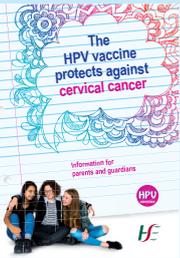


FACT CHECK ABOUT HPV VACCINE AND CERVICAL CANCER

Dear Parents and Guardians, the HSE leaflet that accompanies the consent form for the HPV vaccine makes a number of statements designed to alleviate your concerns over the safety of the HPV vaccine. This document examines these statements for accuracy against available official and verifiable referenced data.

WHO ARE WE?

IFICA is the International Federation for Injured Children and Adults, a new international organisation based in Ireland. Our members include parents, doctors, scientists and patient organisations from all over the world. We represent those adversely affected by the HPV vaccine and wish to foster dialogue, compassion and understanding by all stakeholders, both public and private.

HSE Document	Claim	Fact Check
<p>“Information for parents and guardians” glossy brochure, front</p> 	<p>“The HPV vaccine protects against cervical cancer”</p>	<p>This unqualified statement of efficacy is not true.</p> <p>The following information is taken directly from the Patient Information Leaflet (PIL) written by the vaccine manufacturer, Merck.</p> <ol style="list-style-type: none"> 1. Vaccination with Gardasil is intended to protect against diseases caused by Human Papillomavirus (HPV) types 6, 11, 16, and 18. (Gardasil Package Leaflet).¹ 2. It does not protect against all cervical cancers 3. The length of time for which the vaccine is effective is not known at this time.
<p>“Facts about HPV and Cervical Cancer” leaflet, P2</p> 	<p>“Ongoing analysis has shown that there is no scientific evidence linking HPV vaccines to any long-term medical condition”</p>	<p>According to the manufacturer Merck, 3.3% of trial participants have suffered ‘systemic autoimmune disorders’ after Gardasil. These are long-term effects.²</p> <p>Independent studies into HPV vaccines have shown autoimmune issues and chronic illnesses have occurred after vaccination.³</p> <p>In court proceedings, the HPV vaccine has been identified as the cause of numerous deaths, including in the USA and Spain. ⁴</p>
<p>“Information for parents and guardians” glossy brochure, P3</p>	<p>Under <u>Who should not receive HPV vaccine?</u> It states that only girls who “have had a very severe reaction to a previous HPV vaccine” or “are pregnant” should be exempt.</p>	<p>The adverse events monitoring agency, the Health Products Regulatory Authority (HPRA), advises that as yeast is used in its production process, those with yeast allergies should not have the vaccine.⁵ This advice is not included in the leaflet.</p> <p>The HPRA – whose function includes monitoring adverse reactions to medicines – also stated on RTÉ that those with asthma are more likely to suffer a serious adverse reaction. The Merck PIL states that anyone with a systemic autoimmune disorder should seek medical advice before receiving the vaccine⁶.</p> <p>The school pack does not disclose the Merck trial finding that pre-exposure to the HPV virus significantly increased the risk of cervical cancer for vaccine recipients⁷:</p> <p>“... injection of HPV vaccines into women who have concurrent [our emphasis] vaccine-relevant HPV type infections may increase the risk, by 44.6%, of developing high-grade precancerous lesions in the cervix. Therefore, it would be prudent to perform a sensitive HPV detection assay with accurate genotype determination on the patients to be vaccinated if prior HPV infection is suspected.”</p> <p>Though tests exist for both yeast allergy and HPV pre-exposure, they are not currently available to parents.</p>

HSE Document

Claim

Fact Check

“Facts about HPV and Cervical Cancer” A4 leaflet, P1



Under HPV vaccine side effects, it is stated that “severe allergic reactions with difficulty breathing are very rare (about 1 in 1 million).” It follows with a list of other mild, acute side effects.

The HPRAs has already recorded 12 cases of anaphylaxis, a rate of 1 in 21,000.

The serious side effects listed in the Merck PIL and in the Merck research data are not listed in the HSE information^{8, 9, 10}

The adverse effects recorded on the HPRAs database mirror the side effect listed in the manufacturer PIL.

There are over 1,000 reports of side effects on the HPRAs system, with over 300 unresolved. 60% of these reported adverse events have been classified as serious.¹¹

“Information for parents and guardians” glossy brochure, P2

Under Does the vaccine work? it is stated “Yes. In Australia, Sweden and Finland the vaccine has prevented up to 3 in every 4 pre-cancers.”

In **Australia**¹² and **Sweden**¹³, there has been an increase in cervical cancer rates **amongst the vaccinated population**. Respective governmental statistics below show this. In 2007 (before the vaccine was introduced) the age 0-29 population had an incident rate of 3.7 per 100,000¹⁴ in. In 2018, it is 9.9 per 100,000 in the age group 25-29. This includes the vaccinated population and indicates that there is cervical cancer in a population where it did not exist before.

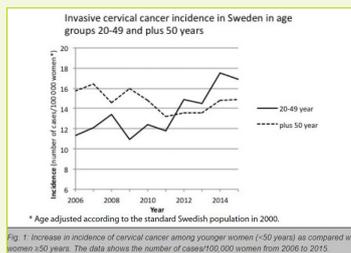
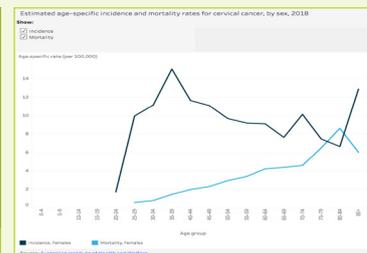
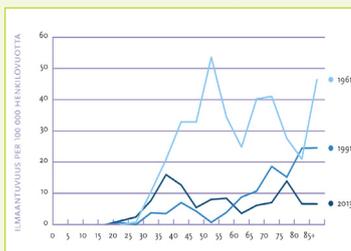


Fig. 1. Increase in incidence of cervical cancer among younger women (<50 years) as compared with women ≥50 years. The data shows the number of cases/100,000 women from 2006 to 2015.



Claims by the HSE that **Finland** have seen a reduction in cervical cancer due to the HPV vaccine are misleading. The Finnish Cancer Registry itself ascribes the decline to the introduction of cervical cancer screening in 1961. The HPV vaccine programme was not introduced until 2013¹⁵. See below:



The HSE figures are arrived at from an assessment of the HPV infection rates of the vaccinated strains, **not** on actual cervical cancer statistics from the respective cancer registries. The scientific evidence actually shows an increase in high-risk HPV strains other than those covered in the vaccine, amongst the vaccinated population. This phenomenon is called “type replacement”, where the reduction of one HPV strain leads to another strain becoming more virulent.

HSE Document	Claim	Fact Check																																
<p>“Information for parents and guardians” glossy brochure, P2</p>	<p>16-year-old girl is quoted: “I’m really glad my mam got me the vaccine a couple of years ago. As I get older I realise how important it is for me.”</p>	<p>This suggests that the advertising for the vaccine is aimed at underage girls. Such advertising is illegal under Irish law.</p>																																
<p>“Facts about HPV and Cervical Cancer” A4 leaflet, P1</p>	<p>“HPV vaccine is recommended by...”</p>	<p>Several organisations listed have been in receipt of significant funding from the manufacturers of HPV vaccines. One such organisation, The Irish Cancer Society, has received over €170,000 directly. We ask whether such an environment can lend itself to impartiality in advocacy.</p> <div data-bbox="683 846 1356 1088" data-label="Table"> <p>MSD INVENTING FOR LIFE This resource is intended for residents of the United States and Canada.</p> <p>2015 Charitable Grants</p> <table border="1"> <thead> <tr> <th>Payee Name</th> <th>Payee City</th> <th>Payee State</th> <th>Payee Country</th> <th>Grant or Payment Type</th> <th>Title of the Activity</th> <th>Payment Amount</th> <th>Payment Date</th> </tr> </thead> <tbody> <tr> <td>Irish Cancer Society</td> <td>Dublin</td> <td></td> <td>Ireland</td> <td>Contributions</td> <td>The Irish Cancer Care to Drive Programme</td> <td>100,000.00</td> <td>7/23/2015</td> </tr> </tbody> </table> <p>MSD INVENTING FOR LIFE This resource is intended for residents of the United States and Canada.</p> <p>2016 Charitable Grants</p> <table border="1"> <thead> <tr> <th>Payee Name</th> <th>Payee City</th> <th>Payee State</th> <th>Payee Country</th> <th>Grant or Payment Type</th> <th>Title of the Activity</th> <th>Payment Amount</th> <th>Payment Date</th> </tr> </thead> <tbody> <tr> <td>Irish Cancer Society</td> <td>Dublin</td> <td></td> <td>Ireland</td> <td>Contributions</td> <td>The Irish Cancer Society Volunteer Driver Scheme</td> <td>\$100,000.00</td> <td>10/5/2016</td> </tr> </tbody> </table> </div> <p>While WHO recommends the HPV vaccine, WHO Uppsala – its drug monitoring agency – recognises shortcomings in safety signal analysis (interpreting adverse events), advising that new approaches are needed to better identify what these signals mean.¹⁶</p>	Payee Name	Payee City	Payee State	Payee Country	Grant or Payment Type	Title of the Activity	Payment Amount	Payment Date	Irish Cancer Society	Dublin		Ireland	Contributions	The Irish Cancer Care to Drive Programme	100,000.00	7/23/2015	Payee Name	Payee City	Payee State	Payee Country	Grant or Payment Type	Title of the Activity	Payment Amount	Payment Date	Irish Cancer Society	Dublin		Ireland	Contributions	The Irish Cancer Society Volunteer Driver Scheme	\$100,000.00	10/5/2016
Payee Name	Payee City	Payee State	Payee Country	Grant or Payment Type	Title of the Activity	Payment Amount	Payment Date																											
Irish Cancer Society	Dublin		Ireland	Contributions	The Irish Cancer Care to Drive Programme	100,000.00	7/23/2015																											
Payee Name	Payee City	Payee State	Payee Country	Grant or Payment Type	Title of the Activity	Payment Amount	Payment Date																											
Irish Cancer Society	Dublin		Ireland	Contributions	The Irish Cancer Society Volunteer Driver Scheme	\$100,000.00	10/5/2016																											
<p>“Facts about HPV and Cervical Cancer” A4 leaflet, P1</p>	<p>Under <u>HPV vaccine side effects</u> it is stated: “About 1 girl in 10 will get pain, swelling and redness at the injection site and/or headache. • About 1 girl in 100 will get nausea, pain in the vaccinated arm and mild fever. • About 1 girl in 1,000 to 1 girl in 10,000 will get an itchy rash or hives. • Severe allergic reactions with difficulty breathing are very rare (about 1 in 1 million people). • Occasionally girls faint after getting an injection. The girls are advised to sit down for 15 minutes after the vaccination. This helps prevent fainting.”</p>	<p>These listed side effects are mild and transient. However, the Merck PIL side effects also include seizures, difficulty breathing, joint pain, muscle pain, Guillain-Barre Syndrome, vomiting, chills, confusion, unusual tiredness and weakness, skin infections, bleeding and bruising more easily, swollen glands (neck, armpit, or groin).</p> <p>Merck also recommends contacting your doctor or pharmacist if you suffer any of these side effects, even weeks or months after vaccination.</p> <p>2.2% of Gardasil 9 recipients and 3.3% of Gardasil recipients reported a new medical condition potentially indicative of systemic autoimmune disorders.</p> <p>Merck also recognises long-term side effects on their safety statements about Gardasil within their Gardasil 9 documentation¹⁷.</p> <p>It should be noted that in the USA the Cervical cancer rate is 8.1 cases per 100,000 women per year¹⁸. Of each 100,000 vaccinated, 3,300 will report a new medical condition potentially indicative of systemic autoimmune disorders. In other words, the chance of acquiring a serious illness in the wake of receiving the HPV vaccine is 400 times greater than the likelihood of being diagnosed with cervical cancer later in life.</p>																																

HSE Document	Claim	Fact Check																																																												
<p>“Facts about HPV and Cervical Cancer” A4 leaflet, P2</p>	<p>Under <u>Impacts of the HPV vaccine</u> it is stated “Precancerous growths of the cervix have been reduced by up to 75% in countries such as Australia, Sweden and Scotland.”</p>	<p>This is factually incorrect. To take the example of Australia: figures from the Australian health authorities clearly show the 75% reduction in cervical cancer rates occurred before the vaccine was introduced. This was the direct result of a smear testing programme introduced there in 1991. Since the vaccine was introduced, there has been a rise in cervical cancer rates¹⁹.</p> <div data-bbox="687 629 1259 1043"> <p>Ovarian cancer is 'extremely aggressive'</p> <p>More than 1600 Australian women will be diagnosed with ovarian cancer this year, a record high. This graph shows incidences of both ovarian and cervical cancers.</p> <table border="1"> <caption>Estimated Incidence of Ovarian and Cervical Cancers (1982-2018)</caption> <thead> <tr> <th>Year</th> <th>Ovarian Cancer Incidence</th> <th>Cervical Cancer Incidence</th> </tr> </thead> <tbody> <tr><td>1982</td><td>800</td><td>1000</td></tr> <tr><td>1984</td><td>850</td><td>1050</td></tr> <tr><td>1986</td><td>850</td><td>1000</td></tr> <tr><td>1988</td><td>900</td><td>1050</td></tr> <tr><td>1990</td><td>950</td><td>1050</td></tr> <tr><td>1992</td><td>950</td><td>1000</td></tr> <tr><td>1994</td><td>1000</td><td>1100</td></tr> <tr><td>1996</td><td>1050</td><td>950</td></tr> <tr><td>1998</td><td>1100</td><td>850</td></tr> <tr><td>2000</td><td>1150</td><td>800</td></tr> <tr><td>2002</td><td>1200</td><td>750</td></tr> <tr><td>2004</td><td>1250</td><td>750</td></tr> <tr><td>2006</td><td>1300</td><td>750</td></tr> <tr><td>2008</td><td>1350</td><td>800</td></tr> <tr><td>2010</td><td>1400</td><td>800</td></tr> <tr><td>2012</td><td>1450</td><td>850</td></tr> <tr><td>2014</td><td>1500</td><td>850</td></tr> <tr><td>2016</td><td>1550</td><td>900</td></tr> <tr><td>2018</td><td>1600</td><td>900</td></tr> </tbody> </table> <p>Source: National Cancer Control Indicators</p> </div>	Year	Ovarian Cancer Incidence	Cervical Cancer Incidence	1982	800	1000	1984	850	1050	1986	850	1000	1988	900	1050	1990	950	1050	1992	950	1000	1994	1000	1100	1996	1050	950	1998	1100	850	2000	1150	800	2002	1200	750	2004	1250	750	2006	1300	750	2008	1350	800	2010	1400	800	2012	1450	850	2014	1500	850	2016	1550	900	2018	1600	900
Year	Ovarian Cancer Incidence	Cervical Cancer Incidence																																																												
1982	800	1000																																																												
1984	850	1050																																																												
1986	850	1000																																																												
1988	900	1050																																																												
1990	950	1050																																																												
1992	950	1000																																																												
1994	1000	1100																																																												
1996	1050	950																																																												
1998	1100	850																																																												
2000	1150	800																																																												
2002	1200	750																																																												
2004	1250	750																																																												
2006	1300	750																																																												
2008	1350	800																																																												
2010	1400	800																																																												
2012	1450	850																																																												
2014	1500	850																																																												
2016	1550	900																																																												
2018	1600	900																																																												
<p>“Facts about HPV and Cervical Cancer” A4 leaflet, P2</p>	<p>“This leaflet includes all the known scientifically proven side effects from HPV vaccine.”</p>	<p>The HSE leaflet does not contain the scientifically proven side effects as outlined by the manufacturer PIL, as outlined above (including seizures).</p> <p>It does not include the post-marketing reports that Merck declare in their safety data^{20,21, 22}.</p> <p>Gardasil 9 draws this comparison: “As a comparison, of the 7,378 individuals who were administered GARDASIL and had safety follow-up, 185 reported a serious adverse event; representing 2.5% of the population.”²³</p>																																																												

1. <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm426457.pdf>
2. <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm426457.pdf>
3. <https://www.sciencedirect.com/science/article/abs/pii/S1043661815001711>
4. <https://www.uscfc.uscourts.gov/sites/default/files/opinions/MORAN.TARSELL033012.pdf>
5. <http://www.hpra.ie/docs/default-source/vaccine-pils/gardasil-pil.pdf?sfvrsn=12>
6. <https://www.hpra.ie/homepage/medicines/special-topics/hpv-school-immunisation/national-monitoring-experience>
7. <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm426457.pdf>
8. <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm111263.pdf>
9. <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm426457.pdf>
10. <https://www.sciencedirect.com/science/article/abs/pii/S1043661815001711>
11. <https://www.hpra.ie/homepage/medicines/special-topics/hpv-school-immunisation/national-monitoring-experience>
12. <https://www.aihw.gov.au/reports-statistics/health-conditions-disability-deaths/cancer/data>
13. <https://ijme.in/articles/increased-incidence-of-cervical-cancer-in-sweden-possible-link-with-hpv-vaccination/?galley=html>
14. <https://www.aihw.gov.au/reports-statistics/health-conditions-disability-deaths/cancer/data>
15. <https://cancerregistry.fi/screening/cervical-cancer-screening/>
16. <http://www.irishstatutebook.ie/eli/2007/act/19/enacted/en/print>
17. <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm426457.pdf>
18. <https://report.nih.gov/nihfactsheets/viewfactsheet.aspx?csid=76>
19. <https://www.aihw.gov.au/reports-statistics/health-conditions-disability-deaths/cancer/data>
20. <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm111263.pdf>
21. <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm426457.pdf>
22. <http://www.hpra.ie/docs/default-source/vaccine-pils/gardasil-pil.pdf?sfvrsn=12>
23. <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm426457.pdf>

 @IFICAEUROPE

 Facebook.com/IFICAEurope/

www.ificaeurope.org