



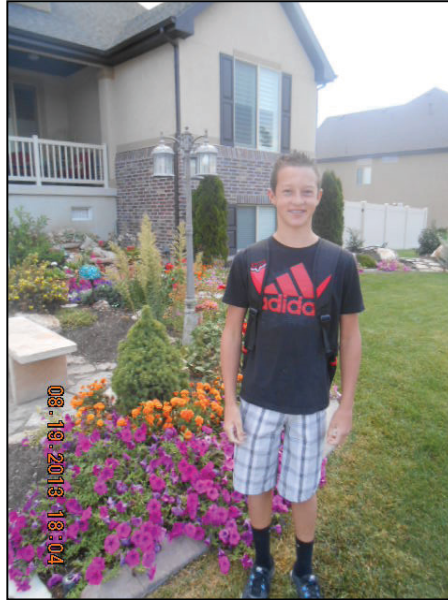
In Chapter 15, we learn about Alexis Wolf, who suffered permanent, serious neurological injury after HPV vaccination. These are before and after photos.

In 2010, Chris Tarsell died shortly after her third Gardasil shot. In Chapter 15, we learn how Emily Tarsell, Chris's mother, took the case through the Vaccine Injury Compensation Program, which determined that Gardasil vaccination likely caused Chris's death.





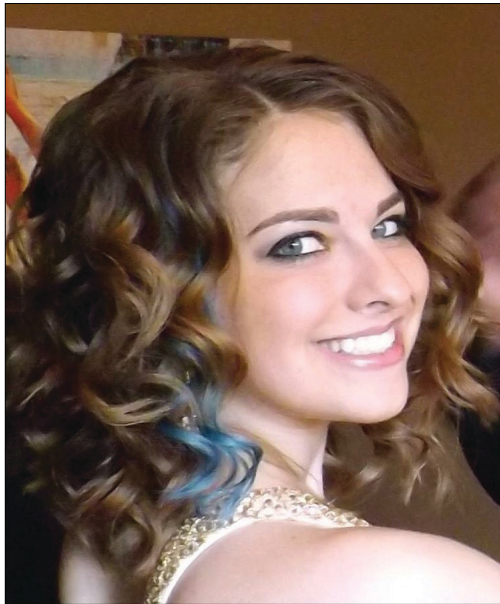
As we discuss in Chapter 15, Chris Tarsell was a talented young artist. Above is one of her paintings.



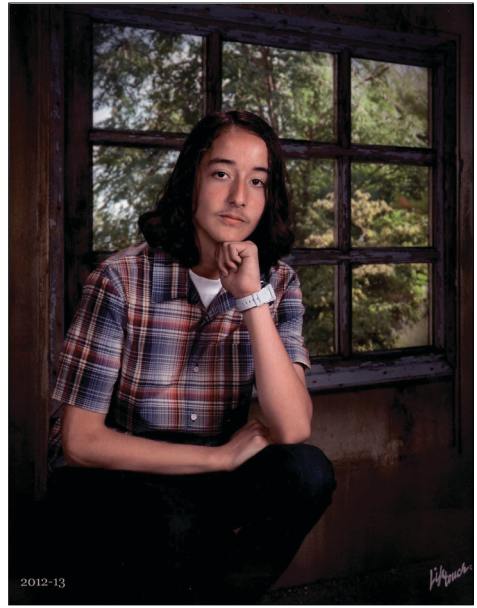
Colton Berrett had a reaction within two weeks of his third Gardasil shot in 2013. He became paralyzed and dependent on a ventilator 24/7. Colton took his own life in 2018, shortly before his 18th birthday. His story is in Chapter 15.



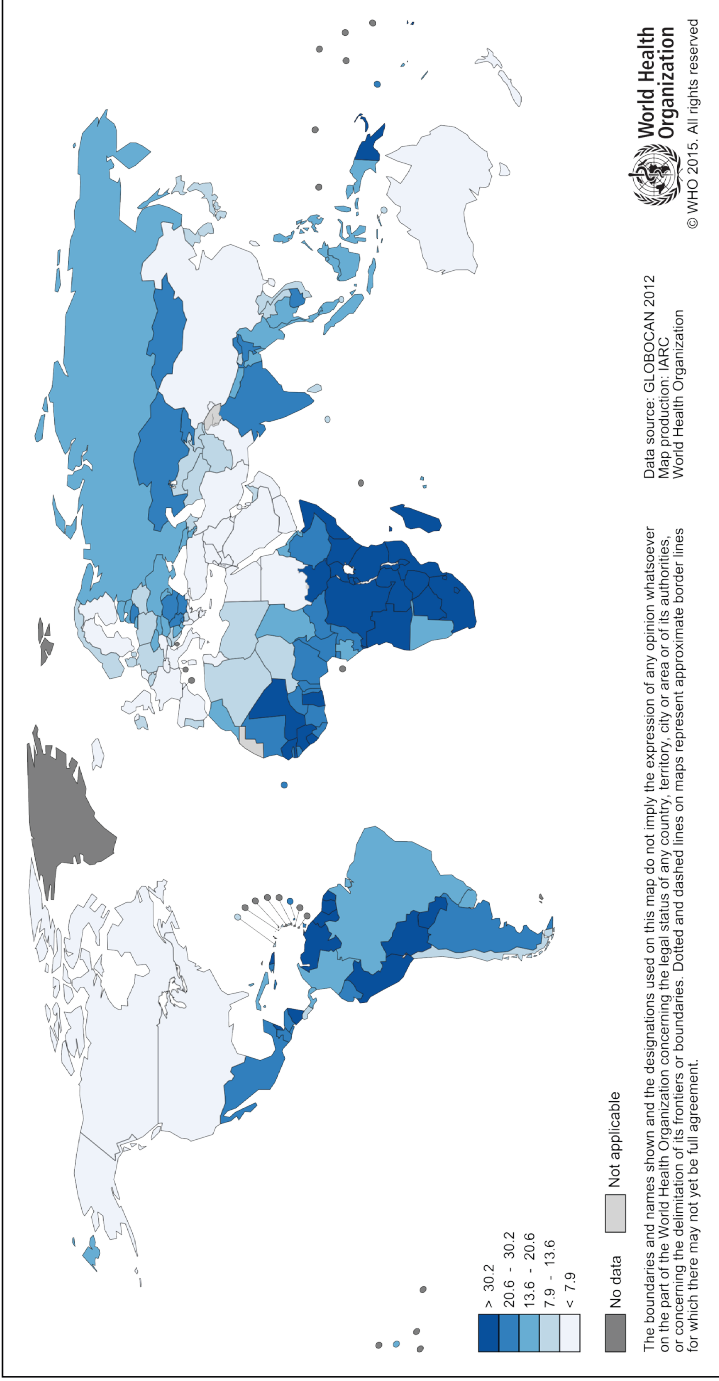




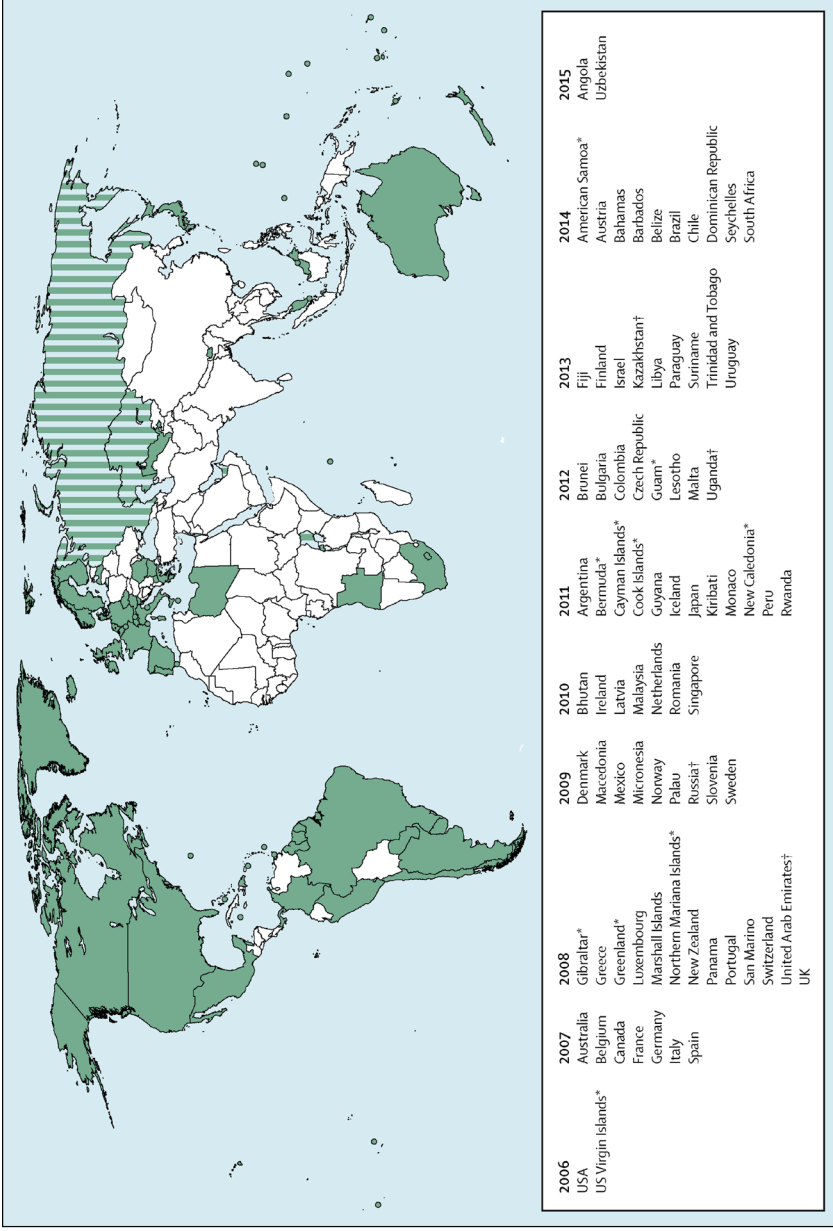
We learn in Chapter 15 of the painful shock Maddie's family suffered when she took her own life, unable to endure the silent pain of her lasting adverse effects from HPV vaccination.



Joel Gomez died within hours of receiving his second Gardasil dose. In Chapter 15, we delve into the case Joel's parents brought to the Vaccine Injury Compensation Program for his death.



The incidence of cervical cancer predominantly affects low resource countries. We explore the many factors influencing cervical cancer incidence in Chapter 4.
 (Source: <http://globocan.iarc.fr/old/FactSheets/cancers/cervix-new.asp>)



Cervical cancer incidence is rare in high resource countries, as we discuss in Chapter 4. Despite low incidence in these countries, HPV vaccine producers market there aggressively, as indicated by the green shading above. (Source: The Lancet, "Global estimates of human papillomavirus vaccination coverage by region and income level: a pooled analysis," [https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(16\)30099-7/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(16)30099-7/fulltext); license agreement: <https://creativecommons.org/licenses/by/4.0/>.)

As we learn in Chapters 13 and 14, the CDC strongly promotes the HPV vaccine. The US government earns substantial royalties from sales, as we analyze in Chapter 3.

**If there were a
vaccine against
cancer, wouldn't
you get it for
your kids?**

**HPV vaccine is
cancer prevention.
Talk to the doctor
about vaccinating
your 11–12 year old
sons and daughters
against HPV.**

www.cdc.gov/vaccines/teens



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention



Distributed by:

HPV Vaccination

can **prevent** an estimated

28,500 new cancers per year.

That's more than the average attendance at one of the largest pop concert tours of last year.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

CS267091

HPV vaccination is the best way to **PREVENT** many types of **CANCER**.

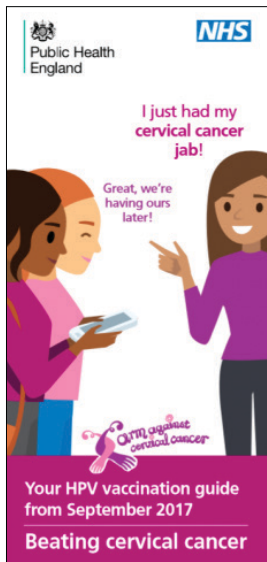
HPV vaccination is **RECOMMENDED** at ages 11 or 12.

HPV vaccination is **REDUCING** HPV DISEASE.

3 THINGS PARENTS
SHOULD KNOW **ABOUT**
PREVENTING CANCER

www.cdc.gov/vaccines/teens





The UK has one of the highest uptake rates of HPV vaccines in the world. In Chapter 27, we examine how UK direct marketing to school children may explain why.

The National HPV Vaccination Program

Males and females aged **12-13** can get the vaccine for **free** at school.



They must return a **signed consent form** to their school.

Males and females need **three doses** of the HPV vaccine for best protection.



If a dose is missed, talk with your **school or GP** about a catch up.

Boasting one of the HPV vaccine co-inventors, Australia was one of the first countries to approve the vaccine. We discuss the vaccine's invention in Chapter 3 and Australia's role in it. Australian children receive HPV vaccines in school, as we discuss in Chapter 18.

GARDASIL
[Human Papillomavirus Quadrivalent
(Types 6, 11, 16, and 18) Vaccine, Recombinant]

Your **SON** or **DAUGHTER** could be **one less** person affected by HPV disease.

PARENTS:
Why GARDASIL for your son or daughter?
[Find Out](#)

This is a Merck ad for Gardasil, using the signature tag line “Be One Less,” which we discuss in Chapter 13.

HPV facts every parent should know.

- Approximately 14 million people will become newly infected with human papillomavirus (HPV) each year.¹
- For most people, HPV clears on its own. But, for others who don't clear the virus, it could cause certain precancers, cancers, and other diseases later in life (such as cervical or anal cancer). Your child may not be at risk for HPV now, but the risk may increase as they get older.
- Talk to your child's doctor about the potential risks of HPV. **Schedule an appointment today.**

Facts about HPV.

What is HPV?
HPV (short for human papillomavirus) is a virus that can cause certain cancers and diseases in both males and females later in life.

Signs and symptoms
Because HPV often has no visible signs or symptoms, many people who have the virus don't even know it.

What can parents do?
Protection starts with knowing the facts. Now that you're armed with more information, talk to your child's doctor.

Talk to your child's doctor about HPV vaccination.

Most preventive services are covered at \$0 out of pocket when you visit a network doctor.*

Don't have a network doctor? Visit provider search on myuhc.com.

*Certain preventive care services are provided as specified by the Patient Protection and Affordable Care Act (PPACA), with no cost-sharing to you. Some plans may require copayments, deductibles and/or coinsurance for these benefits. Always refer to your plan documents for specific benefit coverage and limitations or call the toll-free member phone number on your health plan ID card.
Reference: 1. Centers for Disease Control and Prevention (CDC). Human papillomavirus. In: Hamborsky J, Kroger A, Wolfe C, eds. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. 13th ed. Washington DC: Public Health Foundation; 2015: 175–186.

Merck markets HPV vaccines to parents and children alike. This 2018 flyer from an insurance company urges parents to vaccinate their preteenage children. We discuss marketing in Chapters 13 and 14.



Parents in Ireland (top) and Colombia (bottom), literally continents apart, took to the streets to protest government neglect in the face of severe HPV vaccine injuries. In Chapters 26 and 28, we discuss what happened in these two different countries. Girls suffered the same adverse reactions, yet their injuries were labeled “psychosomatic,” and the girls and their families were branded “antivaccine.” We discuss the marginalization of injury in Chapter 15.

FUTURE 2

er navnet på en stor international undersøgelse af en vaccine til forebyggelse af celleforandringer og livmoderhalskræft. FUTURE 2 står for Females United to Unilaterally Reduce Endo/Ectocervical Disease.

Tavshedspligt og personbeskyttelse

Undersøgelsen er godkendt af Datatilsynet, Videnskabetisk Komité og Lægemiddelstyrelsen. Vi har tavshedspligt, og alle data og svar bliver behandlet fortroligt.

FUTURE 2 er IKKE et bivirkningsstudie

Vaccinen er allerede grundigt testet og har ingen bivirkninger, bortset fra hvad du ellers vil opleve med andre vacciner: Let rødmen og ømhed, hvor du er blevet stukket.

**FUTURE 2 is NOT a side effect study.
The vaccine has already been thoroughly tested and has no side effects, except what you would otherwise experience with other vaccines - light redness and soreness where you have been injected.**

fakta

Source: Excerpt from “Future 2” study recruitment brochure sent to all female 18–23 year-olds in Denmark, 2002.³

How is the study

conducted in practice?

Investigations last for a total of 4 years.

Some get the vaccine, and others receive a placebo preparation (saline).

Who gets what is random and neither you nor the doctor who vaccinates you, know if you get the vaccine or not.

er nogen kendt risiko ved vaccinen.

Hvordan foregår undersøgelsen i praksis?

- Undersøgelsen varer i alt 4 år. Nogle får vaccinen, og andre får et placebo-præparat (saltvand). Hvem, der får hvad, er tilfældigt, og hverken du eller den læge, der vaccinerer dig, ved, om du får vaccinen eller ej.
- Det første år bliver du vaccineret tre gange (en indsprøjtning med en lille tynd kanyl). Ved undersøgelsens start, får du derudover lavet en gynækologisk undersøgelse, får taget en blodprøve, en urinprøve og bliver interviewet om tidligere sygdomme og forskellige livsstilsvaner (herunder seksualvaner).

Source: Excerpt from “FUTURE 2” study recruitment brochure sent to 18–23-year-old women in Denmark, 2002.⁵

Common Types of Cancer	Estimated New Cases 2018	Estimated Deaths 2018
1. Breast Cancer (Female)	266,120	40,920
2. Lung and Bronchus Cancer	234,030	154,050
3. Prostate Cancer	164,690	29,430
4. Colorectal Cancer	140,250	50,630
5. Melanoma of the Skin	91,270	9,320
6. Bladder Cancer	81,190	17,240
7. Non-Hodgkin Lymphoma	74,680	19,910
8. Kidney and Renal Pelvis Cancer	65,340	14,970
9. Uterine Cancer	63,230	11,350
10. Leukemia	60,300	24,370
-	-	-
20. Cervical Cancer	13,240	4,170

Cervical cancer represents 0.8% of all new cancer cases in the U.S.



Source: National Cancer Institute, SEER Cancer Statistics Review¹⁰

PHAS	PROTOCOL	LOCATIONS	POPULATION(s)	FORMULATION(s)	VACCINE RECIPIENTS n=enrolled	CONTROL	CONTROL RECIPIENTS n=enrolled	Dates of Study
PHASE IIb	V501-007	23 sites 5 countries	16-23 yo women	20/40/40/20 & 225 mcg AAHS/0.5ml	290	AAHS: 225 mcg/0.5ml 450 mcg/0.5ml	146 146	5/26/00-5/10/04
				40/40/40/40 & 225 mcg AAHS/0.5ml	284			
				80/80/40/80 & 395 mcg AAHS/0.5ml	292			
PHASE III	V501-013* (FUTURE I)	62 sites 16 countries	16-23 yo women	20/40/40/20 & 225 mcg AAHS/0.5ml	2723	225 mcg AAHS/0/5ml	2732	12/28/01-7/15/05 (& follow up)
	V501-015 (FUTURE II)	90 sites 14 countries	16-23 yo women (26 yo in Singapore)	20/40/40/20 & 225 mcg AAHS/0.5ml	6087	225 mcg AAHS/0/5ml	6080	6/24/02-6/10/05 (& follow up)
	V501-016	61 sites 19 countries	9-15 yo boys and girls 16-23 yo women	20/40/40/20 & 225 mcg AAHS/0.5ml	506 (10-15 yo girls) 510 (10-15 yo boys) 513 (16+ women)	none	none	12/7/02-9/20/04
				12/24/24/12 & 225 mcg AAHS/0.5ml	252 (10-15 yo girls) 256 (16+ women)			
				8/16/16/8 & 225 mcg AAHS/0.5ml	255 (10-15 yo girls) 259 (16+ women)			
			4/8/8/4 & 225 mcg AAHS/0.5ml	252 (10-15 yo girls) 252 (16+ women)				
V501-018	47 sites 10 countries	9-15 yo boys and girls	20/40/40/20 & 112.5 mcg AAHS/0.5ml	616 girls 568 boys	Carrier Solution/0.5ml	322 girls 275 boys	10/8/03-1/19/05 (& follow up)	

Source: Authors, based on data cited in endnotes 19 and 21.

- f. Individuals allergic to any vaccine component, including aluminum, yeast, or BENZONASE™ (nuclease, Nycomed [used to remove residual nucleic acids from this and other vaccines]).

*Source: FUTURE II Protocol, V501-015, Protocol/Amendment
No. 015-00, at 32.²⁶*

Hvad omfatter undersøgelsen?

Der forventes at deltage i alt 11500 kvinder i undersøgelsen, som foregår både i USA, Sydamerika og Europa, herunder i alle de nordiske lande.

I Danmark vil der deltage ca. 1750 kvinder i alderen 18-23 år. Den ene halvdel af deltagerne får den aktive vaccine, mens den anden halvdel får såkaldt placebo vaccine (dvs. en vaccine uden virksomt stof). Det afgøres ved lodtrækning, hvilken en gruppe den enkelte deltager kommer i. Undersøgelsen er "dobbelt-blind", dvs. at hverken du eller den læge der vaccinerer dig, vil vide om du modtager aktiv eller inaktiv vaccine.

Undersøgelsen varer i alt 4 år. I løbet af det første år vil du blive vaccineret 3 gange med enten den aktive eller den inaktive vaccine (ved undersøgelsens start, efter 2 måneder og efter 6 måneder). Udover dette skal du komme til undersøgelse 7 måneder efter forsøgets start og herefter 1 gang årligt. Ved alle besøg, bortset fra besøgene 2 og 6 måneder efter start, vil du få foretaget en gynækologisk undersøgelse samt få taget en blodprøve og en urinprøve. Urinprøverne vil blive undersøgt for bl.a. klamydia- og gonorré-infektion. Ved det første besøg vil du blive interviewet om livsstilsvaner og tidligere sygdom.

Side 2 af 8

V501/015-00, Informeret samtykke og fuldmagt, version 1, 22APR2002

Source: Danish Cancer Society.²⁹

Nogle har oplevet følgende almindelige bivirkninger:

Feber, hovedpine, svimmelhed, kvalme og trætheds-/svaghedsfornemmelse.

Saline

Det vides endnu ikke om ovennævnte bivirkninger skyldes placebo (saltvand) eller aktiv behandling, da data endnu ikke er blevet afblindet.

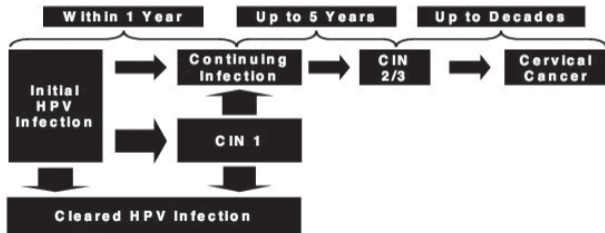
Under behandling med aktiv vaccine eller placebo er der set følgende alvorlige bivirkninger: Et tilfælde af åndedrætsbesvær; et tilfælde af forringet ledbevægelse med smerter; et tilfælde hovedpine, feber og kulderystelser; et tilfælde af hovedpine og forhøjet blodtryk samt et tilfælde af en overfølsomhedsreaktion.

Source: Authors' files.

MERCK'S SUBMISSION TO FDA ON HPV PROGRESSION

Figure 1

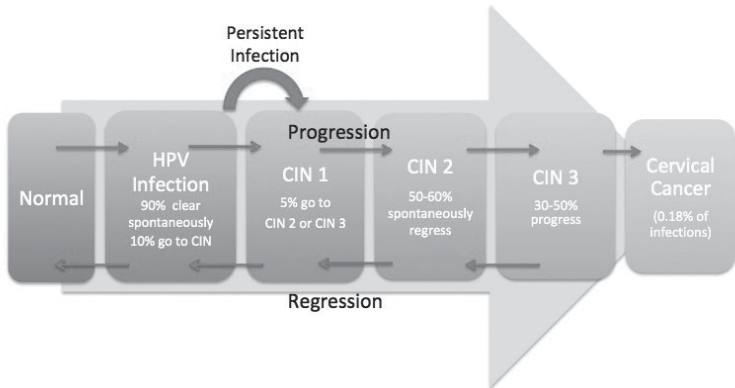
Natural History of Infection With High-Risk HPV Types (Such as HPV 16 and HPV 18)



CIN = Cervical intraepithelial neoplasia; HPV = Human papillomavirus.

Source: Merck April 19, 2006 VRBPAC final briefing document.⁷

Natural Progression of HPV Infection



Source: Authors;⁸
see endnote 8 for details.

Table 5: Common Systemic Adverse Reactions in Girls and Women 9 Through 26 Years of Age (GARDASIL ≥ Control)*

Adverse Reactions (1 to 15 Days Postvaccination)	GARDASIL (N = 5088) %	AAHS Control† or Saline Placebo (N = 3790) %

Source: Gardasil Package Insert, at 6 (Table 5).²⁶

TABLE 229
Protocol 018: Clinical Adverse Experience
Summary Days 1-15 Postvaccination – Protocol 018 (Overall)

	HPV vaccine group N=1179	Placebo group N=594
Subjects with follow-up	1165	584
N (%) with 1+ AE	963 (82.7%)	392 (67.1%)
N (%) with IS AE	877 (75.3%)	292 (50.0%)
N (%) with systemic AE	541 (46.4%)	260 (44.5%)
N (%) with SAE	5 (0.4%)	0 (0.0%)
Deaths	0	0
D/C due to AE	3 (0.3%)	0(0.0%)
D/C due to SAE	1 (0.1%)	0 (0.0%)

Source: From Table 8-1, CSR 018v1, p. 140

Source: FDA 2006 Gardasil Clinical Review, at 316 (Table 229)
 (emphasis added).²⁸

TABLE 295
Protocols 007, 013, 015, 016, and 018: Clinical Adverse Experience Summary
(Days 1 to 15 after any Vaccination Visit) -
Safety Population (Cumulative Data)

	Gardasil N=11778	Placebo N=9686
Subjects with Follow-up	11641	9578
	N/%	N/%
Subjects with > 1 AE	5729 (49.2%)	3659 (38.2%)
Injection Site AEs	5195 (44.6%)	3049 (31.8%)
Systemic AEs	3750 (32.2%)	2571 (26.8%)
Subjects with SAEs	59 (0.5%)	43 (0.4%)
Deaths	3 (0.03%)	1 (0.01%)
Discontinued due to AE	15 (0.1%)	10 (0.1%)
Discontinued due to SAE	4 (0.03%)	3 (0.03%)

Source: Source: Summary of Clinical Safety, Table 2.7.4:4, p. 29 (3/8/06)

Source: FDA 2006 Gardasil Clinical Review, at 378 (Table 295)
*(emphasis added).*³¹

TABLE 210
Protocol 018: Vaccine Products Used

225 mcg of AAHS
 per mL = 112.5
 mcg per 0.5 mL

Clinical Material	Formulation Number	Dosage	Package and Storage
Quadrivalent HPV (Types 6, 11, 16, 18) L1 VLP Vaccine	V501 VAI025T004	40/80/80/40 mcg plus 225 mcg aluminum adjuvant /mL 0.5 mL	0.75-mL single dose vial
Placebo for Quadrivalent HPV (Types 6, 11, 16, 18) L1 VLP Vaccine	PV501 VAI036P001	Carrier Solution Only /0.5 mL	0.75-mL single dose vial

HPV = Human papillomavirus; VLP = Virus-like particles.

Source: FDA 2006 Gardasil Clinical Review, at 301 (Table 210) (emphasis and text box added).³

Products Mandated by Protocol

TABLE 26

Protocol 015: Clinical Products Used

Clinical Material	Formulation Lot Information	Dosage	Package
Initial Enrollment Period			
Quadrivalent HPV 6, 11, 16, 18 L1 VLP Vaccines	V501 VAI018I001, V501 VAI025T001, V501 VAI025T002.	HPV 6, 11, 16, 18 L1 VLP 20/40/40/20 mcg with 225 mcg aluminum adjuvant/0.5 mL	0.75 mL single dose vial
Placebo	PV501 VAI019A001	225 mcg aluminum adjuvant/0.5 mL	cc

Source: Excerpted from Table 26, 2006 FDA Gardasil Clinical Review, at 50. (Emphasis added by authors.)⁴

TABLE 245**Protocol 018: New Medical Conditions Day 1 through Month 12**

Subjects in analysis population	Gardasil N=1128	Placebo N=562
Subjects with new medical history	327 (29.0%)	174 (31.0%)

Source: Excerpted from Table 245, 2006 FDA Gardasil Clinical Review, at 329 (emphasis added).¹²

TABLE 302**Protocols 007, 013, 015, 016 and 018:
New Medical Conditions Day 1 through Month 7 in the
Safety Population**

Subjects in analysis population	Gardasil N=11778	Placebo N=9686
Subjects with new medical history	5842 (49.6%)	4750 (49%)

Source: Excerpted from Table 302, 2006 FDA Gardasil Clinical Review, at 393 (emphasis added).¹³

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]

Endpoint	Gardasil™ N=2717				Placebo N=2725				Observed Efficacy	95% CI
	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		
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%

Negative Efficacy: Gardasil

Source May 2006 VRBPAC Background Document, at 13 (Table 17)

(emphasis added).²

(nb: PCR positive means a positive HPV DNA test result, suggesting current infection; seropositive means testing positive for HPV antibodies in the blood, suggesting a prior exposure.)

Similarly, women who either had a current infection and/or a prior exposure for relevant types showed negative efficacy of -33.7 percent compared to the controls:³

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.]

Endpoint	Gardasil™ N=2717				Placebo N=2725				Observed Efficacy	95% CI
	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		
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%

May 2006 VRBPAC Background Document, at 14 (Table 19)

(emphasis added).⁴

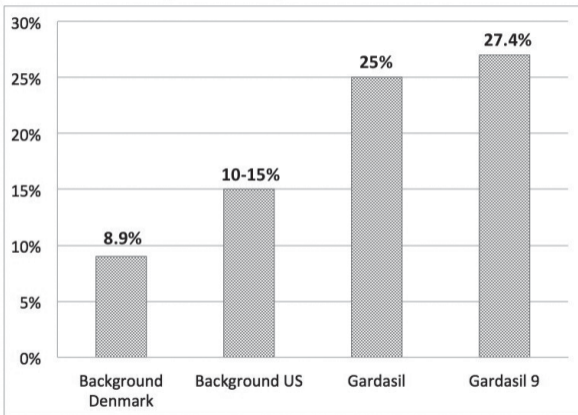
Negative Efficacy: Cervarix

Table 136-Study HPV-008: Incidence rates and vaccine efficacy against CIN2+ associated with HPV-16 and/or HPV-18 (by PCR) in HPV DNA positive and seropositive subjects at baseline with normal or low-grade cytology at baseline, using conditional exact method (Subset of TVC-1)

Event Type	Group	N	n	T (year)	Person-year rate (n/T) per 100 [96.1% CI]	VE % [96.1% CI]
HPV 16/18	HPV	315	43	821.95	5.23 [3.72, 7.15]	-32.5% [-123.1, 20.4%]
	HAV	290	31	784.99	3.95 [2.63, 5.70]	-
HPV 16	HPV	244	39	630.50	6.19 [4.32, 8.58]	-31.2% [-127.8, 23.1%]
	HAV	218	28	594.97	4.71 [3.06, 6.92]	-
HPV 18	HPV	82	4	222.49	1.80 [0.45, 4.77]	-48.1 [-1019.1, 77.0%]
	HAV	91	3	247.10	1.21 [0.23, 3.69]	-

2009 FDA Cervarix Clinical Review, at 218 (Table 136) (emphasis added).⁷

Rate of spontaneous miscarriage in young women age 20-24 in the clinical trials compared to background rates in the US and Denmark.

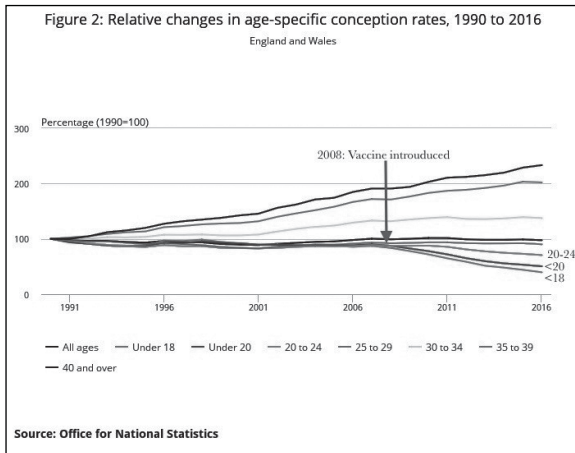


*Source: Authors—see details in endnote and text above.*⁶

Table 35. Distribution of congenital anomaly cases. [From March 8, 2006 safety update submitted to BLA, table 2.7.4:26.]

	Gardasil™	Placebo
Congenital anomaly infant or fetus	15	16
EDC within 30 days	5	0
EDC beyond 30 days	10	16

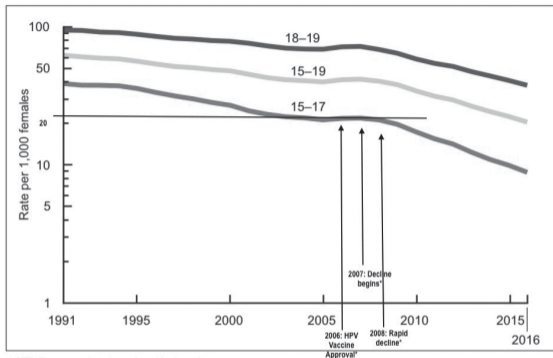
Source: May 2006 VRBPAC Background Document, at 24 (Table 35).²⁰



Source: Office for National Statistics UK Conception Statistics 2016

* Authors inserted vertical line and labels.⁴⁰

Figure 1. Birth rates for females aged 15–19, by age group: United States, final 1991–2015 and provisional 2016



NOTE: Rates are plotted on a logarithmic scale.
SOURCE: NCHS, National Vital Statistics System.

Source: NCHS, National Vital Statistics System, Natality Brief No. 002, June 2017 *Authors inserted vertical lines and labels.⁴⁴

TABLE 302

Protocols 007, 013, 015, 016 and 018: New Medical Conditions Day 1 through Month 7 in the Safety Population

Subjects in analysis population	Gardasil N=11778	Placebo N=9686
Subjects with new medical history	5842 (49.6%)	4750 (49%)

Source: Excerpted from Table 302, 2006 FDA Gardasil Clinical Review, at 393 (emphasis added).¹²

TABLE 303
Protocols 007, 013, 015, 016 and 018:
New Medical Conditions after Month 7 in the
Safety Population

Subjects in analysis population	Gardasil N=10452	Placebo N=9385
Subjects with new medical history	5178 (49.5%)	4883 (52.0%)

Source: Excerpted from Table 303, 2006 FDA Gardasil Clinical Review, at 395 (emphasis added).¹⁴

(Authors' Note: "Placebo" = AAHS adjuvant, sodium borate, polysorbate 80, and L-histidine. A small portion of the "placebo" group was from Protocol 018 and received a nonaluminum placebo, which included sodium borate, polysorbate 80, and L-histidine.)

Table 9: Summary of Girls and Women 9 Through 26 Years of Age Who Reported an Incident Condition Potentially Indicative of a Systemic Autoimmune Disorder After Enrollment in Clinical Trials of GARDASIL, Regardless of Causality

Conditions	GARDASIL (N = 10,706)	AAHS Control* or Saline Placebo (N = 9412)
	n (%)	n (%)
Arthralgia/Arthritis/Arthropathy [†]	120 (1.1)	98 (1.0)
Autoimmune Thyroiditis	4 (0.0)	1 (0.0)
Celiac Disease	10 (0.1)	6 (0.1)
Diabetes Mellitus Insulin-dependent	2 (0.0)	2 (0.0)
Erythema Nodosum	2 (0.0)	4 (0.0)
Hyperthyroidism [‡]	27 (0.3)	21 (0.2)
Hypothyroidism [§]	35 (0.3)	38 (0.4)
Inflammatory Bowel Disease [¶]	7 (0.1)	10 (0.1)
Multiple Sclerosis	2 (0.0)	4 (0.0)
Nephritis [#]	2 (0.0)	5 (0.1)
Optic Neuritis	2 (0.0)	0 (0.0)
Pigmentation Disorder [ⓑ]	4 (0.0)	3 (0.0)
Psoriasis [ⓑ]	13 (0.1)	15 (0.2)
Raynaud's Phenomenon	3 (0.0)	4 (0.0)
Rheumatoid Arthritis [ⓐ]	6 (0.1)	2 (0.0)
Scleroderma/Morphea	2 (0.0)	1 (0.0)
Stevens-Johnson Syndrome	1 (0.0)	0 (0.0)
Systemic Lupus Erythematosus	1 (0.0)	3 (0.0)
Uveitis	3 (0.0)	1 (0.0)
All Conditions	245 (2.3)	218 (2.3)

*AAHS Control = Amorphous Aluminum Hydroxyphosphate Sulfate

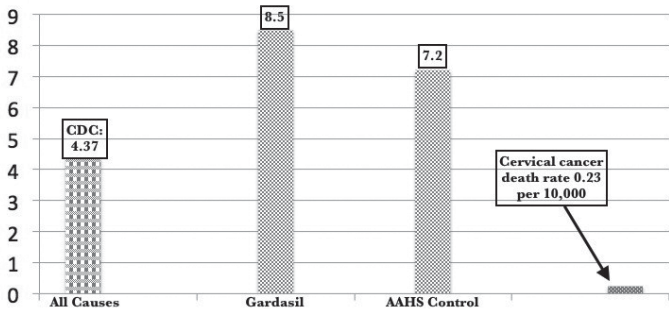
Source: Gardasil package insert (emphasis added).¹⁷

**Listing of Cases of Acute Leukemia
(V503 – P001 and P002 Studies)**

Vaccine group	Allocation Number	Country	Race	Diagnosis	Age at Enrollment	Time of Onset	Age at Diagnosis
Protocol V503-001							
9vHPV	██████	Colombia	Multi-racial	Acute promyelocytic leukemia	█	1285 days post-dose 3	█
9vHPV	██████	Colombia	Multi-racial	Acute lymphoblastic leukemia	█	27 days post-dose 3	█
qHPV	██████	Canada	White	Acute lymphocytic leukemia	█	1279 days post-dose 3	█
Protocol V503-002							
9vHPV	██████	Colombia	Multi-racial	Acute leukemia	█	482 days post-dose 3	█
9vHPV	██████	United States	White	Acute myeloid leukemia	█	705 days post-dose 3	█

Source: Table–Assessment of the responses to the CHMP list of questions, Nov 25, 2014.²⁹

**Age adjusted Incidence of death
per 10,000 girls age 15-26**



*Background CDC rate 4.37, source: National Vital Statistics Report Vol. 53
2002 page 24.³⁸*

*Gardasil rate 8.5: 10/11,778. AAHS control rate 7.2: 7/9,680³⁹
Cervical cancer mortality: 2.3 per 100,000, source: National Cancer
Institute SEER Cancer Statistics Review 2015⁴⁰*

Deaths in the Clinical Trials

	N	Gardasil Deaths	N	AAHS Control Deaths
2006 Approval Data (Protocols 007, 013, 015, 016, 018)	11778	10 (0.08%)	9680	7 (0.07%)
Additional deaths reported*		1		1
Protocol 019	1908	7 (0.37%)	1907	1 (0.05%)
Protocol 020	2020	3 (0.15%)	2030	10 (0.49%)
All Protocols	15706	21 (0.13%)	13617	19 (0.14%)

* Miller, et al., 2008 Table 43: One death in Gardasil group (Protocol 013) and one death in non-alum control (Protocol 018).

Source: Authors, see endnotes.⁴⁶

The Vaccine Adverse Event Reporting System (VAERS) Results

Request Form Results Map Chart Report About

Dataset Documentation Other Data Access Help for Results Printing Tips Help with Exports Save Export Reset

Quick Options More Options Top Notes Citation Query Criteria

Messages:
▶ These results are for 57,620 total events.

Event Category ↓	⇒ Events Reported ↕	⇐ Percent (of 57,620) ↕
Death	420	0.73%
Life Threatening	922	1.60%
Permanent Disability	2,682	4.65%
Congenital Anomaly / Birth Defect *	3	0.01%
Hospitalized	5,751	9.98%
Existing Hospitalization Prolonged	430	0.75%
Emergency Room / Office Visit **	15,303	26.56%
Emergency Room *	246	0.43%
Office Visit *	598	1.04%
None of the above	36,518	63.38%
Total	62,873	109.12%

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).
* These values are only available from VAERS 2.0 Report Form, active 06/30/2017 to present.
** These value are only available from VAERS-1 Report Form, active 07/01/1990 to 06/29/2017.

Source: CDC Wonder Database VAERS⁶¹

Decisions from the US National Vaccine Injury Compensation Program for Injuries and Deaths from HPV Vaccination

Petitioner	Year	Medical Condition	Type of Compensation	Compensation
D. Angell	2016	Seborrheic dermatitis	joint stipulation	\$225,000
Rosalinda Cruz	2013	Limbic encephalitis	joint stipulation	\$200,000
Shermian Daniel, MD	2016	Multiple sclerosis (MS), Aggravated acute demyelinating encephalomyelitis (ADEM)	joint stipulation	\$350,000
Cory Danielson	2016	Pancreatitis	joint stipulation	\$95,000
Bailey Day	2017	Neuromyelitis optica	proffer	\$1.53 million

Angela Disanto	2015	Encephalitis	joint stipulation	\$135,000
Jane Doe 89	2010	MS	joint stipulation	\$500,000
Jessica Ericzon	2015	Death	joint stipulation	\$200,000
Joel Gomez	2016	Death	joint stipulation	\$200,000
V. Huerta	2014	Complex Regional Pain Syndrome	proffer	\$162,000
Susan Ibarra	2011	Death	joint stipulation	\$240,000
Brittney LeClair	2011	ADEM, Transverse Myelitis	joint stipulation	\$150,000
Kevin Lopez	2012	ADEM, Guillain-Barré syndrome (GBS)	joint stipulation	\$1.23 mil.
A. McCulloch	2016	Limbic encephalitis	proffer	\$1.47 mil.
Megan Morgan	2016	Ulcerative colitis	proffer	\$800,000
A. Olund	2014	GBS	joint stipulation	\$185,000
Amanda Ratner	2013	Macrophagic myofasciitis	joint stipulation	\$350,000
Sherry Salmins	2015	GBS	proffer	\$1.4 mil.
Karen Stark	2013	Syncope, head trauma	joint stipulation	\$175,000
Christina Tarsell	2017	Death	adjudicated concession of the maximum death award	\$250,000

[GB] Danger. May damage fertility. May damage the unborn child. Obtain special instructions before use. IF exposed or concerned: Get medical advice/attention. Borax is raw material with wide variety of uses. It is a component of many detergents, cosmetics, and enamel glazes. In cosmetics use with beeswax to form an emulsifier in water-in-oil emulsions. This emulsification system works well in water-in-oil type emulsions where the ratio of water to oil is small.



Source: see note 34 above.

Format: Abstract ▾

Send to ▾

Vaccine. 2016 Jan 9. pii: S0264-410X(16)00016-5. doi: 10.1016/j.vaccine.2015.12.067. [Epub ahead of print]

WITHDRAWN: Behavioral abnormalities in young female mice following administration of aluminum adjuvants and the human papillomavirus (HPV) vaccine Gardasil.

Inbar R¹, Weiss R², Tomljenovic L³, Arango MT⁴, Dori Y⁵, Shaw CA⁶, Chapman J⁷, Blank M⁵, Schoenfeld Y⁸.

Author information

Abstract

This article has been withdrawn at the request of the Editor-in-Chief due to serious concerns regarding the scientific soundness of the article. Review by the Editor-in-Chief and evaluation by outside experts, confirmed that the methodology is seriously flawed, and the claims that the article makes are unjustified. As an international peer-reviewed journal we believe it is our duty to withdraw the article from further circulation, and to notify the community of this issue. The full Elsevier Policy on Article Withdrawal can be found at <http://www.elsevier.com/locate/Withdrawalpolicy>.

Comment in

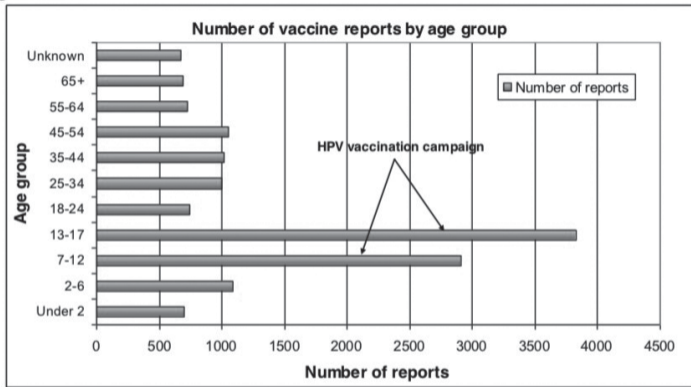
Canadian researchers whose studies questioned vaccine safety face second retraction. [BMJ. 2017]

PMID: 26778424 DOI: [10.1016/j.vaccine.2015.12.067](https://doi.org/10.1016/j.vaccine.2015.12.067)



Source: PubMed, see note 27.

Figure 5.2.3



Source: MHRA UK, Trends in UK Spontaneous Adverse Drug Reaction (ADR) Between 2008–2012.⁴²

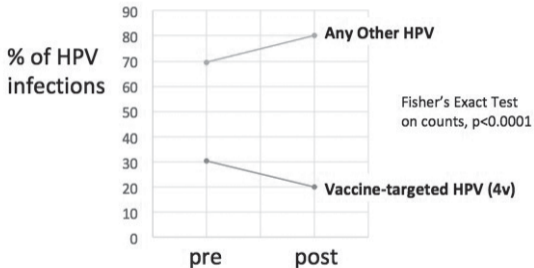
Vaccine Brand	Total number of reports	Number of serious reports (% of total)
Cervarix	6,312	1,812 (29%)
Gardasil	1,858	767 (41%)
Gardasil 9	10	6 (60%)
HPV Brand unspecified	658	456 (69%)
Total for Human Papilloma virus vaccines	8,835*	3,038 (34%)

Source: MHRA sentinel database for adverse reactions.

Note that the total number of reports received will not be equal to the totals in the table above as some reports of suspected adverse reactions may have included more than one vaccine.

Source: see note 45.

Markowitz LE et al., 2016
Prevalence of HPV After Introduction of the Vaccination Program in the United States. *Pediatrics*. 2016 Feb 22. pii: peds.2015-1968.



IPAK

March 22, 2018

Source: Institute for Pure and Applied Knowledge, see note 75 above.