

THE HPV VACCINE
WEIGHING
THE RISKS

What is HPV and do the vaccines prevent HPV-associated cancers?



Empower
Yourself
With
Knowledge



PERK

Protection of the
Educational Rights of Kids

Weighing the Risks



Background on the HPV Vaccines

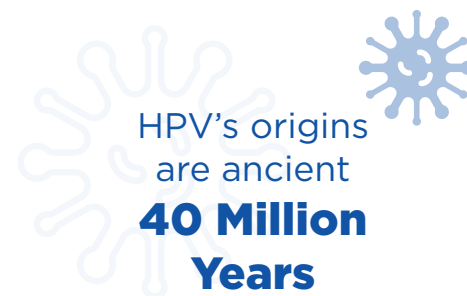
Gardasil 9 was preceded by Gardasil, Cerverix voluntarily withdrawn in 2016

- Gardasil 9 is indicated for prevention of these cancers: cervical, vulvar, vaginal, oropharyngeal, anal, other head/neck cancers

<https://www.fda.gov/vaccines-blood-biologics/vaccines/gardasil-9>

FDA Approved HPV Vaccines (Recombinant)

Product		HPV Types Targeted
Gardasil 9	Merck - approved 2014	nonavalent: 16, 18, 31, 33, 45, 52, 58
Gardasil	Merck - approved 2006	quadrivalent: 6, 11, 16, 18
Cervarix	GSK - approved 2009	bivalent: 16, 18



- All approved HPV vaccines are recombinant DNA technology-viral DNA is spliced with genetically modified yeast, inducing the yeast's cellular machinery to produce viral proteins
- These purified proteins need an **adjuvant** in order to promote a sufficiently strong immune response-for Gardasil, this adjuvant is AHHS (Amorphous Aluminum Hydroxyphosphate Sulfate)
- The vaccine induces the production of antibodies, which is claimed to be an indication of immunity; however, **antibodies do not equal immunity** > see Infosheet #1 "More Than Antibodies" <https://ipak-edu.org/information-sheets/>

What went wrong with the clinical trials?

Fast-tracked, no true placebo studies, safety in doubt

- Gardasil received fast-track FDA approval, allowing for surrogate endpoints, which are not guaranteed indicators of how well a treatment works-it's a stand-in to shorten clinical trials
- Contrary to good safety trial design, Gardasil was **not tested against a true placebo**; instead, a small subset of the control groups in the trials received a 'fauxcebo', and the rest received a solution of AHHS adjuvant <https://www.fda.gov/media/74350/download>



What is a Fauxcebo?

A false placebo-not inert, not saline.

In the Gardasil clinical trials, Merck used a 'carrier solution' instead of saline. This solution was not inert and likely contained toxic components. Inert placebos are irreplaceable for assessing the safety and effects of a vaccine or its ingredients.

Read more about use of placebos in vaccine trials:

https://apps.who.int/iris/bitstream/handle/10665/94056/9789241506250_eng.pdf

- Clinical trials for Gardasil 9 used the previous version of the product, Gardasil, as a surrogate for a true placebo which may have masked safety signals

<https://www.fda.gov/media/90064/download>

Do the vaccines prevent HPV-associated cancers?

Prevention of HPV-associated cancer has not been adequately demonstrated

- Cancer prevention was **not studied in clinical trials** which were the basis for FDA approval
- There are no scientific studies demonstrating prevention of HPV-associated cancer
- The Gardasil package insert states: "Gardasil has not been demonstrated to prevent HPV-related CIN 2/3 or worse in women older than 26 years of age." <https://www.fda.gov/media/74350/download>
- Potential for negative efficacy: women with a prior or current HPV infection who are then vaccinated may have enhanced risk for disease [https://zenodo.org/record/1434214 \(Tables 17 + 19\)](https://zenodo.org/record/1434214/Tables/17+19)

- While cervical cancer attributed to HPV types 16+18 has gone down, other types have risen this is a phenomenon called 'Type Replacement'

What is **Type Replacement**?

While cervical cancer attributed to HPV types 16+18 has gone down, other types have risen-this is a phenomenon called Type Replacement

- In countries that have taken on the HPV vaccine, the rarer types of HPV have increased in prevalence as the vaccine target types have decreased
- In the same countries, the rates of cervical cancer have increased in the younger, vaccinating populations.
- The reports of data showing reduction in HPV-associated cancer is biased: it emphasizes rates of vaccine-targeted

<https://doi.org/10.3892/ol.2016.4668>, <https://doi.org/10.1080/21645515.2015.1066948>,
<https://doi.org/10.1093/aje/kwu038>

- Cancer usually has a long onset and incubation period, so long-term studies are needed-these have not been done.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5691619/>

What are the risks associated with the HPV Vaccine?

Autoimmune conditions, neurological disease, reproductive harm, and death

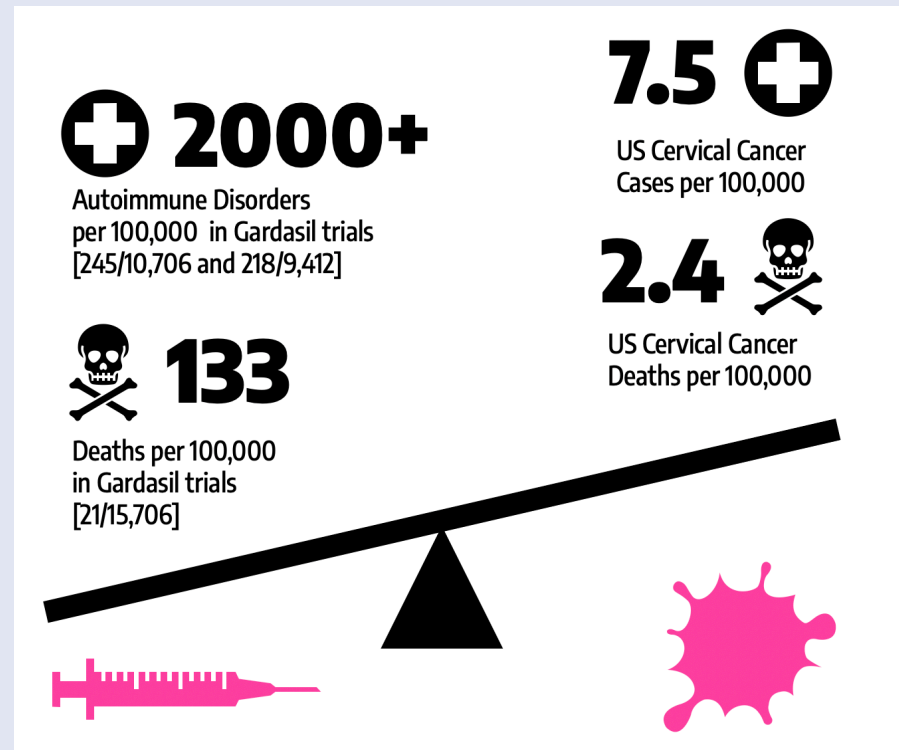
- **The Gardasil 9 package insert lists short-term potential adverse reactions**, such as: fever, nausea, fainting, and anaphylaxis; but follow-up in trials was limited to 15 days
<https://bit.ly/41oDp3e>
- **The Gardasil trials reported nearly half of all subjects developed "new medical conditions" following vaccination, but only 2% were reported on the package insert**
https://www.impfkritik.de/download/gardasil_fda_464_pages.pdf
- **The rate of serious adverse reactions following vaccination in the Gardasil clinical trials is estimated to be 814.9/100,000** (128/15,706 participants, data from the Gardasil package insert)
- **Scientific papers have revealed a range of serious health conditions after HPV vaccination:**
 - POTS (Postural Orthostatic Tachycardia Syndrome)
<https://doi.org/10.1016/j.vaccine.2015.03.098>

90+%
of cases are cleared by the Immune system

- GBS (Guillain-Barré Syndrome)
<https://doi.org/10.1016/j.vaccine.2017.06.030>
- ME/ CFS (Myalgic Encephalomyelitis / Chronic Fatigue Syndrome)
<https://doi.org/10.1016/i.iaut.2022.102921>
- Premature Ovarian Insufficiency
<https://doi.org/10.1038/s41598-020-67668-1>
- Premature Ovarian Failure
<https://doi.org/10.1177%2F2324709614556129>
- Menstrual Irregularity and Premature Menopause
[10.1007/s40801-021-00271-6](https://doi.org/10.1007/s40801-021-00271-6)
- **Life-changing autoimmune conditions have been documented**, including: Bechet's Syndrome, Raynaud's Disease, Type 1 Diabetes, Hashimoto's Thyroiditis, Addison's Disease, Celiac Disease, Lupus Erythematosus, Encephalitis, Myelitis <https://doi.org/10.1111/joim.12694>
- **The death rate in the clinical trials greatly exceeds that of the deadliest cancers**

THE HPV VACCINE Weighing the Risks

Vaccine Risk vs Cancer Risk



Data: Gardasil Package Insert <https://bit.ly/41oDp3e>
 CDC Cancer Statistics <https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/>

WHAT DO We Know About HPV



What is HPV?

HPV is a virus that infects skin and mucous membranes

- HPV, or Human Papilloma Virus, is a DNA virus, like herpesvirus. By contrast, the coronavirus is an RNA virus, like influenza
- **Human papillomaviruses are very common and widespread**, ancient with hundreds of varieties, or types, that have been identified
- **HPV is endemic** - as long as there are humans, there will be HPV - **HPV cannot be eradicated with vaccines**
- Humans are the only known natural reservoir for HPV
- HPV co-evolved with humans, pre-dating neanderthals and homo sapiens
<https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1007352>

What do we know about HPV infection?

HPV infection is very common and usually cleared by the immune system

- HPV is transmitted through intimate skin-to-skin contact, most commonly through sexual activities <https://www.cdc.gov/vaccines/pubs/pinkbook/hpv.html#epidemiology>
- **Nearly all sexually active people are infected** within a few months or years of becoming active <https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-and-cancer>
- Most HPV infections are asymptomatic-infected people do not know they have it
- **For 90% of cases, the immune system destroys and clears**
<https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-and-cancer>
- Persistent infections (higher risk) are uncommon <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3059725/>
- Some types, like HPV 6 and 11 cause warts, but are not associated with cancer

What does HPV have to do with cancer?

A very small group of HPV types are associated with cancer

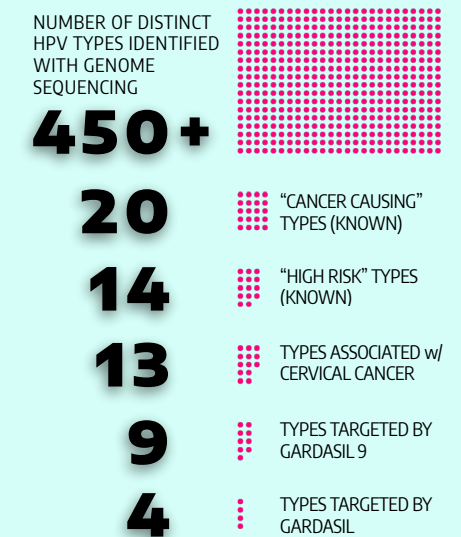
- An HPV-associated cancer is diagnosed in parts of the body where HPV is found
- The CDC claims that HPV “probably” causes 79% of all HPV-associated cancers
- The CDC claims 91% of cervical cancer cases are “probably caused” by a type of HPV
<https://www.cdc.gov/cancer/hpv/statistics/cases.htm>
- **HPV infection is a cancer risk factor, but cancer causation is multi-factorial, complex, and nearly impossible to reduce to a single factor.** Risks for cervical cancer include age (over 55+), obesity, smoking, poor nutrition, long-term use of oral contraceptives, and a weakened immune system
<https://www.cancer.org/cancer/cervical-cancer/causes-prevention/risk-factors.html>
- The HPV types widely recognized as onconogenic, or cancer-promoting (that are known, so far), are: Types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, and 59.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5597740/>

What do statistics say about HPV-associated cancer risk?

HPV Cancer risk is quite low-the public receives mixed messages

- The most common HPV-associated cancer affects the cervix, and ranks 20th in the US for prevalence
- **Cervical cancer is rare**, 0.7% of all new cancer cases-the true risk may be misunderstood by the public
<https://seer.cancer.gov/statfacts/html/cervix.html>
- Risk of getting cervical cancer is around 0.0075%; Risk of death is approximately 0.0024%
- Median age at diagnosis is 50 yrs; new diagnoses are frequently between 35-44 yrs
- Cervical cancer is rare in developed countries-because outcomes are tied to income and access to resources
<https://acsiournals.onlinelibrarywiley.com/doi/10.1111/1471-2547.15660>

How many varieties of HPV are there?



<https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1007352>
<https://www.nature.com/articles/s41579-021-00617-5>
<https://dceg.cancer.gov/research/cancer-types/cervix/hpv-viral-genomics>

Cancer Rates Compared - Cases/Deaths

Rank	2019 US Data	Cases	Deaths
1	Breast	129.7 / 100,000	19.4 / 100,000
2	Prostate	111.6 / 100,000	18.4 / 100,000
3	Lung	48.1 / 100,000	28.1 / 100,000
4	Colon	31.8 / 100,000	10.8 / 100,000
10	Pancreas	11.6 / 100,000	9.6 / 100,000
20	Cervical	7.5 / 100,000	2.4 / 100,000

<https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/>

Cervical Cancer - Perspective

2019-20 Data	Cases	Deaths
Global (2020)	15.1 / 100,000	8.5 / 100,000
USA (2019)	7.5 / 100,000	2.4 / 100,000

<https://www.who.int/news-room/fact-sheets/detail/cervical-cancer>
<https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/>

Cervical Intraepithelial Neoplasia Grades

Grade	Description	Estimated Cancer Progression Risk
CIN 1	Mild - often resolves on its own	< 1%
CIN 2	Moderate - may need treatment	5%
CIN 3	Severe - requires treatment	12%

<https://pubmed.ncbi.nlm.nih.gov/8463044/>

How effective is cancer screening?

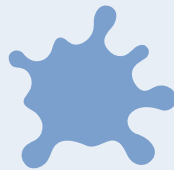
With regular testing, early diagnosis and treatment is highly effective

- Screening typically involves a Pap test, which looks for cervical dysplasia (abnormal cells on the surface of the cervix); **Pap testing works - it reduces cervical cancer incidence** and mortality by as much as 80%, especially for advanced stage cancers <https://pubmed.ncbi.nlm.nih.gov/19638651/>
- Current PCR screening has built-in false positive results; it can detect presence or pieces of the virus, but cannot on its own indicate disease; <https://pubmed.ncbi.nlm.nih.gov/31029852/>
- Another name for cervical dysplasia is Cervical Intraepithelial Dysplasia, or CIN for short
- Only a few persistent infections advance to CIN 2 or 3 and transition to cancer is often long, 20+ years, so in most cases, there is ample time to intervene <https://academic.ouo.com/aie/article/178/7/11611211254>
- **Pap tests are highly effective, but testing has declined in the post-vaccine era—yet, only regular screening prevents cervical cancer** <https://pubmed.ncbi.nlm.nih.gov/20670593/>



<5%

of known HPV types are the be cancer-causing



Cervical cancer is less than

<1%

of new cancer cases



Regular Pap testing can reduce cancer and death by as much as

80%

of new cancer cases



For more **IPAK-EDU information sheets** use QR code.

Takeaway

Vaccination Should Be an Informed Choice Based on Actual Risks and Proven Benefits