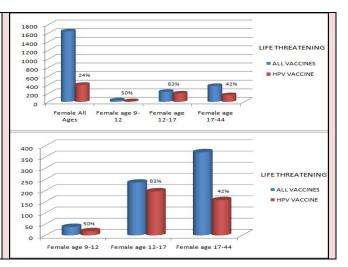
| Event | Total | Female | Male | Unknown |
|-----------------------------------|--------|--------|------|---------|
| Reports | 21,282 | 20,510 | 324 | 448 |
| Deaths | 93 | 77 | 2 | 14 |
| Abnormal Pap Results | 376 | 376 | N/A | N/A |
| Life-Threatening | 411 | 400 | 8 | 3 |
| ER Visit | 8,661 | 8,490 | 93 | 78 |
| Hospitalized | 2,118 | 2,079 | 27 | 12 |
| Did Not Recover | 4,382 | 4,308 | 37 | 37 |
| Disabled | 702 | 695 | 3 | 4 |
| Abortions/Spontaneous Stillbirths | 252 | 252 | N/A | N/A |
| Anogenital Warts | 106 | 106 | N/A | N/A |
| Papillomavirus Infections | 222 | 222 | N/A | N/A |
| Cervical Cancer | 29 | 29 | N/A | N/A |

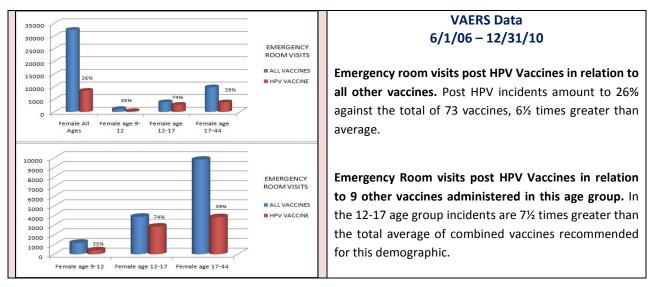
VAERS data from January 1 to February 25, 2011 now reports 21,634 adverse injuries; 94 deaths; 41 reports of cervical cancer – a significant increase in 6 weeks.

VAERS DATA 6/1/06 - 12/31/10

Life threatening incidents post HPV Vaccines in relation to all other vaccines. Post HPV incidents amount to 24% against the total of 73 vaccines, 6 times greater than average.

Life threatening incidents post HPV Vaccines in relation to 9 other vaccines administered in this age group. In the 12-17 age group incidents are 8 times greater than the total average of combined vaccines recommended for this demographic.

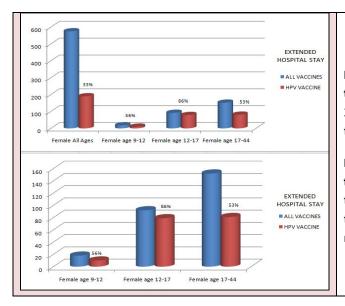


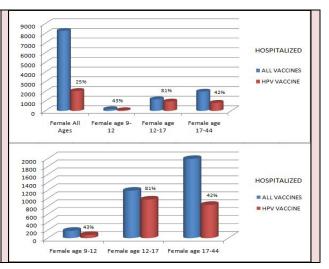


VAERS Data 6/1/06 - 12/31/10

Hospitalizations post HPV Vaccines in relation to all other vaccines. Post HPV incidents amount to 25% against the total of 73 vaccines, 6 times greater than the average.

Hospitalizations post HPV Vaccines in relation to 9 other vaccines administered in this age group. In the 12-17 age group incidents are 8 times greater than the total average of combined vaccines recommended for this demographic.





VAERS DATA 6/1/06 - 12/31/10

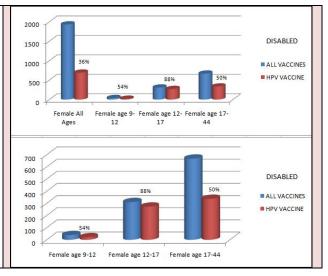
Extended hospital stay post HPV Vaccines in relation to all other vaccines. Post HPV incidents amount to 33% against the total of 73 vaccines, 8 times greater than average.

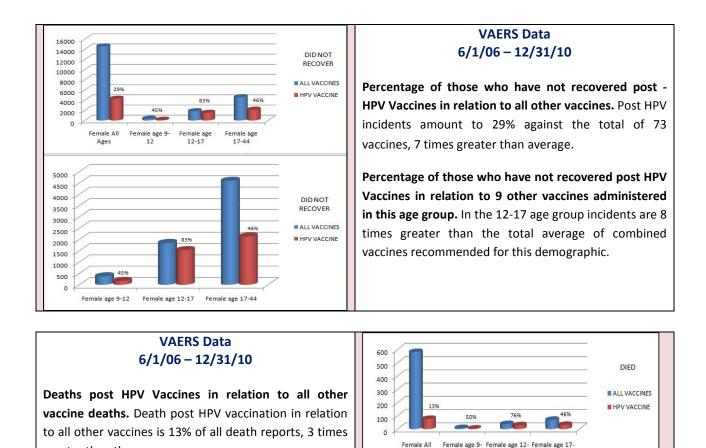
Extended hospital stay post HPV Vaccines in relation to 9 other vaccines administered in this age group. In the 12-17 age group incidents are 8½ times greater than the total average of combined vaccines recommended for this demographic.

VAERS Data 6/1/06 - 12/31/10

Disabling events post HPV Vaccines in relation to all other vaccines. Post HPV incidents amount to 36% against the total of 73 vaccines, 9 times greater than average.

Disabling events post HPV Vaccines in relation to 9 other vaccines administered in this age group. In the 12-17 age group incidents are 9 times greater than the total average of combined vaccines recommended for this age demographic.





Ages

50%

Female age 9-12

70

60

50

40

30

20

10

12

Female age 12-17

17

44

46%

Female age 17-44

DIED

ALL VACCINES

HPV VACCINE

Deaths post HPV Vaccines in relation to 9 other vaccines administered in this age group. In the 12-17 age group deaths are 7½ times greater than the total average of combined vaccines recommended for this demographic.



greater than the average.

GARDASIL VACCINATION: EVALUATING THE RISKS VERSUS BENEFITS

Cervical cancer is a rare disease in developed countries which invalidates the recommendations for universal immunization with any HPV vaccine. The incidence of cervical cancer has dropped substantially since implementation of regular Pap screening procedures. Currently, in the US, the death rate from cervical cancer (2.4/100,000 women) is lower than the rate of reported serious adverse events, including death, from Gardasil (3.34/100,000 doses distributed).

Lucija Tomljenovic, PhD, University of British Columbia http://sanevax.org/news-blog/?p=1353

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