CHANGING TIMES

The Gardasil controversy: as reports of adverse effects increase, cervical cancer rates rise in HPV-vaccinated age groups

Annette Gartland 7 months ago

This article has been updated to include news of the expulsion of Peter Gøtzsche from the Cochrane Collaboration, new information about the flawed HPV vaccination trials, and cervical cancer statistics from the Netherlands.

The Gardasil vaccines continue to be vaunted as life-saving, but there is no evidence that HPV vaccination is reducing the incidence of cervical cancer, and reports of adverse effects now total more than 85,000 worldwide. Nearly 500 deaths are suspected of being linked to quadrivalent Gardasil or Gardasil 9.

As Merck's latest human papillomavirus (HPV) vaccine, Gardasil 9, continues to be fast tracked around the world, the incidence of invasive cervical cancer is increasing in many of the countries in which HPV vaccination is being carried out.

HPV vaccination is meanwhile causing dozens of serious adverse effects, and hundreds of deaths are suspected of being linked to Gardasil. While health authorities insist that causality is unproven, evidence that there is cause and effect is growing.

Quadrivalent Gardasil and Gardasil 9 are lauded as "cervical cancer vaccines". Merck has never said that cervical cancer rates are decreasing as a result of vaccination, but many health professionals, and the media, are already claiming that HPV vaccination is leading to a reduction in incidence.

Official statistics, however, prove the opposite.

The media regularly run headlines stating that cervical cancer rates are dropping when the studies they are citing are in fact about a reduction in the incidence of HPV infection, or dysplasia[1], or genital warts, never invasive cancer.

It is being widely predicted that cervical cancer will be eliminated by HPV vaccination, but the modelling and analysis is not backed up by data from the past decade.

"HPV vaccination is not reducing cervical cancer rates," said French orthopaedic surgeon, oncologist, and statistician Gérard Delépine. "To the contrary, research shows that it is making matters worse.

"Studies should be carried out immediately to find out why these increases are occurring. This is a public health catastrophe that necessitates an urgent rethink about HPV vaccination policies."

Delépine told Changing Times: "In several countries, cervical cancer rates have increased since HPV vaccination was introduced.

> "The biggest increases are among young women aged 18 to 26, the age group in which there is the highest vaccination rate.
>
> "These increases come after steady decreases in incidence in the years before HPV vaccination began."

Delépine (*pictured left*) says that, in the countries he has studied where there is a high rate of HPV vaccination, official statistics show an increase in the incidence of invasive cervical cancer that is appearing three to five years after the start of the vaccination programme and is affecting only the age groups in which there was the highest vaccination rate.

> "The authorities are mixing up the age groups when providing statistics relating to invasive cervical cancer.
>
> "They put statistics about young woman who are now at very high risk with those relating to older women who did not receive HPV vaccination and this hides the true increase in incidence and

risk."

In an article published in the journal Human Vaccines and Immunotherapeutics in October 2015, Fangjian Guo et al. say their research showed that, while the quadrivalent vaccine was effective against the four types of HPV targeted, the prevalence of high-risk, non-vaccine types was higher among vaccinated women than unvaccinated women.

They state: "Vaccinated young adult women had a higher prevalence than unvaccinated women of high-risk types other than HPV 16 and 18, and thus are still at risk of cervical cancer and other HPV-related cancers.

"This is consistent with clinical trials on the quadrivalent vaccine which showed it provided some protection against HPV 31 and 59, but not other types. Thus, the limitations of the HPV vaccine should be discussed with all patients, so they understand the need to obtain regular cervical cancer screening after vaccination as recommended for their age group."

While it is also being claimed that HPV vaccination provides protection against anal, vulvar, vaginal, and anal cancer, along with throat cancer and other cancers of the head and neck, the major argument in favour of its use is that it is said to protect girls and young women from cervical cancer.

A poster in Britain.

Publicity for HPV vaccination has been focused on people's fear of cancer, and it is this fear – and people's belief that HPV vaccination will protect them – that is driving take-up.

There is also a massive, well-funded lobbying machine, involving health authorities, politicians, and most of the world's mainstream media, that persuades the public that HPV vaccination is beneficial.

Only in Japan has the government suspended the proactive recommendation of HPV vaccination because of reports of adverse effects.

Austria rejected the inclusion of HVP vaccination in its schedule after the death of 19-year-old student Jasmin Soriat in 2007, but quadrivalent Gardasil has been included in the free national vaccination programme for girls and boys aged 9 to 11 years since 2014.

Soriat exhibited neurological symptoms after receiving a second dose of the vaccine, and suffered respiratory failure three weeks later.

Austria was the first country in Europe to make the quadrivalent Gardasil available for free for both girls and boys. The switch was made to Gardasil 9 in 2016 and Austria was the first European country to make it available in its national vaccination programme. Two doses are recommended with an interval of at least six months between them.

Adverse effects

As the lobbying in favour of HPV vaccination continues apace, the reports of serious adverse effects and fatalities linked to the vaccine are increasing.

As of May 2018, the World Health Organisation's pharmacovigilance database, VigiBase, listed 499 deaths that were reported as being linked to HPV vaccination.

According to VigiBase, more than 86,000 adverse events relating to HPV vaccination have been reported.

Adverse drug reactions (ADRs)

- Blood and lymphatic system disorders (2001)
- Cardiac disorders (2553)
- Congenital, familial and genetic disorders (285)
- Ear and labyrinth disorders (1838)
- Endocrine disorders (375)
- Eye disorders (5035)
- Gastrointestinal disorders (15671)
- General disorders and administration site conditions (46056)
- Hepatobiliary disorders (261)
- Immune system disorders (1850)
- Infections and infestations (4691)
- Injury, poisoning and procedural complications (13482)
- Investigations (12947)
- Metabolism and nutrition disorders (1824)
- Musculoskeletal and connective tissue disorders (14510)
- Neoplasms benign, malignant and unspecified (incl cysts and polyps) (1041)
- Nervous system disorders (38063)
- Pregnancy, puerperium and perinatal conditions (1180)
- Product issues (127)
- Psychiatric disorders (5286)
- Renal and urinary disorders (1170)
- Reproductive system and breast disorders (3210)
- Respiratory, thoracic and mediastinal disorders (5965)
- Skin and subcutaneous tissue disorders (14699)
- Social circumstances (1979)
- Surgical and medical procedures (2196)
- Vascular disorders (5635)

One major concern is that HPV vaccination may be causing premature ovarian failure (POF) in adolescent girls.

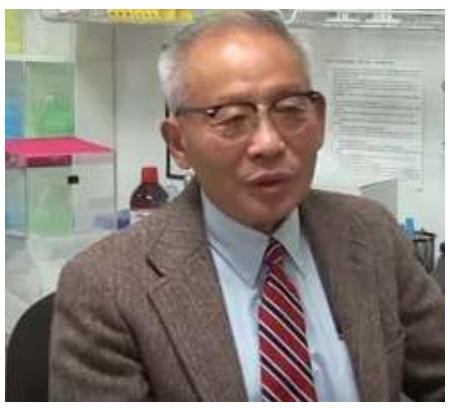
Another is that there is more than twice as much aluminium in Gardasil 9 than in the original Gardasil vaccination.

Gardasil	Ingredient	Gardasil 9
225 mcg	AAHS (aluminum adjuvant)	500 mcg
9.56 mcg	Sodium Chloride	9.56 mcg
.78 mcg	L-Histidine	.78 mcg
50 mcg	Polysorbate 80	50 mcg
35 mcg	Sodium Borate	35 mcg
<7 mcg	Yeast Protein	<7 mcg
20 mcg	HPV 6 L1 protein	30 mcg
40 mcg	HPV 11 L1 protein	40 mcg
40 mcg	HPV 16 L1 protein	60 mcg
20 mcg	HPV 18 L1 protein	40 mcg
	HPV 31 L1 protein	20 mcg
	HPV 33 L1 protein	20 mcg
	HPV 45 L1 protein	20 mcg
	HPV 52 L1 protein	20 mcg
	HPV 58 L1 protein	20 mcg

There have been numerous cases of people developing chronic pancreatitis after HPV vaccination.

Other reported adverse effects include paralysis, narcolepsy, respiratory dysfunction, cognitive impairment, involuntary movements, blood clots, and a rapid heartbeat.

‘A marketing slogan’



The director of Milford Molecular Diagnostics in Connecticut in the United States, Sin Hang Lee (*pictured left*) says the statement that HPV is a virus that causes cervical cancer is “half-true at best”, and is a slogan used by the pharmaceutical industry to market HPV vaccines.

Cervical cancer is primarily a disease among unscreened or rarely screened women, Lee says.

The accurate statement, Lee says, should be that persistent infection by certain specific genotypes of HPV, validated by L1 gene DNA sequencing, carries the risk of developing invasive cervical cancer.

> "HPV is not one virus. There are at least 150 genotypes of HPV, and more than forty HPV types or subtypes are commonly found in humans," Lee said.
>
> "Most HPV infections and even repeated transient infections by the high-risk HPV genotypes do not lead to cervical cancer."

Lee also says that the statement that the HPV vaccination on offer "protects against seven out of ten cervical cancers" needs a peer-reviewed reference to support its accuracy.

> "The truth is that there is no proof that HPV vaccination has prevented a single case of cervical cancer in any countries," Lee said.

Lee cites the case of the Australian champion rower Sarah Tait. The Olympic medallist died from cervical cancer in March 2016 at the age of 33, even though she was vaccinated with Gardasil.

> "We may not stop people from getting HPV infection by vaccination, let alone stop the cause of these cancers," Lee has said.

The leading Israeli obstetrician-gynaecologist Uzi Beller, who is an authority on gynaecological cancers, reported in 2009 that two young women developed invasive cervical cancer shortly after receiving HPV vaccination in a clinical trial and he urged precaution about relying on using HPV vaccination to prevent cancer.

Sin Hang Lee says that cervical cancer is nearly 100 percent preventable, as testified by Nancy C. Lee, M.D., the then associate director for science at the Centers for Disease Control and Prevention, before the US House Committee on Commerce's sub-committee on health and the environment on March 16, 1999.

Nancy C. Lee testified that screening, and treating precancerous lesions, prevents cervical cancer from ever developing.

Decrease in incidence reversed

Gérard Delépine says that, from 1989 to 2006, in all industrialised countries where cervical cancer smear testing was being carried out, there was a very significant decrease in the age-standardised incidence of invasive cervical cancer.

He points to statistics from the National Health Service in the United Kingdom, which indicate that, after the screening programme was introduced there in the 1980s, the number of cervical cancer cases decreased by about 7 percent each year up until 2006.

According to France's national public health agency, *Santé publique France*, in the period before HPV vaccination, there was a very significant decrease in the age-standardised incidence of invasive cervical cancer, with an average decrease of 2.5 percent between 1989 and 2000 and a slowing down of that decrease to one percent between 2000 and 2007.

Since 2006, Delépine says, the trend has reversed in young women, whereas, in the older age groups of women who did not receive HPV vaccination, the risk of cervical cancer is remaining stable or continuing to decrease.

Delépine is calling for HPV vaccination recommendations to be halted while the increase in cancer incidence is investigated, and he is campaigning against a proposal to make HPV vaccination mandatory in France.

He wonders whether cervical cancer rates might be increasing because fewer women are now having Pap smear tests.

"This has been observed in Australia," he said, "and could partly explain the cervical cancer increases in some countries.

> "However, according to recent studies, it is not the case in Britain or Sweden, and it would in no way explain the rapid global increase in incidence in the HPV-vaccinated age group."

Delépine hypothesises that HPV vaccines may be acting as a kind of "booster" that is speeding up the development of cervical cancer in some women.

> "It is the only logical conclusion. The increase in the rates of invasive cervical cancer in young women is being observed just five years after vaccination whereas it usually takes ten to twenty years for cervical cancer to become invasive after HPV infection occurs," he said.

Delépine says that HPV vaccination may also be causing a proliferation of other viral strains that could be even more dangerous than those that were already in existence, as suggested by such researchers as George F. Sawaya and Karen Smith-McCune.

> "However," Delépine says, "these are just hypotheses. Health ministers should no longer be recommending HPV vaccination when there are such increases in incidence and we don't know why."

'Modest efficacy'

In an article published in the New England Journal of Medicine in May 2007, Sawaya and Smith-McCune write about the "modest efficacy" of quadrivalent Gardasil in the cohort studied in the FUTURE I and II trials conducted between December 2001 and May 2003.

Sawaya and Smith-McCune cite the role of "oncogenic[2] HPV types not included in the vaccine". They say that findings from the FUTURE II trial showed that the contribution of non-vaccine HPV types to pre-cancerous dysplasia was sizeable.

"In contrast to a plateau in the incidence of disease related to HPV types 16 and 18 among vaccinated women, the overall disease incidence regardless of HPV type continued to increase, raising the possibility that other oncogenic HPV types eventually filled the biologic niche left behind after the elimination of HPV types 16 and 18," they wrote.

Another factor to take into account, the researchers say, is HPV vaccination's apparent lack of efficacy among women who were previously exposed to the HPV types included in the vaccine.

> "In contrast to the CDC's guidelines, the American Cancer Society does not recommend universal vaccination among women between 18 and 26 years of age, citing probable diminished vaccine efficacy as the number of lifetime sexual partners increases," Sawaya and Smith-McCune state.

The US Food and Drug Administration (FDA) states itself that HPV vaccination brings a significantly higher risk of developing precancerous lesions to women already infected with the virus.

According to Merck's own trial data, Gardasil vaccination of women who are already seropositive and polymerase chain reaction (PCR) positive for vaccine-relevant HPV genotypes has been found to increase the risk of developing high-grade precancerous lesions by 44.6 percent.

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 vaccination is carried out without any testing of a person's HPV status.

Researchers Carmen Lía Murall, Chris T. Bauch, and Troy Day investigated the potential of HPV to evolve higher virulence in response to vaccination. They published their findings in an article

published in November 2104 in the journal "Proceedings of the Royal Society B: Biological Sciences".

Murall et al. say that HPV vaccines "hold great promise for preventing several cancers caused by HPV infections", but little attention has been given to whether HPV could respond evolutionarily to the new selection pressures imposed on it by the novel immunity response created by the vaccine.

> "The uniqueness of the HPV vaccines lies in that they target a virus that is avirulent for the majority of hosts, but has strong cell transformation properties," the researchers state.

In the article entitled "Could the human papillomavirus vaccines drive virulence evolution?" the researchers say that, with a "high oncogene expression strategy", the virus is able to increase its viral load and infected cell population before clearance by the vaccine, thus improving its chances of transmission.

"This new rapid cell-proliferation strategy is able to circulate between hosts with medium to high turnover rates of sexual partners," they state.

Murall et al. point out that HPV is mostly avirulent and asymptomatic, and is carried at low within-host densities.

> "Only after several years of persistence do HPV infections become deadly by the transformation of host cells that have become malignant after the infection has stopped being productive for the virus," they state.

The researchers say that the evolutionary responses of viruses to vaccines are "of serious concern".

They compare "successful vaccines that stimulate natural immunity" with "novel vaccines that stimulate new responses that differ considerably from natural immunity".

They say that the HPV vaccines change the within-host ecology encountered by the virus in three main ways. These include the fact that "the vaccine-targeted types experience a strong antibody response that is unnaturally high".

Fast tracked and promoted

Gardasil 9 has just been fast tracked in China and is being heavily promoted in other countries around the world.

In Britain, it has been proposed that children in primary schools should undergo HPV vaccination, and, in the US, Merck has applied for approval to extend Gardasil 9 vaccination to women and men aged 27 to 45.

HPV vaccination has already been extended to boys in Australia and other countries are preparing to follow suit.

While members of the public are bombarded with such headlines as "New HPV vaccine could prevent almost all cervical cancers" and "Fears for women's health as parents reject HPV vaccine", very little media attention is given to the thousands of cases of adverse effects being reported globally.

The media focus is more on what health authorities consider to be the "risks" of low take-up, not the dangers of the HPV vaccines themselves.

Gardasil 9 was first licensed for use in the US on December 10, 2014, for girls and women aged 9 to 26, and boys aged 9 to 15.

On December 15, 2015, the indication for Gardasil 9 was expanded to include boys and men aged 16 to 26.

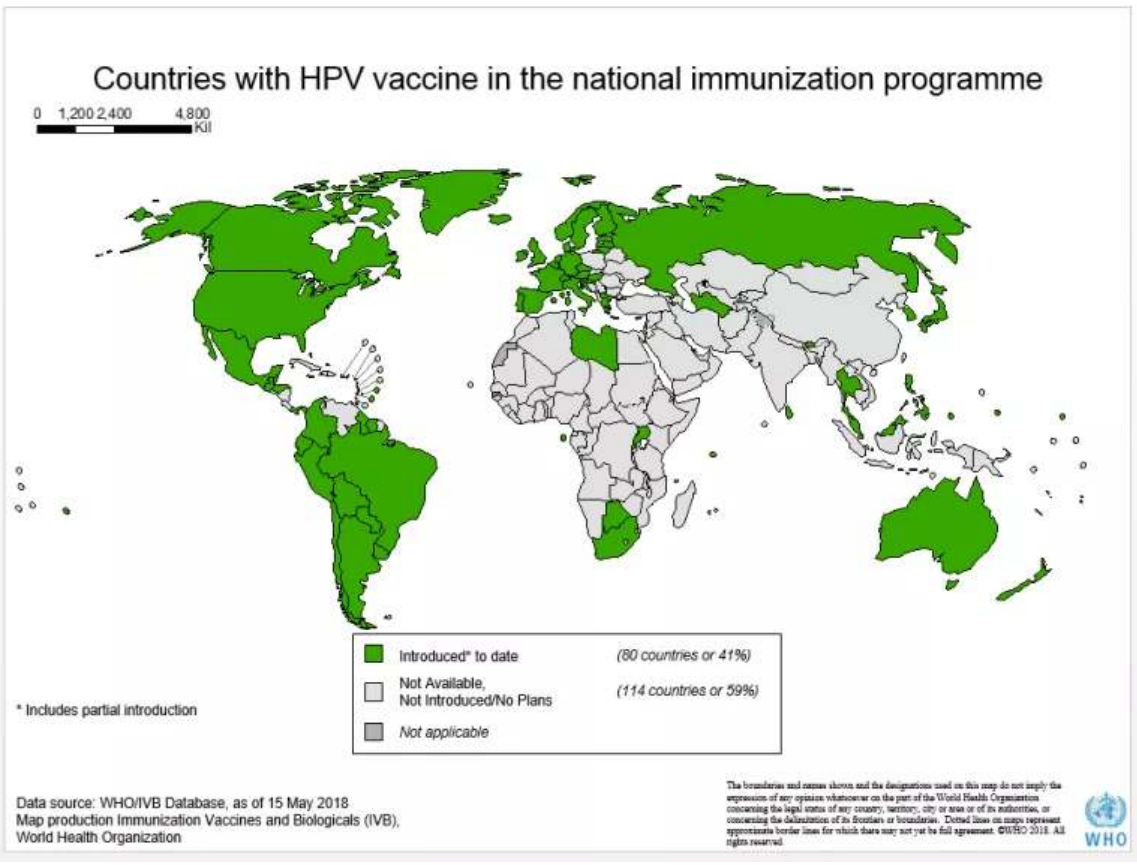
In July this year, after a recommendation from the Joint Committee on Vaccination and Immunisation (JCVI), the British government decided that HPV vaccination will be extended to boys.

Extension of HPV vaccination to boys has also been recommended by the National Immunisation Advisory Committee in Ireland.

Gardasil 9 has never been clinically tested on boys and has still not been assessed by the FDA's Vaccines and Related Biological Product Advisory Committee.

According to the WHO, as of May this year, 80 countries had introduced HPV vaccination. Twenty countries have extended it to boys.

More than 270 million doses of HPV vaccines have been distributed worldwide.



Originally, the HPV vaccines used were quadrivalent Gardasil, produced by Merck, and, to a much lesser extent, Cervarix, produced by GlaxoSmithKline (GSK).

Quadrivalent Gardasil contains LI protein from four HPV types: 6, 11, 16, and 18. It is approved for use in 132 countries and, to date, more than 208 million doses have been distributed worldwide.

Gardasil 9, which contains proteins from HPV types HPV 6, 11, 16, 18, 31, 33, 45, 52, and 58, is taking over from the quadrivalent vaccine and is now approved for use in more than seventy countries.

Merck said at the EUROGIN 2017 Congress held in the Netherlands last October that final analyses of its clinical trial for Gardasil 9 indicated that there was "efficacy for up to six years following receipt of first vaccine dose, and antibody responses over five years".

National increases in cervical cancer

Sweden

Table 1: Age-standardised (according to the standard Swedish population in 2000) incidence of invasive cervical cancer (per 100,000 women)

County	2006 – 2009	2010 – 2013	2014 – 2015	Average change 2005 – 2015 expressed as percentage	p value for trend
Sweden, total	9.71	9.56	11.49	1.7	0.03

Gardasil vaccination began in Sweden in 2006 and was generalised in 2010, with a vaccination coverage among 12-year-olds of close to 80 percent. There was a catch-up programme in 2012-2013 and nearly all Swedish teenagers aged 13-18 were vaccinated.

The Centre for Cervical Cancer Prevention in Sweden states in its 2018 annual report that the incidence of cervical cancer in the country increased by 2 percent each year between 2007 and 2016.

There was a dramatic increase of more than 18 percent in 2014-2016 as compared with 2011-2013, the report states. The incidence rose to 11.43 per 100,000 women.

An increase occurred in all counties except Stockholm, Södermanland, and Skåne, where the incidence has remained almost unchanged or has decreased in recent years.

Statistics from the NORDCAN database indicate that the increase in the incidence of invasive cervical cancer in Sweden is almost entirely due to a rise in incidence among women aged 25 to 49 (11 cases in 2006 as compared with 17 in 2015).

The incidence increased by more than 19 percent among women aged 20 to 29 (from 6.69 to 8.01 per 100,000), by more than 47 percent among those aged 30 to 39 (from 14.78 to 21.81 per 100,000), and by nearly 40 percent among those aged 40 to 49 (from 14.68 to 20.50 per 100,000).

There was, by contrast, a decrease in the incidence of invasive cervical cancer among women in Sweden aged over 50. (The women in this age group did not receive HPV vaccination.)

There was a decrease in incidence of 6.3 percent between 2007 and 2015 among women aged between 50 and 59 (from 14.24 to 13.34 per 100,000), 4.6 percent among those aged 60 to 69 (12.63 to 12.04 per 100,000), just over 17 percent among those aged 70 to 79 (from 15.28 to 12.66 per 100,000), and just over 12 percent among those aged over 80 (15.6 to 13.68 per 100,000).

According to the Centre for Cervical Cancer Prevention in Sweden's 2018 report, the incidence of cervical cancer among women aged 29-65 who had had normal results in their two previous screening tests was unchanged from 2002 to 2013, but increased by 60 percent in 2014-2015. Cases of invasive cervical cancer after two normal samples is rare, the report states.

In an article published in the Journal of the Swedish Medical Association in June 2018, Joakim Dillner et al. point to an increase in incidence of 17 percent in 2014-15 as compared to 2002-13 (a rise from 450 to 550 cases annually).

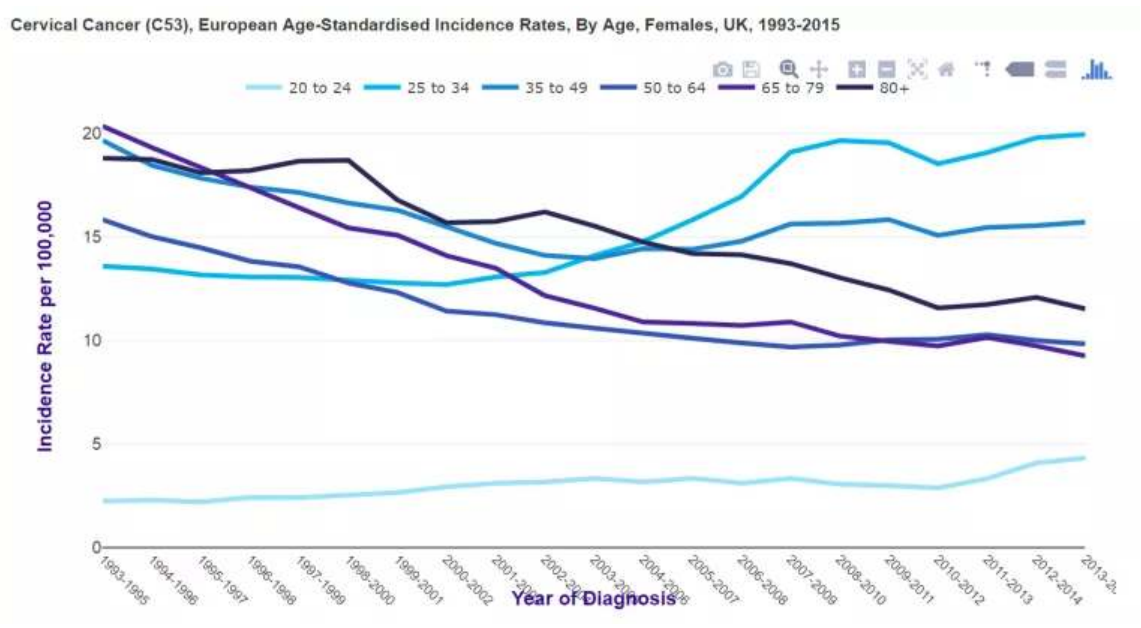
Dillner et al. analysed the possible causes of the increase in the incidence of cervical cancer. They put forward a hypothesis about screening providing less protection than before, but have not been able to come to a definitive conclusion about the cause of the increased incidence.

Britain

In the UK, HPV vaccination was introduced in September 2008 for girls aged 12-13 years. A catch-up programme started at the same time and the vaccine was proposed to older girls up to the age of 18. In September 2012, the Cervarix vaccine was replaced by quadrivalent Gardasil.

In September 2014, the schedule was changed from three doses to two for girls starting their vaccination when aged under 15.

Since the early 1990s, the cervical cancer incidence in the UK has increased by 93 percent in women aged 20-24, and by 47 percent in those aged 25-34.



Data from Cancer Research UK.

Statistics from Cancer Research UK show that, over the decade between 2003-2005 and 2013-2015, the age-standardised incidence of cervical cancer among women in the UK overall increased by 5 percent. Between 1993-1995 and 2013-2015 the incidence had decreased by 24 percent.

According to Cancer Research UK, the incidence among women aged between 20 and 24 increased by 38.7 percent between 2007 and the end of 2014, from 3.1 per 100,000 to 4.3 per 100,000.

Over the same period, incidence in the 25 to 34 age group increased by nearly 18 percent (17 per 100,000 to 20 per 100,000). The HPV vaccination rate was lower in this age group than among the younger woman as those aged 25 to 34 received only catch-up shots.

Among older women, who didn't receive HPV vaccination, there was either no increase in incidence or a lower one (decreases of 13 percent among women aged 65 to 79 years and 10 percent among those aged 80 or above).

According to the Office for National Statistics, the incidence of cervical cancer among women in England aged 20 to 24 increased by 70.37 percent between 2012 and 2014 (from 2.7 to 4.6 per 100,000).

The incidence among women aged 25 to 29 doubled between 2007 and 2015, going from 11 to 22 per 100,000.

According to statistics from Public Health England, by the end of 2014, more than 2.3 million girls had received three HPV vaccinations. Between 2012 and 2014, coverage with the full three-dose course was consistently above 86%, with more than 40 percent of primary care trusts reaching coverage of at least 90 percent.

Between the early 1990s and 2015, the cervical cancer incidence in the 35-49 age group decreased by 20 percent. The decrease in the 50-64 age group was 38 percent, in the 65-79 group 55 percent, and, among women aged 80 and above, the decrease was 39 percent.

Cervical Cancer (C53): 1993-2015

European Age-Standardised Incidence Rates per 100,000 Population, Females, UK

Sex	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Female	13.7	12.9	12.3	11.9	11.5	11.2	11.3	10.3	10.3	9.6	9.6	9.3	9.4	9.6	9.4	9.8	10.9	9.3	9.8	9.8	10.1	10.0	9.6

Norway

The age-standardised incidence of invasive cervical cancer has also increased in Norway since HPV vaccination began.

It went from 11 women per 100,000 in 2007 to 12.2 per 100,000 in 2009, 13.2 per 100,000 in 2012, and 14.3 per 100,000 in 2015, which is an increase of 30 percent over the nine years.

Again, the rise in incidence is almost entirely due to an increase in incidence among young women.

NORDCAN statistics show that the average age at which women were diagnosed with invasive cervical cancer dropped dramatically, from 48 in 2002-2006 to 45 in 2012-2016.

Between 2007 and 2015 the incidence of invasive cervical cancer increased by nearly 9 percent among women aged between 20 and 29 (from 7.78 to 8.47 per 100,000), just over 66 percent among women aged 30 to 39 (from 16.92 to 28.11 per 100,000), and more than 50 percent among women aged 40 to 49 (from 19.62 to 29.56 per 100,000).

Over the same period, there was a decrease in incidence among older women, who were outside of the vaccinated age group.

The decrease was 11.4 percent among women aged 55 to 64 (15.47 to 13.7 per 100,000), nearly 17 percent among those aged 65 to 74 (17.7 to 14.71 per 100,000), and just over 29 percent for those aged 75 to 85 (18.39 to 13 per 100,000).

The United States

According to the 1975-2015 SEER Cancer Statistics Review in the US, where HPV vaccination coverage is close to 60 percent, the cervical cancer incidence decreased by nearly 35 percent between 1989 and 2006. There was a slight decrease in 2007, then increases in most years since then.

There was a decrease of nearly 5 percent in incidence among women aged 50 and above between 2007 and 2015, but an increase of just over 4 percent among women in the age group receiving HPV vaccination.

In a report published in August this year, the Centers for Disease Control and Prevention (CDC) says the number of new cases of HPV-associated cancer in the US rose from 30,115 in 1999 to 43,371 in 2015. Throat cancer has become the most common HPV-related malignancy, the CDC says.

The CDC also reported that, in 2017, 65.5 percent of American teenagers had received at least one HPV vaccination and 48.6 percent had received the recommended series.

Australia

Australia has also seen an increase in cervical cancer cases among young women since the HPV vaccination programme began in 2007.

According to statistics from the Australian Institute of Health and Welfare (AIHW), the incidence in women in the 20-24 age group, in which HPV-vaccination coverage was more than 80 percent,

doubled between 2007 and the end of 2014 and the incidence in the 25-34 age group, where there was a lower vaccination rate, increased by a third over the same period.

Incidence among women aged 55 to 59 decreased by 17 percent. The decrease among women aged 60 to 64 was 16.5 percent, and among women aged 65 to 69 was nearly 8 percent.

Incidence of cervical cancer, by age, 2007 to 2014.

	15–19	20–24	25–29	30–34
2007	0,1	0,7	5,9	9,9
2008	0,1	1,6	8,6	10,7
2009	0	1,6	7,6	11,9
2010	0	2,8	7,6	9,9
2011	0	1,5	8,4	12,6
2012	0,3	1,9	8,4	12,1
2013	0	1,7	9	12,4
2014	0,2	1,5	8	13,2

Between 2007 and 2014, the cervical cancer incidence in Australia among girls aged 13-17 increased by 114 percent, among young women aged 18-22 by 35 percent, and among women aged 23-27 by 40 percent.

Between 1982 and 2006, the age-standardised rate of cervical cancer overall in Australia had decreased by 52 percent, from 14.2 per 100,000 to 6.8 per 100,000. Between 2007 and 2014 there was an overall increase of 5.7 percent (from 7 per 100,000 to 7.4 per 100,000.)

Denmark

During a symposium about HPV vaccination held in Dublin in April this year, the chairman of the Danish Patient Association of HPV-vaccine victims, Karsten Viborg, pointed to statistics from the Association of Nordic Cancer Registries, which show that, between 2000 and 2015, the incidence of cervical cancer in Denmark increased in the 10-29 age group.

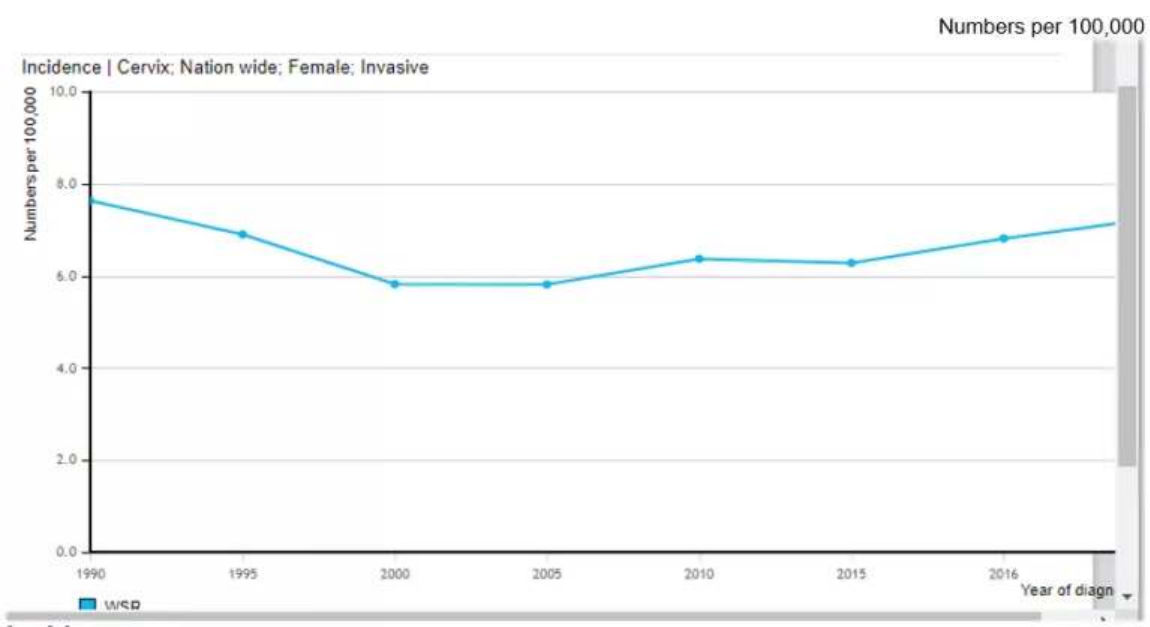
There are 600,000 people in that age group in Denmark who have received HPV vaccination, Viborg says.

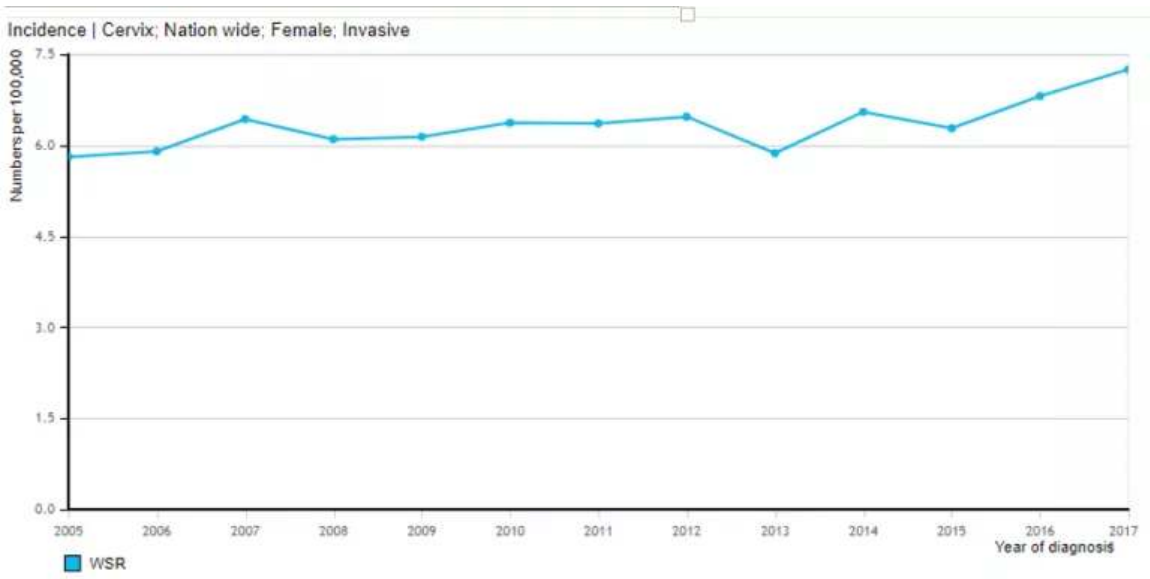
The NORDCAN data base shows an estimated 1.7 percent increase in cervical cancer incidence per year over the past decade in the Nordic countries overall.

According to NORDCAN, the annual increase in cervical cancer incidence over the past decade was 2.5 percent in Sweden, 2.2 percent in Finland, 3.3 percent in Iceland and 1.6 in Norway. The increase was lower in Denmark, at 0.1 percent.

The Netherlands

Statistics from the Netherlands Comprehensive Cancer Organisation (Integraal Kankercentrum Nederland), indicate that the incidence of invasive cervical cancer is also increasing in that country after a decrease in the 1990s and a levelling out in the early 2000s. HPV vaccination was introduced in the Netherlands in 2008.





The incidence in the Netherlands was 6.1 per 100,000 women in 2008, 6.47 per 100,000 in 2012, and 6.81 per 100,000 in 2016. The estimated incidence for 2017 is 7.25 per 100,000. This represents an increase of about 19 percent between 2008 and 2017.

Table

Incidence | Cervix; Nation wide; Female; Invasive

	BEHAVIOR	Invasive
	GENDER	Female
	REGION	Nation wide
TUMOUR	PERIOD	OUTCOME
		WSR
Cervix	2004	5.96
Cervix	2005	5.81
Cervix	2006	5.90
Cervix	2007	6.43
Cervix	2008	6.10
Cervix	2009	6.14
Cervix	2010	6.37
Cervix	2011	6.36
Cervix	2012	6.47
Cervix	2013	5.87
Cervix	2014	6.55
Cervix	2015	6.28
Cervix	2016	6.81
Cervix	2017 *	7.25

WSR = World Standardised Rate.

France

Gérard Delépine points out that in France, where there has been a low take-up of HPV vaccination (about 15 percent of those eligible to receive it), the incidence of cervical cancer continues to decrease in all age groups and the number of deaths from cervical cancer has also decreased.

Approved since 2006

The FDA approved the marketing of quadrivalent Gardasil to females aged 9 to 26 in June 2006, and to males aged 9 to 26 in October 2009.

In October 2016, it approved the use of Gardasil 9 (in two doses) for girls and boys aged 9 to 14.

In April 2017, the European Commission approved a two-dose Gardasil 9 schedule for girls and boys aged 9 to 14 in the 31 countries regulated by the European Medicines Agency (EMA).

Merck states that Gardasil 9 can also be administered in three doses. "For the two-dose schedule, the second dose should be administered 6-12 months after the first dose. If the second dose is administered less than five months after the first dose, a third dose should be given at least four months after the second dose."

Since 2015, more than 26 million doses of Gardasil 9 have been distributed worldwide, although the exact number of doses that have been administered is unknown.

The quadrivalent Gardasil vaccine is no longer available in the US.

Merck admits in the package insert for Gardasil 9: "Because vaccinees may develop syncope[3], sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended."

Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination, Merck states.

> "When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position."

Merck says that Gardasil 9 will protect girls against cervical, vulvar, vaginal, and anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58, and genital warts caused by HPV types 6 and 11.

It says the girls will also be protected against a number of precancerous or dysplastic lesions.

It adds, however, that Gardasil 9 "does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening" and those vaccinated "should not discontinue anal cancer screening if it has been recommended by a health care provider".

Boys, Merck says, will be protected against anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58; genital warts caused by HPV types 6 and 11; and the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58: anal intraepithelial neoplasia (AIN) grades 1, 2, and 3.

> The company states that Gardasil 9 "has not been demonstrated to provide protection against disease from vaccine HPV types to which a person has previously been exposed through sexual activity" and "has not been demonstrated to protect against diseases due to HPV types other than 6, 11, 16, 18, 31, 33, 45, 52, and 58".

Merck adds that "vaccination with Gardasil 9 may not result in protection in all vaccine recipients".

The vaccination is contraindicated in individuals with hypersensitivity, including severe allergic reactions to yeast, the company states.

Adverse event reports

Reports to the Vaccine Adverse Event Reporting System (VAERS) in the US relating to all HPV vaccination globally total 58,490 up to June this year. A total 44,194 were related to Gardasil and 8,363 to Gardasil 9.

A total 4,284 of the reports related to Cervarix, and this included 38 deaths, 91 cases of life threatening injury, and 361 cases of permanent disability.

A total 430 deaths were reported to the VAERS in relation to all HPV vaccination globally, including 310 that cited Gardasil and ten that cited Gardasil 9. There were 927 reports of life threatening illness and 2,739 cases of permanent disability.

A total 747 of the reports of life threatening illness related to Gardasil and 55 to Gardasil 9. A total 2,086 cases of cases of permanent disability related to Gardasil and 94 to Gardasil 9.

The CDC points out that a report to VAERS "does not necessarily mean that the vaccine caused the reported adverse event – only that the adverse event happened sometime following vaccination".

Deaths

In September last year, Special Master Christian J. Moran in the Office of Special Masters at the United States Court of Federal Claims awarded compensation to the family of Christina Richelle Tarsell from Sparks, Maryland, who died suddenly, aged 21, on June 21, 2008, after receiving a third Gardasil vaccination 18 days earlier.

Doctors determined that Christina Tarsell died from an arrhythmia[4] .In February 2016, Moran ruled that Christina's mother, Emily Tarsell, filing the case as the executrix of Christina Tarsell's estate, had not met her burden of establishing her case with preponderant evidence.

"Ms Tarsell has not persuasively established a basic proposition of her claim, that Christina did not experience an arrhythmia until after the first dose of the HPV vaccine," Moran said at that time.

He said the evidence was not sufficient to establish the causal relationship between the vaccination and the arrhythmia and Tarsell was consequently not entitled to compensation.

Emily Tarsell filed a motion for review and, in a later ruling in September last year, Moran said that causation could be inferred and compensation should be awarded.

He stated: "Logically, because the undersigned does not find that preponderant evidence supports a finding that Christina's arrhythmia started before the vaccination, Christina's arrhythmia must have started after vaccination."

He added that, "under the assumption that Christina's arrhythmia started after the vaccination" he found that her arrhythmia began within a time that was "medically appropriate to infer causation".

> Moran concluded: "Ultimately, because of the finding that Christina began to experience arrhythmia after her HPV vaccination, Ms Tarsell has presented preponderant evidence of a logical sequence of cause and effect, connecting the HPV vaccination to the ensuing arrhythmia."

He said that, "under the approach dictated by the court", Christina Tarsell was entitled to compensation.

The respondent in the case proffered compensation of $310,130: $250,000.00 for Christina Tarsell's vaccine-related death; $60,000.00 for past pain and suffering for Christina Tarsell's vaccine-related injury; and $130 for past unreimbursable expenses related to Christina Tarsell's vaccine-related injury.

Vaccine manufacturers cannot be held liable under the law for injuries and deaths caused by their vaccines. The only recourse the Tarsell family had was to file a claim against the Secretary of Health and Human Services.

In another case brought before the Court of Federal Claims, the parents of 14-year-old Joel Gomez were awarded US$200,000 in compensation in September 2016.

Joel, who was an athletic boy, training for his high school football team for four to five hours a day, died in his sleep on August 20, 2013, the day after receiving his second dose of Gardasil.

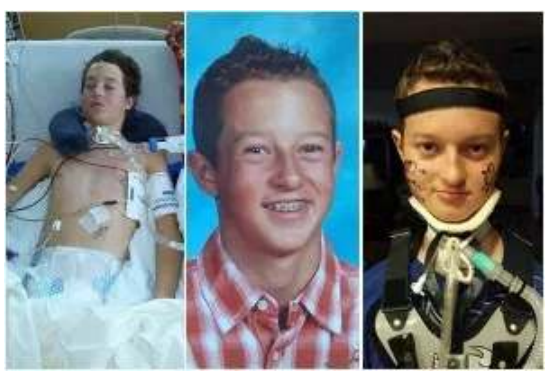
The conclusion of the doctor who performed the autopsy was that Joel had myocarditis, an inflammation of the heart muscle (the myocardium).

The cause of death was listed as unknown, but Sin Hang Lee, who was Joel's parents' expert witness, said that "the most plausible cause" of Joel's death was cardiac failure "brought about by a surge of myocardium-depressing cytokines[5]... released from the macrophages activated by the HPV L1 gene DNA fragments present in the vaccine product".

The respondent in the case, the Secretary of Health and Human Services, denied that the HPV vaccine caused Joel's myocarditis, any other injury, or his death.

Another American teenager, Colton Berrett, passed away on January 5 this year, aged just 17. He took his own life.

When he was 13 years old, Colton was paralysed after receiving three Gardasil vaccinations. He was diagnosed with transverse myelitis, a rare clinical syndrome in which an immune-mediated process causes neural injury to the spinal cord.



A sports enthusiast from an early age, Colton loved baseball, riding motorcycles, indoor skydiving, skiing, and especially motocross.

Two weeks after his third Gardasil vaccination, in February 2014, Colton started to get severe neck ache. He felt nauseous and exhausted.

When his parents took him to the hospital the next morning, his mother had to hold his head up, and he could no longer move his right arm.

Colton became paralysed from the neck down, and, at one stage, was only able to communicate with his eyebrows. He was in intensive care for more than twelve weeks.

He recovered sufficiently to be able to do some sporting activities, but his right arm remained paralysed and he had only minimal function in the left one. He had to have a breathing apparatus with him at all times.

Maddie Moorman, from Kansas City, Missouri, took her own life at the age of 21. She had received her first Gardasil shot when she was 15 and was immediately unwell, but it wasn't clear at the time whether this was because of the vaccination. Her mother thought birth control pills were to blame.

After the second shot, Maddie couldn't get out of bed for five days. "Her memory was gone," her mother Tracie told Vaxxed TV. "She used to have what she called a photographic memory."

Prior to the vaccination, Maddie was healthy and active, but afterwards she suffered from chronic exhaustion, exruciating headaches, nausea, insomnia, and difficulties processing information. She also developed twenty food allergies and became extremely sensitive to light and sound.

Maddie battled depression because of her ill health, and had a constant buzzing sound in her head. Her family described her as "an avid musician, a world traveller, a brilliant writer, and an unbelievably beautiful soul".

Fourteen-year-old Christopher Bunch from Moline, Illinois, in the US died on August 14 this year, just three weeks after receiving a Gardasil vaccination.

After receiving the vaccine, Christopher (*pictured left*) became ill almost right away. After being admitted to the hospital, he was diagnosed with acute disseminated encephalomyelitis (ADEM), which is listed on the Gardasil vaccine package insert as a reported adverse reaction.

The story of another death in the US is recounted in an interview on the Vaxxed TV YouTube channel with a nurse in Long Beach, California. She is not named.

The nurse explains that all her children were up-to-date with their vaccines at the time her daughter had her first Gardasil shot at the age of 16.

She said that, when she heard that Gardasil was a vaccine to prevent cancer, and that her daughter needed to have it before she became sexually active, she had no hesitation in administering it.

After the first shot, she says, her daughter was always tired and she complained constantly that her legs ached. "It was hard for her to get across campus because she felt very winded all the time."

Before the HPV vaccination, she was "healthy, vibrant, outgoing, fun, healthy, and full of life".

Because of her daughter's fear of vaccines, the nurse gave her the second Gardasil vaccine at home. After the vaccination there was blood gushing from her arm. Soon after that shot, the girl was diagnosed with leukemia and she died just ten months later.

"I feel really responsible because I gave it to her physically," the nurse told Vaxxed TV.

> "I just thought I was doing what was right to protect my daughter from cancer, and she got cancer. I tried to protect her."

Links between sporting activity and adverse reactions

There is research that indicates a possible connection between the adverse effects of HPV vaccination and the level of sporting activity of the person injured.

In his presentation about "Autoimmunity as an adverse effect of HPV vaccination" at the Dublin symposium, Jesper Mehlsen, who is the director of research at the Centre for Patients with Suspected Side-Effects to HPV Vaccination in Copenhagen, Denmark, said that HPV vaccination caused a very large increase in cytokines from the immune system.

> "When you vaccinate with HPV it has what we would call a very, very high antigen density. That means that the rise in antibodies is to about 10,000 times the level you have if you have a natural infection.

"It's a really, really hard rise, a really solid stimulation of the immune system."

Dormant cells are woken up, Mehlsen says, and these cells start producing antibodies against the person vaccinated. This is known as bystander activation.

The presence of aluminium in the HPV vaccine increases the risk of bystander activation, Mehlsen says.

"The number of viral matches and their locations make the occurrence of side autoimmune cross-reactions in the human host following HPV16-based vaccination almost unavoidable," he adds.

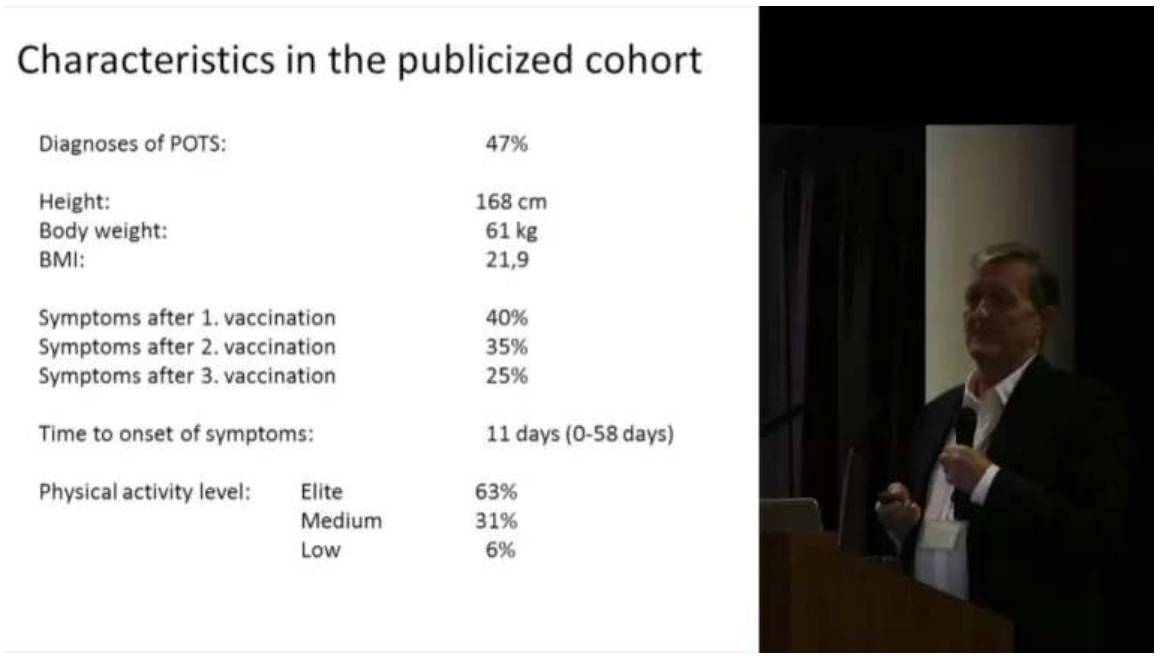
Mehlsen gives the example of one of the first patients who came to the Copenhagen clinic. She was an 18-year-old who used to play on the national soccer team.

He says that 63 percent of the teenagers coming to the clinic because they were suffering adverse effects after HPV vaccination had what is described as an "elite" level of physical activity.

"What was striking was that the level of physical activity was very high in these girls," Mehlsen told symposium attendees.

"Elite level means that you're training between ten and twenty hours a week. One third of our patients were on a national team in their sports so maybe there was a connection between training and this response.

> "We know that if you exercise a lot it changes your immune system. My recommendation is that, if you are competing in sports, don't get the vaccination."



Mehlsen says that the 18-year-old soccer player suffered burning pain and muscle weakness within seven days of her first HPV vaccination and had to quit her studies at university.

There is an intense programme of treatment at the Copenhagen centre and Mehlsen says the teenager is no longer dependent on help 24/7 and has been able to resume her studies.

About eight hundred people have been treated in the centre and most of them have been able to go back to their studies or resume work.

"There was even a 91-year-old woman who had been given the HPV vaccination," Mehlsen says, "and a 73-year-old man."

In an article about suspected side effects to the quadrivalent HPV vaccine, published in the Danish Medical Journal in April 2015, Mehlsen and his three co-authors state: "During the past years, a collection of symptoms primarily consistent with sympathetic nervous system dysfunction have been described as suspected side effects to the Q-HPV vaccine."

Quadrivalent Gardasil was introduced in Denmark in 2009.

The scientists studied side effects in 53 patients referred to the Syncope Unit for tilt-table testing and evaluation of their autonomic nervous system function.

> "All patients had symptoms consistent with pronounced autonomic dysfunction including different degrees of orthostatic intolerance, severe non-migraine-like headache, excessive fatigue, cognitive dysfunction, gastrointestinal discomfort and widespread pain of a neuropathic character," they wrote.

The scientists said they found consistency in the reported symptoms as well as between their findings and those described by others.

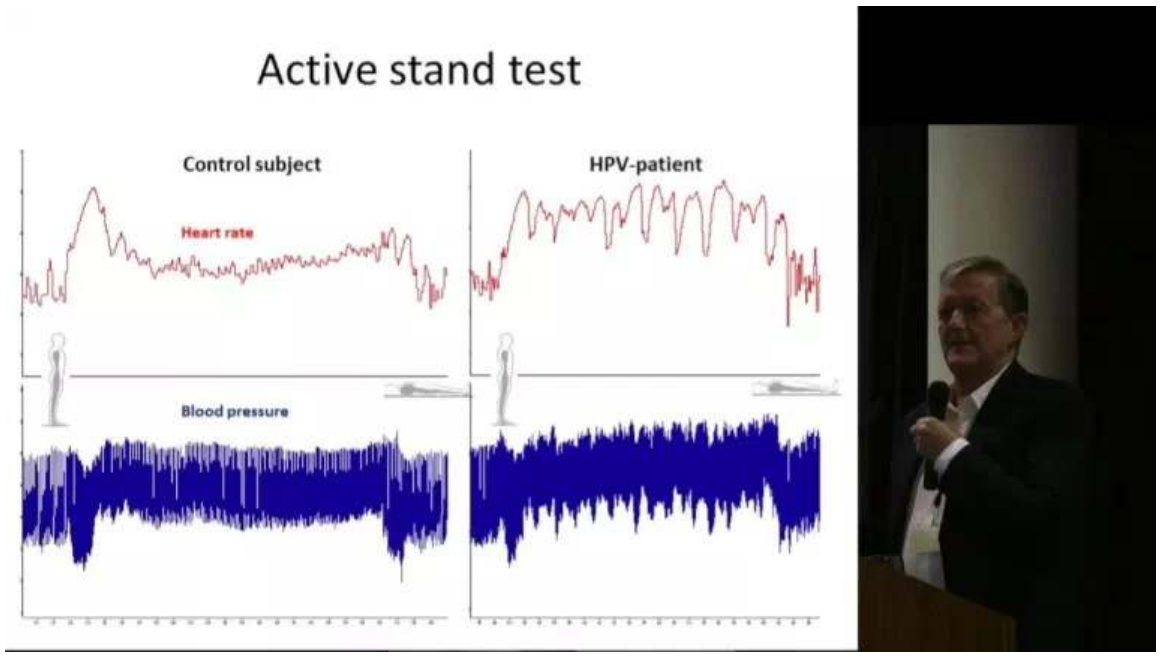
> "Our findings neither confirm nor dismiss a causal link to the Q-HPV vaccine, but they suggest that further research is urgently warranted to clarify the pathophysiology behind the symptoms experienced in these patients and to evaluate the possibility and the nature of any causal link and hopefully establish targeted treatment options."

About 1,300 female patients who received HPV vaccination have been referred to specialist centres in Denmark with symptoms of complex regional pain syndrome (CRPS) or postural orthostatic tachycardia syndrome (POTS), in which the heart rate increases abnormally, causing dizziness, fainting, chest pain, headache, and weakness.

Mehlsen spoke about POTS at the Dublin symposium. It's a subject on which he has been working for about 35 years.

He spoke about the way that the heart rate in patients who have received HPV vaccination stays high, then oscillates. Their blood pressure also oscillates.

> "They get mentally fogged and simply can't concentrate; they can't work; their cognitive ability's gone."



Mehlsen and his colleagues at the Copenhagen centre found that antinuclear antibodies, which indicate whether someone has an autoimmune condition, were present in 60 percent of a group of patients with side effects from HPV vaccination as compared with 25 percent in a control group.

Sin Hang Lee says that, in Gardasil, a Toll-like receptor 9 agonist is used in the form of recombinant HPV L1 DNA fragments, whose presence in the HPV vaccine has been confirmed by the FDA.

Activation of Toll-like receptor 9 leads to secretion by the antigen-presenting cells ((APCs)) and other immune cells of numerous pro-inflammatory cytokines, including tumour necrosis factor-alpha and interferon gamma, Lee says.

“In certain genetically and physically predisposed persons, the pro-inflammatory cytokines and interferon gamma may cause serious autoimmune disorders, including myocardial damage, acute disseminated encephalomyelitis, multiple sclerosis, and type 1 diabetes.

Lee says that the Toll-like receptor 9 agonist has not been officially approved for human vaccine formulations.

> “The short-term and long-term pathophysiological consequences in the human body after activation of the Toll-like receptor 9 of the immune cells by an artificial long-acting Toll-like receptor 9 agonist consisting of recombinant HPV L1 DNA fragments bound to an aluminium salt are virtually unknown and should be investigated,” he said.

Dublin protest

There was a protest in Dublin’s Kildare Street by the families of vaccine-injured girls during a visit by the co-creator of HPV vaccination, Ian Frazer, in July this year.

Two girls suffered seizures during the protest and needed assistance from paramedics, and one of them was taken to hospital. They were accused of staging the fits.

Frazer is lauded around the world. While in Dublin, he received an award from the Royal College of Physicians.

During his visit, he pushed heavily for the inclusion of boys into Ireland’s vaccination programme.

Irish vaccine-injured girls and their families have been targeted for serious abuse and members of Ireland’s parliament who have tried to raise questions about the dangers of Gardasil have been shouted down and pulled into line.

The mainstream media are vociferously in favour of HPV vaccination and the director-general of the Health Service Executive (HSE), Tony O’Brien, accused the families of vaccine-injured girls of “emotional terrorism”.

The Irish support group R.E.G.R.E.T (Reactions and Effects of Gardasil Resulting in Extreme Trauma) says that, according to the most recent statistics from the Health Products Regulatory Authority (HPRA), there have been 1,138 reports of adverse events related to HPV vaccination in Ireland and, in 648 of those cases, medical intervention was required.

R.E.G.R.E.T points out that the adverse events reported in relation to Gardasil total more than the total adverse events reported for all other vaccines combined that are given to girls.

Including preliminary figures for the first dose of HPV vaccine given in 2018, as of July 2 this year, 665,769 doses of HPV vaccine had been administered since the school-based HPV vaccination programme began in Ireland.

Ireland began its Gardasil vaccination program in 2010 and the mainstream media has thrown its full weight behind it, hailing it as a panacea that will bring an end to cervical cancer in the country.

About three hundred Irish women are diagnosed with cervical cancer annually and there are about ninety deaths.

There are now, however, at least 450 young girls who were active and healthy before they had their Gardasil shots, but now suffer debilitating, chronic cluster symptoms.

R.E.G.R.E.T was formed by a group of parents whose daughters were suffering similar adverse reactions after HPV vaccination.

After a TV3 documentary "Cervical Cancer Vaccine: Is It Safe?" was broadcast, more parents contacted the group and, before long, R.E.G.R.E.T was supporting more than four hundred families.

"The primary goal of the parents in the group is to get help for their daughters who, like many girls around the world, have experienced 'Reactions and Effects of Gardasil Resulting in Extreme Trauma'," R.E.G.R.E.T. says.

"Many are not receiving effective medical treatment and cannot attend school regularly due to the debilitating health conditions they still suffer from."

R.E.G.R.E.T members prioritise raising awareness about the safety issues surrounding HPV vaccination "so that other parents can be in a position to make a truly informed decision on this issue".

Gardasil 9 is not yet available in Ireland, but is expected to be introduced into the country's vaccination programme in the near future.

A life turned upside down

One of the Irish teenagers who went unconscious during the Dublin protest is Georgia Tysom.

> When she comes around she's fine."

Her mother, Debbie Sargent Tysom, told Changing Times that her daughter has been having seizures since about six months after her third Gardasil vaccination in June 2016.

"They last anything from twenty minutes to three hours and are happening in all kind of places about once a week without any warning, except a pain in her chest and sometimes numbness in the legs," Debbie said.

"She's unconscious, but she shakes and her eyes are open.

Debbie says that hospital doctors have told her that Georgia is not having seizures or fits because her vital signs remain stable. Georgia has even been told that, when she passes out, the cause is psychological.

"I call them seizures even though the doctors don't," Debbie said. "A psychiatrist has confirmed that this is not Georgia seeking attention; that this is not all in her head."

Georgia first passed out on Christmas Eve, 2016. "That was a real shock," her mother said. "I thought she had just fainted. She was in the city centre, shopping with me. Then she passed out in school and that was for an hour and a half. An ambulance was called and she was taken to hospital and kept in for ten days."

During Georgia's ten-day stay in hospital doctors carried out electrocardiograms (ECGs) and electroencephalograms (EEGs), which evaluate electrical activity in the brain, and put Georgia on heart monitors.

"They say she is fit and healthy," Debbie said.

Now Georgia is waiting for a date to go to the main Beaumont hospital in Dublin, where she will be on 24-hour EEG monitoring for five days.

In May this year, Georgia saw a specialist and doctors attempted, to no avail, to induce a seizure. She was told that she was not suffering epileptic seizures because she would not have survived such a seizure if it lasted more than 15 minutes.

"When she passes out her heart rate is fine, her bloods are fine, and her pulse and and breathing are fine," Debbie said.

Georgia says that most of the time when she comes around from passing out she feels fine, but sometimes she feels very sleepy.

Georgia missed part of her fifth year at school, and more than half of her sixth year, because she was passing out so frequently.

She has just started a new college course in travel and tourism management, so is feeling less in limbo. She is very athletic and loves Gaelic football. She still plays, but her activity is limited by her condition.

"Georgia was due to take part in trials to play for the Dublin Gaelic Athletic Association, but she can't now because she passes out," her mother said.

"It's got to the stage now that, when she passes out, I don't even bring her to A&E.

Georgia (in blue and yellow).

"They don't do anything for her, because they're so used to her now. When she is passed out, they keep an eye on her, then, when she wakes up she's pushed down a corridor out of the way and we're left there for hours.

"I sat there one night with her for 22 and a half hours, then they came and said 'she's fine, she can go home now'."

Debbie points that Georgia, along with most of her other children, have a hereditary blood disorder, Von Willebrand (VWD) disease, so they should never have received the HPV vaccination.

VWD is a genetic disorder caused by a missing or defective von Willebrand factor (VWF), which is a blood clotting protein.

"It was only afterwards, when the seizures started happening, that I began reading up on it and children with bleeding disorders are not supposed to get the vaccine," Debbie said. "I had told the doctor about Georgia's disorder, but they still went ahead and gave her the vaccine."

Georgia Tysom

Georgia was the third of Debbie's daughters to undergo HPV vaccination. Four of them have had it and Georgia is the only one affected. The youngest girls had just one shot.

"It's like having a toddler again," Debbie said. "We don't let Georgia do anything on her own. She has to have a chaperon with her all the time. If myself and my husband are going out we need two babysitters, one for the younger kids and thensomeone there for Georgia in case she passes out."

When Georgia went to her Debs ball recently (*photo left*) her mother had to book a hotel so that she would be nearby in case her daughter passed out during the event. Luckily, she didn't.

"We went swimming two weeks ago and she passed out in the swimming pool." Debbie said. "She passed out twice in the swimming pool last year as well, so no more swimming.

"She's passed out on the Gaelic football pitch, but she won't give it up. The team is going away in October and I don't know if I can allow her to go. She's missing out on an awful lot that a teenage girl should be doing. Out of fear of her passing out, we can't let her do what she should be doing."

Georgia puts on a brave face, but she says it is scary not knowing when or where she might pass out.

"It's a pain having to be followed around by my mum or my dad, or my brothers and sisters. I have to watch what I do, where I go, and what I wear; no necklaces, for example.

"And it's annoying not being able to go out and make new friends. Not many people know what to do if I pass out and so many people panic when it happens."

#whataboutus

Irish mothers of girls injured by HPV vaccination have launched a worldwide campaign under the hashtag #whataboutus, which highlights the plight not only of those injured in Ireland, but those affected worldwide.

The campaign includes graphic images of the impact of the debilitating symptoms suffered by those injured by HPV vaccination.

Karen Smyth, whose daughter Laura is still suffering severely debilitating adverse effects that started after HPV vaccination, says one of the aims of the campaign "is to point to the utter disregard shown towards these young girls by our health authorities, who are now pushing boys into the programme without even investigating what is happening to our daughters".

She added: "The contempt and abuse levelled at our families for daring to speak out is unprecedented."

Smyth said during the Dublin protest: "All we want is help for our children and that other parents know the full risks before they sign the consent form.

> "I now know that, when I gave consent, the Gardasil HPV vaccine was a black triangle[6] product. I was not told that at the time. That means it's under scrutiny for post-marketing surveillance."

Smyth says that Laura's adverse effects were never reported "even though she was sent home from school by the public health nurse on each of the three occasions that she was vaccinated".

She says that the mothers of girls injured by HPV vaccination want a proper treatment protocol put in place to help them recover.

"Those treatment protocols are available in other countries, but the HSE are doing nothing for us here."

The HSE, Smyth says, is withholding information from the public. There are, she says, more than twenty possible side-effects listed in the patient information leaflet for Gardasil that the public are not being made aware of.

R.E.G.R.E.T says the information provided by the HSE about HPV vaccination is "incomplete and biased, downplaying the safety issues while exaggerating its effectiveness".

The HSE says that it is providing the public with all necessary information and tells people where to go if they want to know more. The message from the HSE is the same as that of most health authorities around the world, and the WHO: that HPV vaccination is totally safe.

"Gardasil HPV vaccine is safe and effective and will prevent girls from developing cervical cancer in the future," the HSE says on its website. It tells the public that the effects of Gardasil are "mild and short lasting" and that there are no long-term side effects.

Karen Smyth says Laura used to be a normal, active girl but, after receiving her first Gardasil shot in 2010, when she was 12 years old, she started to complain of dizziness, headache, nausea, joint pain, memory loss, and extreme fatigue. Her condition worsened after her second and third vaccinations to such an extent that she missed out on almost her entire second-level education.

"She didn't get a chance to go to university and missed out on all the things a young person should experience," Smyth said.

Dublin symposium

The Dublin symposium that took place in April this year was organised by the International Federation for Injured Children and Adults (IFICA).

The HSE refused to attend the event, and there was no mainstream media coverage.

The HSE also rejected the invitations for a private meeting with IFICA group members and doctors speaking at the conference.

Ireland's Health Information and Quality Authority sent one delegate to the symposium, but there were no representatives from the Department of Health, the Department of Education, or the Department of Children, and no ministers or TDs (members of parliament) attended, despite being invited.

The founder of the Jack & Jill Children's Foundation, Jonathan Irwin, was one of the speakers at the Dublin symposium. His daughter Molly was a competitive show jumper, but became bedridden after she received a HPV vaccination at the age of 16. Irwin stepped down from his position as a CEO to care for her.

In his opening presentation, Irwin addressed himself to the HSE. "What I find extraordinary in this situation is the vilification; we never expected to become the object of actual hatred," he said.

> "We are faced at this moment with a trail of destruction. We expected you to help us, but instead we have been called 'emotional terrorists' by the head of our own health authorities."

Irwin describes HPV vaccination as a "disaster" and says it should never have been included in the national programme.

He has called on the health minister to review the HPV vaccination programme and is opposed to plans to extend it to boys.

Molly became ill six weeks after being given the HPV vaccine. She began getting severe headaches and developed brain fog. She had to be home schooled and could no longer get on a horse.

Irwin says that tests conducted in Germany and the US have shown that Molly had mercury and aluminium in her bloodstream

Molly's health has been improving very slowly, but Irwin says they feel abandoned by the health authorities.

Other speakers at the symposium included Karsten Viborg, who spoke about the treatments being given to Gardasil-injured girls in Denmark.

Viborg's daughter, Rikke, suffered an adverse reaction to Gardasil.

Trolls worldwide dismiss those who question vaccine safety as being against vaccination, Viborg says. He points out that he, his son, and his daughter are all fully vaccinated, "so we can't be called anti-vaxxers".

The vaccine industry, Viborg told the symposium, is manipulating information. "We don't get a clear picture," he said.

Viborg says his daughter became an invalid in 2011 after HPV vaccination in 2010. Before the vaccination, he says, she was very active in sports. She played handball and was a scuba diver.

After her HPV vaccination, she started to have severe chronic headaches and fainted frequently without any warning and had more than thirty different symptoms.

"She started to get brain fog, blurred vision, and blurred hearing," Viborg said. "She had paralysis from her hips down, and insomnia."

In February 2011, Rikke was examined by a doctor. "Her heart, lungs, blood pressure, everything was normal. Then, less than half a year later, everything was absolutely abnormal. Her heart rate, her blood pressure, everything was going up and down."

For three years, Rikke was absent from school 70 percent of the time.

"Being a teenager, not going to school, not socialising with everyone, that was really, really hard for her," Viborg said.

From 2011 to 2013, they were at the university hospital every week. Rikke would faint while crossing the road and people would call an ambulance.

It was only in 2013, when Viborg heard about many other girls with the same symptoms, that he realised that HPV vaccination must have been the cause.

"Proper information is not provided," Viborg told symposium attendees. "Much is being hidden. We don't know what the risk is so how can anyone say the risk/benefit ratio is OK. Who is actually deciding that?

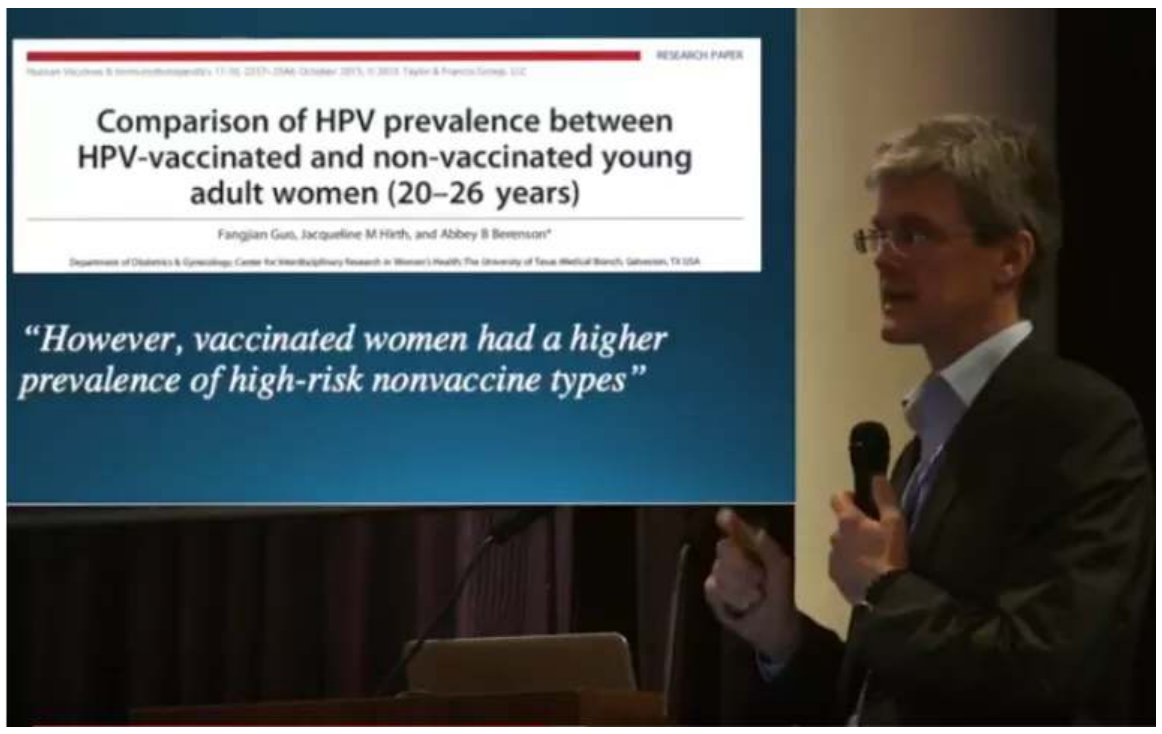
> "There's no standard procedure for approving vaccines. It's all decided by the manufacturer. And at the same time the manufacturers don't have any liability for their products. That's scary."

The risk of dying from cervical cancer before the age of 75 is 0.2 percent, Viborg says.

He also points to the FDA's own evidence that if you already have HPV when you receive a HPV vaccination your risk of developing high-grade precancerous lesions increases by 44 .6 percent.

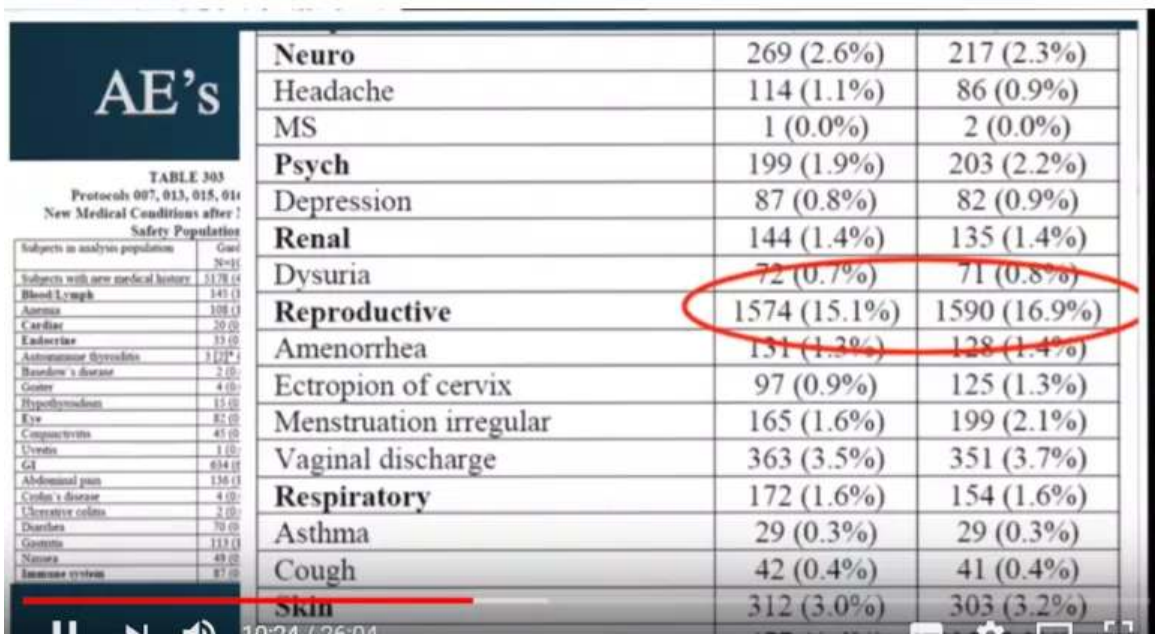
"Who tested you to see whether you had a HPV virus at the time you got vaccinated? No one."

Viborg says research has shown that when women aged 20 to 26 are vaccinated against two of the high-risk types of HPV, there is a higher than usual prevalence of infection with other types of HPV.



Viborg said that, during clinical trials, those injected with Gardasil suffered new medical conditions, including high rates of reproductive disorders, after the seventh month.

"Ovarian damage was 14 times higher in the group that received the HPV vaccine compared to those who didn't," he said.



In Denmark, Viborg says, 2,563 people have reported side-effects to HPV vaccination. They reported 23,494 symptoms and two deaths. About half of the adverse events reported were serious.

Adverse effects not included in trial data

Kesia Lyng from Denmark told the Dublin symposium how she participated in the Gardasil "FUTURE 2" clinical trial in 2002 when she was 18 years old and how her debilitating side effects were not included in the trial data.

Lyng had received a letter inviting her to participate in the trial. "It described this revolutionary vaccine that could prevent cervical cancer," she said. "I found it very intriguing and very exciting.

"Six months earlier, my grandmother had passed away from cervical cancer. It had been a big loss for my family. It had been a nasty fight ..."

Lyng said she was told that the trial was an efficacy study and that prior safety studies had shown that there were no side effects other than a little stinging and redness at the injection site.

She said she felt it was safe to participate. She was a student so welcomed the 54 euro she received at each hospital visit for the study.

Lyng, who discovered when the trial was unblinded in 2007 that she was in the cohort of girls who received the actual vaccine, was given her first Gardasil shot in September 2002. "There was a big requirement that we had to be healthy," she said.

She felt unwell after the first shot. In November 2002, she had her second shot and again felt unwell, and dizzier than after the first injection.

> "After two weeks I started noticing that I became much more tired. I woke up in the morning with aches in my body and my muscles. My joints would just feel stiff and weak and I started having a headache that I had never experienced before.
>
> "It was like a helmet being pulled over my head and nothing would help. It wasn't a migraine because it was on both sides."

Later Lyng started having difficulty falling asleep and staying asleep.

When going for her third Gardasil shot, Lyng was nervous. She told the hospital staff about her symptoms, but felt she was not listened to. "They didn't note down what I told them," she said. No diagnostic tests were carried out.

After her third injection, Lyng immediately felt much worse. She was so tired she had to quit school. Hospital staff involved in the trial told her that the vaccine was safe and her symptoms must have been caused by something else.

Lyng married and had two children. Dealing with her symptoms became much more difficult because she had more responsibilities. "It was like running marathons several times a day," she said. "It was a really, really rough time and my doctor was at a loss about what to do."

In April 2016, Lyng saw a woman talking on TV about symptoms she suffered after HPV vaccination and realised that their stories were exactly the same.

She felt utter relief when she met Jesper Mehlsen in 2017 and got some answers.

When a Danish journalist managed to get hold of the trial protocols, Lyng discovered that her symptoms had not been registered. Only her medical history before vaccination was recorded.

"They only had to register the first 14 days after each vaccination," Lyng told delegates in Dublin. "If I were to faint on the 16^{th} day and keep fainting, they didn't have to register it as a side effect."

Lyng said she felt outraged. "They had my health in their hands," she said.

She is also angry that what she thought was an efficacy study was later referred to as a safety trial. "That was not what I signed up for. That was not what I was told."

Lyng was visibly upset as she told symposium attendees how heartbreaking it had been for her to see so many other young girls going through the same thing she had gone through, "being betrayed by the authorities and their doctors", and not receiving any help.

Extension of HPV vaccination to boys

The argument for vaccinating boys is that it will help to prevent anal and throat cancers in men and help prevent men from passing on HPV to their partners.

HPV vaccines have not, however, been approved for the prevention of throat cancer.

It has been pointed out that Ian Frazer used to be on the clinical and scientific board of the Scottish charity, the Throat Cancer Foundation, which has been running a "Jabs For The Boys" campaign.

Frazer and his Gardasil co-creator Jian Zhou both earn royalties on sales of the vaccine.

Margaret Stanley, who is a consultant for Merck, is still on the Throat Cancer Foundation's advisory board.

In July 2017, the JCVI said that extending the HPV programme to adolescent boys would not be a cost-effective use of health service resources in the UK and it was unable to recommend such an extension.

In its interim statement, it said the additional benefits gained from extending the programme to adolescent boys would be small, relative to the impact of the girls programme.

A year later, the committee changed its mind and recommended that HPV vaccination be extended to boys.

The British charity, the Terrence Higgins Trust, which campaigns about, and provides services relating to, HIV and sexual health, welcomed the JCVI's recommendation, but there are concerns that the desire for "gender equality" in HPV vaccination will lead to more vaccine injury without any benefits in terms of protection.

In its statement in July this year, the JCVI said: "There is evidence of benefit in vaccinating boys and a gender neutral programme would provide resilience against short-term fluctuations in uptake as well as offer the prospect of better control of the main cancer causing types of HPV."

The committee said that, using standard economic methodology, the findings of modelling work at Warwick University predicted that extending the HPV programme to adolescent boys would not be cost-effective.

It decided, however, that "because of the long natural history of HPV-associated disease" the discount rate used to make its calculations should be changed from 3.5 percent to 1.5 percent.

The discount rate is the rate that Britain's Department of Health and Social Care uses to calculate the level of health benefits that a vaccination might confer to people throughout their lives.

"This lower discount rate would better take into account the longer term impact of HPV vaccination in cancer prevention, and the life years lost to cancer," the committee stated.

> "Using a 1.5 percent discount rate it is likely that a gender neutral programme would be cost-effective, and on the basis of these findings JCVI would advise extending immunisation to adolescent boys."

The committee added: "If considering a cost-effectiveness analysis where a combined girls' and boys' programme is compared to no vaccination, gender-neutral HPV vaccination is highly likely to be cost-effective."

In Ireland the Health Information and Quality Authority (HIQA) is undertaking a health technology assessment (HTA), at the request of the Department of Health, about extending HPV vaccination to

boys.

A spokesperson for the health department said the HTA would establish the clinical benefits and cost-effectiveness of providing the vaccine to boys and would also provide advice on how it should be implemented.

The HIQA has undertaken public consultation on the draft HTA, which ended on September 7. The completed assessment will be submitted to the Minister for Health and the HSE.

A private member's motion calling on the Irish government to extend the vaccination programme to boys was presented in the lower house of parliament, the Dáil, on March 28 this year, and was accepted on condition that the HIQA recommends it.

"Both the Minister for Health, Simon Harris, and the Minister of State for Health Promotion, Catherine Byrne, indicated during the debate that, subject to a favourable recommendation from the HTA, the government will seek to extend this vaccine universally as a priority," the health department spokesperson said.

R.E.G.R.E.T members were shocked when Harris announced on radio yesterday (Wednesday), ahead of the HIQA's final assessment, that HPV vaccination would be extended to boys in 2019.

Head and neck cancers

Emotive headlines such as "HPV jabs will be offered to thousands of teen boys on the NHS as well as girls to protect against deadly cancer virus" (in Britain's Daily Mail) dominate the debate about extending HPV vaccination to boys.

Health authorities in Britain and Ireland are vaunting, without proof, the purported ability of HPV vaccination to prevent head and neck cancers.

The Oral Health Foundation expressed its delight at the extension of HPV vaccination to boys and enthused: "The charity sees this as a huge step in reducing the number of mouth cancer cases in Britain and is calling for a quick implementation of the programme to help save lives."

Gardasil is, however, only approved for "the prevention of cervical, anal, vulvar and vaginal cancers caused by the human papilloma virus". Other uses are all off-label.

In Ireland, the head of the HSE's National Immunisation Office, Brenda Corcoran, has said "the expectation is that the vaccine will protect against all head and neck cancers and all HPV-related cancers which both boys and girls get".

Sin Hang Lee, says this is "just a great expectation".

Lee says that, since head and neck cancers were not part of the scope of the clinical trials for Gardasil, Corcoran's claim falls under the category of "off-label marketing" and should not be used as the basis for making health care policies.

Cervical screening

In its comments about extension of HPV vaccination to boys, the JCVI said there might be additional future savings in the cervical screening programme.

There is significant concern that increased use of HPV vaccination will lead to a reduction in cervical screening.

Australia has already introduced a new five-yearly HPV test for women aged 25 to 74 that replaces the two-yearly Pap tests that used to be carried out on women aged between 18 and 69.

According to Australia's Department of Health, the new test is more effective than the Pap smear at preventing cervical cancers, "because it detects HPV, whereas the Pap test looked for cell changes in the cervix".

Australian writer Helen Lobato, who has written a book entitled Gardasil: Fast-Tracked and Flawed, asks, however, why the successful Pap smear programme is being replaced with an HPV test "when we don't know if HPV is the cause of cervical cancer".

Australian GP Deirdre Little points out that the Pap smear programme in Australia reduced cervical cancer by about 70 percent.

In a paper published in August last year, George Koliopoulos et al. said that, for every one thousand women screened, about twenty women will have precancerous changes.

The HPV test, they said, would correctly identify 16 of these twenty women and would miss four while the Pap test would correctly identify 12 women and miss eight of them.

"For women screened who will not have precancerous changes (980), the HPV test will correctly identify 879 women and 101 women will be incorrectly told that they have a lesion while the Pap test will correctly identify 951 women and 29 will be incorrectly told that they have a lesion.

> "Women who are incorrectly told that they have a lesion may have their cervix examined or may receive surgery unnecessarily."

Simultaneous HPV and Pap testing (co-testing) is used for primary screening in the US and Canada. "It would be useful," G. Koliopoulos et al. said, "to compare the accuracy of co-testing to HPV testing alone in another meta-analysis.

"Another important issue is that most of the studies were performed before the introduction of the HPV vaccine. It will be interesting to study how the accuracy of of the two tests compares in a widely vaccinated population."

Age extensions

Delegates at this year's annual conference of the British Medical Association (BMA) voted overwhelmingly in favour of a motion that called for HPV vaccination to be offered to "all school-age children of both sexes and administered at primary school to be more effective".

Currently, in Britain, HPV vaccination is carried out on girls aged 12 and above.

In the US, the FDA has accorded "priority review" status to Merck's application for approval to extend the use of Gardasil 9 to include vaccination for women and men aged 27 to 45.

Merck states that HPV causes virtually all cervical cancer cases.

"Each day, about 36 women are diagnosed with cervical cancer in the United States – about 13,200 women per year. HPV also causes approximately 70-75 percent of vaginal cancer cases and approximately 30 percent of vulvar cancer cases in females, and approximately 85-90 percent of anal cancers and 90 percent of genital warts in both females and males," the company states.

Citing American Cancer Society statistics, Merck says that an estimated 2,960 men and 5,620 women in the US will be diagnosed with anal cancer in 2018, and overall rates have been increasing.

Merck says that, after HPV types 16 and 18, the five additional HPV types in Gardasil 9 are the most common types of HPV that cause cervical cancer

The company states: "Seven HPV types in Gardasil 9 (HPV 16, 18, 31, 33, 45, 52 and 58) cause approximately 90 percent of cervical cancer cases and approximately 80 percent of high-grade cervical lesions (cervical precancers, defined as CIN 2, CIN 3 and AIS) worldwide."

It further states that these seven HPV types also cause 90 percent of HPV-related vulvar cancers, 85 percent of HPV-related vaginal cancers, and 90 percent of HPV-related anal cancers.

"HPV types 6 and 11 cause approximately 90 percent of genital warts cases. In addition, approximately 50 percent of cases of low-grade cervical lesions (CIN 1) are caused by the nine HPV types included in the vaccine," Merck states.

Merck admits that the safety and effectiveness of Gardasil 9 have not been established in pregnant women.

The company also admits that, in most cases, HPV clears by itself. "In the United States, human papillomavirus (HPV) will infect most sexually active males and females in their lifetime. According to the CDC, there are approximately 14 million new genital HPV infections in the United States each year, half of which occur in people 15 through 24 years of age.

"For most people, HPV clears on its own, but for others who don't clear the virus it could lead to certain cancers and other diseases in males and females. There is no way to predict who will or won't

clear the virus," Merck states.

Aluminium in placebos

In a new book about HPV vaccination, "The HPV Vaccine on Trial: Seeking Justice for a Generation Betrayed", the authors – Mary Holland, Kim Mack Rosenberg, and Eileen Iorio – state that Merck used "fauxcebos" – or false placebos – as controls in the Gardasil trials, with the FDA's blessing. They say that none of the participants in HPV vaccine clinical trials received a true saline placebo.

"These fauxcebos appear to have masked Gardasil's ill effects," the authors state. "For all but a few hundred clinical trial participants, Merck used AAHS, Gardasil's aluminum-containing adjuvant, as the primary control.

> "AAHS is an active ingredient that boosts the immune system to enhance the vaccine's effect. Only one small group of approximately six hundred 9- to-15-year-olds in Protocol 018 received something other than AAHS. But they didn't receive saline, either.

"It looks like they got an active 'carrier solution' fauxcebo, which contained everything in the vaccine except the VLPs [virus-like particles] and AAHS."

However, when the FDA approved Gardasil, it described the Protocol 018 control as a "true saline placebo", Holland, Rosenberg, and Iorio point out.

They add that GSK had no saline placebos in its clinical trials.

"GSK's Cervarix vaccine used a novel and proprietary adjuvant called 'Adjuvant System 04', or 'AS04' for short.

> "This adjuvant system includes aluminum hydroxide and a substance that has a potent immune system effect called MPL. In the clinical trials, GSK used fauxcebos, including unlicensed vaccines, and different adjuvants as 'controls' to assess Cervarix's safety."

In an article published in "Collective Evolution" in December last year, the renowned lawyer and environmentalist Robert F. Kennedy Jnr wrote: "One does not have to be a scientist to understand that using aluminium-containing placebos is likely to muddy the comparison between the treatment and control groups."

Kennedy (*pictured left*) points out that critics of HPV vaccination have pointed to the aluminium adjuvant as the most likely cause of adverse reactions, and some researchers have questioned the safety of using aluminium adjuvants in vaccines at all, given their probable role as a contributor to chronic illness.

"The aluminium-containing placebos appeared to provoke numerous adverse reactions among the presumably unwitting patients who received them, allowing the pharma researchers to mask the cascade of similar adverse reactions among the groups that received the vaccines," Kennedy wrote.

> The National Vaccine Information Center said in a statement in June 2006: "A reactive placebo can artificially increase the appearance of safety of an experimental drug or vaccine in a clinical trial.

"Gardasil contains 225 mcg of aluminium and, although aluminium adjuvants have been used in vaccines for decades, they were never tested for safety in clinical trials. Merck and the FDA did not disclose how much aluminium was in the placebo."

Kennedy says Merck found that "astronomical casualty counts" were equal among both Gardasil and aluminium "placebo" recipients.

"The inescapable implication is that aluminium adjuvants may be a principal culprit in the flood of injuries reported for the various HPV vaccines."

In their article published in the journal Clinical Rheumatology in October 2017, Mexican researchers Manuel Martínez-Lavin and Luis Amezcua-Guerra also highlight the fact that Merck used placebos containing aluminum or other aluminum-adjuvanted vaccines.

"Two of the largest randomized trials found significantly more severe adverse events in the tested HPV vaccine arm of the study," the researchers wrote.

A total 2,871 women received the aluminium placebo, and 2,881 women were injected with the bivalent HPV vaccine, Cervarix.

The group receiving the vaccine had more vaccine-related general symptoms during the seven-day post-vaccination period and a four-fold increase in the death rate, the researchers state.

When compared with the quadrivalent formula, the nine-valent HPV vaccine was associated with significantly more severe local swelling, more vaccine-related systemic adverse events, and more serious systemic adverse events.

"These disparities suggest that HPV immunization adverse events may be dose-dependent," the researchers state.

"Practically, none of the serious adverse events occurring in any arm of both studies were judged to be vaccine-related," they said.

Martínez-Lavin and Amezcua-Guerra critically reviewed the adverse events described in HPV vaccine pre-licensure randomised studies and in reports of post-marketing cases.

They referred to adverse events reported after vaccination with Cervarix, quadrivalent Gardasil, and Gardasil 9.

They found that, in Spain, there was a ten-fold higher incidence of vaccine-related adverse events after HPV vaccination as compared to other types of vaccination.

Martínez-Lavin and Amezcua-Guerra found that, in Alberta, Canada, one in ten previously healthy girls needed to visit a hospital emergency department within 42 days of receiving a HPV vaccination.

"HPV vaccine post-marketing safety studies done in Valencia, Spain, and Alberta, Canada, endorsed HPV vaccine safety. Nevertheless, these investigations contain disquieting findings," the researchers wrote.

> "It seems perilous to blame bad press for the ten times higher than expected HPV vaccine adverse events notification by Valencian doctors and nurses."

Martínez-Lavin and Amezcua-Guerra compared approximately 14,000 women who received either Gardasil 9 or quadrivalent Gardasil.

They calculated the likelihood of being "helped or harmed" by Gardasil 9 and found that the number needed for harm to be caused was just 140, whereas 1,757 women would need to receive the vaccine for one of them to enjoy its projected benefits.

The researchers stated that, "at this stage of knowledge", it seemed premature and risky to propose any pathogenetic mechanism linking HPV vaccination to the purported adverse events.

"Based on our previous fibromyalgia research, we speculate that in susceptible individuals, the HPV virus-like particles and/or aluminum adjuvant may be neurotoxic, damaging the dorsal root ganglia and triggering dysautonomia and small fiber neuropathy.

"The recent case reports describing antibodies to different autonomic nervous system receptors in patients that became ill after HPV immunisation go along with this hypothesis."

The researchers criticise the authors of the various post-marketing studies about HPV vaccination for failing to ask essential questions, to evaluate the many serious adverse events, or to elaborate on their often-troubling findings.

Both pre-licensure randomised trials and post-marketing independent reports describe similar clusters of adverse events symptoms, including headache, fatigue, dizziness, musculoskeletal pain, and gastrointestinal symptoms, Martínez-Lavin and Amezcua-Guerra state.

> "In the post-marketing studies, this cluster of symptoms was labelled with different diagnoses such as complex regional pain syndrome, chronic fatigue syndrome, fibromyalgia, or postural orthostatic tachycardia syndrome."

When looking at these diagnoses separately, HPV vaccine safety signals may be diluted, Martínez-Lavin and Amezcua-Guerra say.

> "This possible post-marketing HPV vaccine adverse reaction under-recognition is reinforced by the recent WHO VigiBase report.

"Symptoms clusters of headache and dizziness with either fatigue or syncope were found to be more commonly described, and more severe, in HPV vaccine reports compared with non-HPV vaccine reports for females of similar age."

Only a minority of reports contained specific diagnoses to explain these symptoms, the researchers say.

Kennedy says that, typically, the FDA requires drug companies seeking approval for a new drug to observe health outcomes in both the placebo and study groups for 4-5 years.

> "Vaccine manufacturers take advantage of FDA regulatory loopholes that allow fast tracking of vaccines and cut that period down to a few weeks or even a few days.
>
> "This means that injuries that manifest, or are diagnosed, later in life – most neurodevelopmental disorders, for example – will escape attention entirely."

Kennedy points out that, according to the National Institutes of Health, an estimated 2.4 women per 100,000 die of cervical cancer in the US each year.

FDA statistics, he adds, indicate that 2.3 per 100 girls and women developed an "incident condition potentially indicative of a systemic autoimmune disorder" after enrolling in the Gardasil clinical trial.

> "It is difficult to understand how any rational regulator could allow more than two in 100 girls to run the risk of acquiring a lifelong autoimmune disorder, particularly when Pap smears are already doing an effective job of identifying cervical abnormalities," Kennedy wrote in "Collective Evolution".

The NIH notes that the incidence and death rates for cervical cancer in the US declined by more than 60 percent, after Pap smear screening was introduced, he explains.

> "Even in countries such as India, where cervical cancer mortality is high due to late detection, leading Indian physicians argue that comprehensive screening should be the country's top priority rather than the 'panacea' of HPV vaccination."

Gardasil in Japan

Press conference by 64 Japanese women suing over injury they allege is from HPV vaccination.

On June 14, 2013, the Japanese government halted proactive recommendation of HPV vaccination, stating that it could not provide the public with sufficient information to recommend it.

To mark the five-year anniversary of that decision, a group comprising the National Plaintiffs Association for the HPV Vaccines Lawsuits in Japan, the National Attorneys Association for the HPV Vaccines Lawsuits in Japan, and other representatives issued a statement.

They said that, compared to other routine vaccinations, an average of more than seven times the number of serious adverse effects had been reported per one million HPV vaccinations, and the number of disability certifications by the Adverse Drug Reaction Relief System was almost ten times higher.

"The government officially endorsed the HPV vaccine nine years ago, and many of the victims who were junior or high school students at the time of their HPV vaccination have now grown into adults," the group stated.

Those injured had received no effective medical treatment and suffered from serious adverse effects that included pain all over their bodies, involuntary movements, perceptual disorders, impaired mobility and memory, sleep disruption, and learning disabilities.

> "While their classmates became working adults, they have been incapable of fully attending classes and have abandoned their plans for higher education or getting a job," the group said.

The group cited several studies, one of which indicates that a range of adverse effects to HPV vaccination develop in a multi-layered manner over an extended period of time.

Another study reported changes in cerebrospinal fluid, cerebral blood flow, and peripheral nerves.

In a third study, researchers said that, in vaccinated mice, HPV vaccination causes impaired mobility and other adverse effects and that this is due to neurological damage.

A fourth study indicated that individuals develop chronic ailments soon after receiving HPV vaccination.

The group referred to a paper written by researchers from the WHO Collaborating Centre for International Drug Monitoring, in which the researchers argue that previous signal evaluations and epidemiological studies have relied primarily on the reporting of a specific diagnosis or a single-symptom concept.

The researchers said a focus on symptomatology and seriousness in combination with an investigation of the underlying pathology may be required to fully elucidate the safety signals.

The Japanese representatives say that the WHO's Global Advisory Committee on Vaccine Safety and other authorities may have declared HPV vaccination to be safe, but the epidemiological studies they rely on were not conducted with proper understanding of the adverse effects of HPV vaccination and cannot be a basis for confirming safety.

> "It has also become clear that there are conflicts of interests and a lack of neutrality in the WHO," the group said.

The overall rate of HPV vaccination in Japan had dropped to less than 1 percent, and few new cases of adverse effects had been reported from clinical practices, the group added.

The lawsuit representatives say that, while the government updated its HPV vaccine leaflets in January this year, those intended for girls due to be vaccinated and their parents intentionally omit the risk of impaired memory and learning disabilities, thereby delivering misleading information to the public.

> "Far from resuming proactive recommendation of the HPV vaccine, what the government must do now is to remove the HPV vaccine from its routine vaccination list," the representatives said.

Tokyo symposium

Representatives of victim support groups from Britain, Spain, Ireland, Colombia, and Japan participated in an international symposium held at the University of Tokyo in March this year, and, in April, they published a joint statement calling for a fact-finding investigation to be carried out, and for the development of treatment methods and support for the daily life, education, and employment of those injured by HPV vaccination.

The groups stated that the clinical features of adverse effects were "common to victims in all the five participating countries and also very similar to those of victims in other countries", and the number of adverse effects reported for HPV vaccines in each of the individual countries were "overwhelmingly higher than adverse effects for other vaccines".

Despite this, the groups say, national health authorities and medical professionals "continue to deny any causal relationship between HPV vaccines and adverse effects, using a fundamentally flawed epidemiological argument not designed to detect the signals of HPV vaccine damage".

Because adverse effects are reported with long incubation periods, "they are denied any connection with the vaccine, and the cases displaying diverse symptoms are diagnosed as separate known illnesses", the groups say.

They cite the following adverse effects:

- systemic pain, including headache, myalgia, and arthralgia;
- motor dysfunction, such as paralysis, muscular weakness, involuntary movement, and seizures;
- numbness and sensory disturbance;
- autonomic symptoms, including dizziness, hypotension, tachycardia and diarrhoea;
- respiratory dysfunction;
- endocrine disorders, such as menstrual disorders and hypermenorrhoea;
- hypersensitivity to light and sound;
- psychological symptoms, such as anxiety, hallucinations, and suicidal tendencies; and
- sleep disorders, including hypersomnia and narcolepsy.

In many cases, the groups say, these symptoms impair learning and result in extreme fatigue and decreased motivation.

The vice-chairman of the UK Association of HPV Vaccine Injured Daughters (AHVID), Steve Hinks, said the groups' statement was a "testament to the very high number of girls and boys around the world who are suffering the same, severe, long-term disabling side-effects because of this vaccine, despite there being no evidence yet that it will prevent a single case of cancer".

Hinks pointed out that the WHO's global database reported more than 305,000 adverse effects for HPV vaccines, which was far higher than for any other vaccine. "These cannot all be a coincidence," he said.

According to the WHO's global database, 85,120 adverse effects have been reported since 2006. The largest number (27 percent) were reported in 2010. Fifty-five percent of the reports were in the Americas.

Speaking for R.E.G.R.E.T, and representing Ireland at the Tokyo symposium, Anna Cannon said: "The Tokyo symposium and the joint statement highlight how the same neglect of the HPV vaccine victims is experienced in each country represented.

"It's time that we come together to find urgent resolutions for those affected."

Cannon said that the Dublin and Tokyo symposia, held in quick succession, highlighted "the global nature of what has become an HPV vaccine emergency" and underlined the urgent need to find worldwide solutions.

The groups called on the media "to raise awareness of the dire consequences of this critical social and healthcare issue".

They called on governments, vaccine manufacturers, and healthcare experts to take a series of actions:

- conduct a protracted follow-up study, by a neutral third party, of the health status of all those who received the HPV vaccines;
- promote research to develop effective therapies to treat the side-effects of HPV vaccination;
- provide treatment, and support HPV vaccine victims in their daily activities, education, and employment;
- disseminate information about all possible side effects, in the form of a Patient Information Leaflet to be given to children, adolescents, and parents so that they can make an informed decision about HPV vaccination "based on fundamental human rights to informed consent";
- cease all advertising campaigns that promote HPV vaccination without highlighting the full risks;
- suspend the recommendation of HPV vaccines for routine immunisation, until a safer system is established ensuring that serious side-effects are avoided; and
- refrain from actions "that discriminate against, or slander, victims of HPV vaccination".

The groups at the Tokyo symposium described the social treatment experienced by the victims of HPV vaccination as "deeply disturbing".

They said that, across all countries represented at the symposium, the treatment of victims was found to be similar.

> "Health authorities and medical professionals in all participating countries deny any causal relationship with the vaccine and regard post-vaccination adverse effects as either psychogenic in nature, a form of functional disability, or malingering disorders.
>
> "As a consequence, victims of the HPV vaccines have to endure not only physical suffering but also emotional distress, as they are often abandoned without recourse to adequate medical treatment."

Victims in other countries not represented at the symposium have been treated in the same way by their health authorities, the groups state.

> "Moreover, despite the fact that the victims and their parents consented to the HPV vaccine … they are now accused of being an 'anti-vaccination group'."

The groups said that proponents of HPV vaccination had shown no interest in correlating victim's symptomatology and vaccine-induced adverse effects.

> "Studies of CRPS, CFS, and POTS, which call into question the safety of HPV vaccines, have been excluded on the grounds that the diagnosis is difficult and lacks specificity.
>
> "On the other hand, the authorities argue that vaccine safety has been fully established through epidemiological analysis."

Cannon says that, together with the Irish HSE, the Irish Cancer Society (ICS) is leading the campaign in pushing for HPV vaccination.

"In the second half of 2016, they directly lobbied 130 Irish politicians. They also organised public information evenings around the country and, one month after the lobbying campaign ended, Merck gave the ICS a $100,000 donation, and this was in addition to the $100,000 donation they got the previous year, shortly after R.E.G.R.E.T was formed."

By 2017, with a huge fall in the uptake of HPV vaccination, the Irish health authorities started to take a much more adversarial approach, Cannon says.

"In the weeks leading up to the most recent round of HPV vaccinations in Ireland, the head of the HSE accused us parents of emotional terrorism. That same day the minister for health said that those who aren't medical professionals needed to 'butt out' of the conversation."

During the annual Irish medical organisation's meeting, the health minister, Simon Harris, urged Irish doctors to "come out fighting" on HPV vaccination, Cannon says.

"This fuelled a renewed hate campaign directed directly at our families and sick girls on social media."

The cases of the large group of Irish girls who are experiencing documented cluster symptoms after HPV vaccination have still not been investigated, Cannon points out.

> "The HSE is pushing the chronic fatigue syndrome diagnosis without any investigation into the girls' cluster symptoms."

Anna Cannon talks about post-Gardasil cluster symptoms.

Cannon says that, in 2015, the HPRA removed seven of the original ten columns in its report about adverse effects of Gardasil, so it became impossible to conduct comparisons with background rates and make statistical calculations.

The removed fields were the injection date, the date of notification of the adverse effect, the reaction onset date, age and gender, the date the reaction ceased, and the outcome field, Cannon says.

Irish parents say they were only told about four or five possible minor adverse effects when giving their consent to HPV vaccination.

Cannon said at the Tokyo symposium: "Many girls developed symptoms after the first dose and, if parents had been informed of the possible side effects, they could have made the connection and avoided the second and third doses, which multiplied the negative effects."

She told the story of one family in which three sisters are suffering serious adverse effects after Gardasil vaccination.

All three girls were healthy and sporty before getting the vaccination when they were 12 to 13 years old. The youngest girl, who is now aged 15, has chronic Lyme disease. After one injection in 2015, she suffered flu-like symptoms, a pityarosia rash, headaches, and other aches and pains.

The second youngest, now aged 16, suffered bad cases of hives after each of her three injections and now has Raynaud's syndrome.

The eldest, who had three Gardasil shots and is now aged 20, has chronic pancreatitis. Eighteen days after receiving her first shot, in October 2010, the girl had a severe attack of pancreatitis and was hospitalised. In the following December, she was hospitalised with suspected appendicitis, then for a blocked colon.

The young woman, whose mother prefers that she not be named, is now in a life-threatening situation and may have to have her entire pancreas removed.

There has been no investigation of her case by the HSE or the HPRA, Cannon says.

Pancreatitis

A group of doctors in Australia have drawn a link between HPV vaccination and the pancreatitis suffered by a young woman after she was vaccinated with quadrivalent Gardasil.

In a letter to the editor of the Medical Journal of Australia, published in August 2008, surgeons Amitabha Das and Neil Merrett, surgeon and researcher David Chang, and head of the Sydney-based Pancreatic Cancer Research Group, Andrew Biankin, said an extensive investigation of the case could find no other cause for the pancreatitis.

They said that, while a coincidental illness causing pancreatitis could not be ruled out, "neither can HPV vaccination be excluded as a potential cause".

They added that "the close temporal relation of the HPV vaccination, the development of a prodromal[7] illness, and fever without evidence of sepsis led us to postulate that pancreatitis was secondary to vaccination."

They suggested that pancreatitis be considered in cases of abdominal pain following HPV vaccination and, if proven, be notified to the Adverse Drug Reactions Advisory Committee.

The letter's authors tell of the case of a 26-year-old woman who experienced 24 hours of severe constant epigastric pain and vomiting four days after receiving her first HPV vaccination.

> "She had no history of similar pains, alcohol consumption, or gallstones," the authors wrote. "Two days after vaccination she developed a fever and self-limiting rash of three days' duration."

The authors said the patient was diagnosed with pancreatitis and treated with intravenous fluids and analgesia. "Pain, symptoms and biochemical abnormalities settled after 10 days," they wrote. "She was discharged and remains well."

The authors said that the pathophysiology linking vaccination with pancreatitis was unclear.

"It has been postulated that viral replication in immunodeficient hosts receiving live attenuated viral vaccines can cause pancreatitis. Alternatively, 'molecular mimicry' could stimulate production of auto-antibodies, which react with host antigens and cause autoimmunity."

The HPV vaccine is a quadrivalent, recombinant, non-infectious formulation, so this eliminates viral replication as a mechanism of pancreatitis, the authors say. "Therefore, an autoimmune mechanism is possible."

Molecular mimicry occurs when a foreign antigen, such as a viral protein or peptide, looks like human proteins or peptides and confuses the immune system.

One case of pancreatitis was cited by Bizjak, Yehuda Shoenfeld, et al. They report on the case of a 20 year-old male who developed severe abdominal pain one week after being vaccinated with quadrivalent Gardasil.

Even though he was suffering ongoing symptoms of nausea and pain, he received a second dose of the vaccine.

"Only ten days later, laboratory results revealed significantly elevated pancreatic enzymes, and with concomitant abdominal pain and vomiting," Bizjak et al state.

The patient was diagnosed with acute pancreatitis.

"This case of acute pancreatitis after HPV vaccination is not a novel entity," the researchers state.

"Although confirming the relationship between pancreatitis and vaccine is challenging, some factors suggest a possible link, they add.

These factors, they say, include the positive re-challenge upon repeated exposure to the vaccine, there being a probable causal relationship between HPV vaccination and autoimmune diseases, "and a

probable mechanism of molecular mimicry".

The researchers say that, in conjunction with the aluminum adjuvant, the induction of immunity through molecular mimicry "may potentially culminate in production of cytotoxic autoantibodies with a particular affinity for pancreatic acinar cells".

They also cite the case of a 26-year-old woman who developed epigastric pain four days after her first dose of Gardasil. The examination of the woman excluded other causes of pancreatitis, the researchers say. They concluded that the only other likely causation in a previously healthy young woman was the HPV vaccine.

A spokeswoman for the Therapeutic Goods Administration (TGA) said that, following several reports of pancreatitis in 2007 and 2008, the TGA conducted an investigation that concluded that a causal association between Gardasil and pancreatitis could not be established.

The TGA's Database of Adverse Event Notification (DAEN) contains ten reports of pancreatitis following Gardasil vaccination out of 4,258 total reports for the Gardasil quadrivalent vaccine.

Gardasil in China

In China, approval was given for clinical trials of Gardasil 9 late last year. The China Drug Administration gave the vaccine a conditional green light just nine days into its review, and gave it final approval on April 28 this year. The first Gardasil 9 vaccinations were given at the end of May.

Gardasil 9 is the third HPV vaccine approved for use in China since the middle of last year. It is approved for young women aged between 16 and 26.

Quadrivalent Gardasil was given approval in China in March last year and the use of Cervarix was approved the following July.

In China, Cervarix is being recommended for girls and women between 9 and 25 and the original Gardasil was recommended for women aged 20 to 45.

Gardasil in Australia

Gardasil was first given to teenage girls in Australia in 2007, and has been given to boys aged 13 to 15 since 2013. It was approved on June 16, 2006, for females aged from 9 to 26 years and males aged from 9 to 15 years.

Gardasil 9 became available in school-based vaccination programmes in January this year.

The new vaccine was rolled out to great fanfare and such headlines as "Cervical cancer could be eliminated in Australia within 40 years, experts say" dominate in the media.

In Australia, 4,367 adverse reactions have been reported to the TGA since Gardasil was first used in the country (up until May this year). A total 4,258 of these adverse effects are reported to be related to Gardasil, 109 to Gardasil 9, and 18 to Cervarix.

In 2,702 of the 4,367 cases there is reported to be a single suspected medicine.

Only one case is cited in which death was a reported outcome, and Gardasil is cited in that report.

While it gives no details, the report relates to the death of Gabby Larkin, on June 4, 2009, at the age of 16. She had an extremely rare form of ovarian cancer.

Gabby's mother Patrice, from Mont Albert North in Victoria, tells how Gabby was very athletic and active prior to receiving the Gardasil vaccination.

Patrice said in an interview with

Vaxxed TV that her daughter played netball and was a very strong girl, who ran on the treadmill every night.

After her first Gardasil shot, Gabby developed a headache that wouldn't go away.

About three weeks later, she developed a severe pain on the right side of her abdomen. A cancerous tumour was discovered in her right ovary. The tumour grew very quickly, and was the size of a grapefruit, Patrice says. The tumour burst, and Gabby's ovary was removed. She then underwent chemotherapy.

Patrice said her daughter died an excruciating death.

She and her husband tried to get tests done on the tumour to see if a link with Gardasil could be shown, but they failed and the case was closed.

Patrice fears that because of HPV vaccination there may even be more cases of cervical cancer in the future as girls are being given a false sense of security. "Girls are thinking that they are safe, that they don't have to have smear tests," she said.

She told Vaxxed TV that she had worried about the Gardasil vaccination as the permission form mentioned possible allergies to a list of substances contained in the vaccine. How, Patrice wondered, could she know what Gabby might be allergic to and whether there might be a risk.

Patrice said she had a very bad feeling about the vaccination as it was so new, and she wanted her daughter to at least wait 12 months before having it, but Gabby wanted the vaccination because all the other girls were having it, and believed that it would protect her from sexually transmitted diseases.

Publicity about Gardasil was everywhere, Patrice said. "It was on every five minutes on the TV … It was on every notice board you looked at, or when you turned on the radio. It was just full on."

Patrice said that, despite her doubts, the media pressure led her to feel compelled to have Gabby vaccinated. People were also being encouraged to get the three Gardasil shots for their daughters while the vaccination was still available for free.

Ashlea Smith's 15-year-old son Hunter is still seriously ill after receiving two doses of Gardasil. He had the first injection in December 2017 and the second in June this year.

"Three weeks after the second Gardasil vaccination our very fit, healthy, happy son was rushed to hospital with a sudden onset of inexplicable paralysis," said Ashlea, who lives in Queensland.

"An hour prior to first losing feeling in his right arm and right leg, he was winning the 100-metre sprint final at his athletics carnival.

"Within a few hours he was completely paralysed and incontinent."

Ashlea says doctors kept telling her that her son had suffered a dehydration migraine and that his symptoms would resolve with time.

Hunter's condition didn't improve, Ashlea says, and on the third day of his hospitalisation she asked for a magnetic resonance imaging (MRI) scan to be done on his spine.

The MRI showed multiple lesions on Hunter's spine, Ashlea says, and he was diagnosed as having the autoimmune disease Transverse Myelitis.

"Our son has no allergies or previous autoimmune disorders. He eats extremely well and was very fit. I know it has to be the Gardasil vaccination," Ashlea said.

"Ironically, we didn't allow either of our older daughters to get the vaccine because I feared that it was not safe at all. I feel so very guilty that, given everything I already knew, we allowed our son to get it."

Ashlea says her son has had to retrain the nerve pathways between his brain and his legs and hands, and has literally been learning to walk again.

"All this is heartbreaking for a young man who was so passionate about fitness and loved to snowboard," she said.

The story of Asha Stubbs, from Cairns in northern Queensland, is told in this earlier Changing Times article.

Asha received her first two Gardasil injections when she was 15 years old. When she received her third injection in July 2008, she was 16.

Two weeks after that injection, Asha was diagnosed with idiopathic thrombocytopenic purpura (ITP), a disorder that can lead to easy or excessive bruising and bleeding, which results from unusually low levels of platelets.

Asha with her mother Michelle.

When Asha was 19, the ITP turned into paroxysmal nocturnal hemoglobinuria (PNH), which is a rare and life-threatening blood disease in which red blood cells are destroyed, blood clots develop, and there is impaired bone marrow function.

About six months later Asha was also diagnosed with myelodysplastic syndrome (MDS), in which the bone marrow does not produce sufficient healthy blood cells. She was told she was in the early stages of developing Acute myeloid leukaemia (AML).

Beauty queen now a warning voice

Christy Cormack was a Miss England semi-finalist when she was vaccinated with Gardasil. The 14-year-old loved ballet and horse riding.

Now aged 23, she is a powerful voice warning of the dangers of HPV vaccination.

After her Gardasil shot, she was struggling to walk and was passing out up to eight times a day.

She told journalist Jacqui Deevoy, writing in the Mirror: "The day after the jab I was unbelievably tired. I had a terrible headache and chest pain and couldn't stay awake. Then I kept feeling numbness in my limbs."

She recalled: "They listened to my heart then immediately referred me for an ECG."

After her third Gardasil shot, Cormack collapsed.

She told Deevoy: "Some days, my chest pains would get so bad, I'd think 'This is it – I'm going to die I lost count of my trips to A&E."

A year later Cormack was skeletal, having constant blackouts, breathing difficulties, loss of vision, and digestive problems.

In her interview with Deevoy, she said: "Every part of my body hurt. I'd lost sensation in my legs and found it hard to walk. I couldn't go outside as I was hypersensitive to light and temperature."

Cormack was prescribed beta blockers, which made her symptoms worse, and spiralled into a depression. At times, she felt suicidal.

She was eventually diagnosed with suspected POTS.

The AHVID has collated numerous case studies that provide shocking examples of parents being bullied into consenting to HPV vaccination and of adverse reactions happening very soon after the girl receiving the HPV shot.

In one case of a girl vaccinated in 2012, there was an immediate adverse reaction within ten minutes of her receiving one Gardasil shot. Her symptoms included dizziness, fainting, nausea, acid reflux, abdominal, muscle and facial pain, headaches, pains in her bones, sensitivity to light, noise, and movement, distortion of taste and smell, muscle weakness, fever, exhaustion, mental fatigue, a recurrent sore throat, and vomiting.

The girl became unable to do anything for herself, was confined to bed, and needed care 24/7.

She reported having new menstrual problems: periods that were irregular, lengthy, very heavy, and painful.

She told the AHVID that she was "humiliated, ridiculed, and demeaned by doctors" and was told that what was happening to her was "all in your head".

In another case, a girl who was vaccinated with Cervarix in 2008 was also told that what was happening to her was in her head. She says she was bullied into having the vaccination. She was so ill after the first two doses that she was advised at the hospital not to have the third.

The girl was a talented athlete who dreamed of being a professional sportswoman, but, after HPV vaccination, she was unable to even walk down the road. She also reported serious menstrual problems.

She was initially unable to attend school or even receive home tutoring, but was gradually able to go to school on a reduced timetable and managed to go to university, while living with her parents because of her health care needs.

Another case detailed by AHVID is that of a girl whose adverse reactions started on the day of her third Cervarix injection.

> "She was taken to A&E that night, burning up and the site of injection was inflamed and hard. She had a headache, and was sick and distressed," AHVID reported.

The girl's symptoms included vomiting, light-headedness, her joints dislocating and locking, a poor appetite, irritable bowel syndrome, and visual disturbances.

Other adverse reactions described in the various case histories include temporary blindness, mood swings, total hair loss, nose bleeds, open sores that won't heal, vertigo, coma-like sleeping, and mouth ulcers.

One mother, whose daughter received three doses of Gardasil in 2012/2013, told the AHVID: "My daughter had a horrific and immediate reaction to the vaccine and was rolling on the floor screaming and crying in pain."

The girl was expected to achieve B grades in her GCSE school exams, but only got D, E, and F grades. "She could not attend the last three months of school and has tried to attend college twice, but cannot get through a whole week," her mother said.

"Her life is ruined and she will never be able to fulfil her dream of being an engineer."

The girl was unable to socialise with friends or stay out for long because of fatigue and noise aversion, her mother said.

The girl's parents said they received no support from doctors and no tests were carried out. Their daughter was simply referred to a psychologist after one year. "All treatments have been paid for privately by us," the girl's mother said.

Another girl who received three Gardasil shots in 2012/13 suffered adverse reactions after each dose that started just days after the vaccination and worsened each time.

The girl's mother also said she felt coerced into agreeing to the vaccination.

The family described the effect on the girl as devastating. She was very athletic before the Gardasil shots, but had to give up trampolining, gymnastics, and swimming. As in all the case histories reported by AHVID, she had menstrual problems and her periods became light and scant.

"I have felt bullied, threatened, and intimidated by doctors when discussing the vaccination," her mother said.

Another mother said: "Before the vaccine, my daughter was energetic and full of life. She was very academic, but only passed five GCSEs. She should have taken ten. She was unable to go to school for some months as she could only rest in bed. She had to have home tuition in the end after a fight to get it.

"It has had a devastating effect on not only her life, but on my life as the parent. My role has become that of a carer. She lost all her friends and became terribly isolated."

Alleged maladministration in Europe

Peter Gøtzsche, who set up the Nordic Cochrane Centre in Copenhagen, gave a presentation to this year's Dublin symposium about alleged maladministration at the European Medicines Agency (EMA)

in relation to the safety of the HPV vaccines.

Speaking via Skype, he talked about the three syndromes suffered by those receiving HPV vaccination: POTS, CRPS, and chronic fatigue syndrome and said that the story of HPV vaccination "is an example among many others that we cannot trust our drug regulators".

In 2015, the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) conducted a safety review of HPV vaccination.

Gøtzsche (*pictured left*) told symposium attendees that, in November 2015, the EMA issued a report whose main messages were that there was nothing to worry about and that "the benefits of the vaccines outweighed their harms".

In May 2016, the deputy director of the Nordic Cochrane Centre in Denmark, Karsten Juhl Jørgensen, and others[8] filed an official complaint about the way the EMA had handled the HPV safety issue.

The complaint to the EMA alleged maladministration in its assessments of the possible serious neurological harm caused by the HPV vaccines.

"EMA's replies to us were disappointing," the Cochrane centre representatives stated. "Some of our concerns were not addressed. Several of EMA's statements were wrong, seriously misleading, or irrelevant to the criticisms we had raised."

In October 2016, the Cochrane centre representatives filed a complaint about the EMA to the European ombudsman, Emily O'Reilly. The ombudsman made a decision a year later and the Nordic Cochrane centre issued a response.

O'Reilly states in her decision, published on October 16, that "there was no maladministration by the European Medicines Agency in the handling of the referral procedure on HPV vaccines".

She states that her inquiry did not identify any procedural issues that could have negatively affected the work and conclusions of the Pharmacovigilance Risk Assessment Committee in the referral procedure.

"The examination of the scientific evidence was complete and it was independent," O'Reilly stated.

She said she considered that the EMA's conflict of interest policy was fully complied with during the referral procedure on HPV vaccines.

"There were no identified conflicts of interest. The procedure in question was therefore deemed to have been conducted in full independence by the relevant scientific experts."

O'Reilly suggests that the EMA "continue to explore ways to explain to the public in more detail how its scientific committees arrive at scientific conclusions, and how differences in views that arise during the assessment are addressed".

She said this could be done, for example, by publishing more information online. She suggests that the EMA consider making publicly available lists of all relevant documents in its possession related to a specific referral procedure, or that it consider other ways of helping citizens to identify the documents they wish to obtain.

The EMA said it would review the confidentiality requirements imposed on experts so that they may discuss in public the details of a scientific debate once that debate has been completed.

In their response to the ombudsman's decision, which they issued in November last year, Gøtzsche and others said they disagreed with the ombudsman's conclusion. They said they had found many examples of scientific maladministration.

"As long as the ombudsman is not willing to comment on scientific maladministration, even when it is apparent for people without a scientific background, there is, in reality, no public safeguard against poor conduct by EMA," they stated.

"As far as we know, there is no disciplinary committee in the European Union that can take appropriate action against EMA. We find this deeply concerning."

Gøtzsche and his colleagues said they questioned the EMA's independence from industry "because chairs of important committees are allowed to have conflicts of interest in relation to the companies whose products are being evaluated".

Gøtzsche told Changing Times: "People postulate that the ombudsman exonerated the EMA. This is not true. The ombudsman refused to deal with the scientific issues, which were the main part of our complaint."

In their response, Gøtzsche and his colleagues stated: "The main part of our complaint is about the substandard way that EMA evaluates science. This has huge consequences for public health.

"We acknowledge that it is not the ombudsman's task to take a view on the science. However, we note that the ombudsman on many occasions has chosen to trust EMA's scientific assessments, which are based on the data the drug companies gave them, even though EMA knew that the companies could not be trusted."

Gøtzsche and his colleagues say the ombudsman does not challenge the fact that the assessment of a possible relationship between a drug or vaccine and serious harm is provided by the marketing authorisation holders without independent re-analysis of the underlying raw data and scrutiny of the methods used to reach the conclusions.

"The evidence is, however, that drug companies often underreport even lethal harms for the authorities, and it has been documented, both to EMA and to the ombudsman, that Sanofi Pasteur MSD, one of the HPV vaccine manufacturers, on two occasions, both in Sweden and Denmark, had seriously underreported neurological harms associated with its HPV vaccine to the authorities."

Gøtzsche et al. add: "The ombudsman does not believe that pooling heterogenous active substances (misreported as 'placebos') is scientific misconduct.

"It also appears to be acceptable to dismiss the results of independent researchers and the Uppsala WHO Monitoring Centre, which found signals that suggested neurological harms."

Furthermore, Gøtzsche et al. say, "the EMA has not been reprimanded for the excruciating slowness with which it releases clinical study reports of the HPV vaccines, and with its unnecessary redactions that make any independent re-analysis very difficult".

The Cochrane Review

Gøtzsche was one of the authors of a paper that is highly critical of the review of HPV vaccines published by the Cochrane Collaboration in May this year. The review primarily assessed the vaccines' effect on precursors to cervical cancer.

The paper is entitled "The Cochrane HPV vaccine review was incomplete and ignored important evidence of bias" said the authors say that the Cochrane review missed nearly half of the eligible trials.

The review incompletely assessed serious and systemic adverse events, the paper's authors add.

Gøtzsche, Jørgensen, and Jefferson said the Cochrane review conducted trial searches up until June 2017 and included 26 randomised trials involving 73,428 women.

The review was influenced by reporting bias and biased trial designs, the three researchers state.

"In January 2018, we published an index of the study programmes of the HPV vaccines that included 206 comparative studies," they wrote.

"As of June 2017, about one-third of the 206 studies were not published and half of the completed studies listed on ClinicalTrials.gov had no results posted."

The three researchers said they sent their index to the group handling the Cochrane review, but the review stated that "nearly all end-of-study reports have been published in the peer-reviewed literature".

The researchers said that, when they applied the Cochrane review's inclusion criteria to the 206 studies, they identified 46 completed and eligible trials.

"With nearly half of the trials and half of the participants missing, the Cochrane authors' conclusion, 'that the risk of reporting bias may be small', was inappropriate," they added.

The authors of the Cochrane review would have identified more trials if they had searched ClinicalTrials.gov in more depth and searched additional trial registers, Jørgensen, Gøtzsche, and Jefferson say.

In their paper, published in the journal "BMJ Evidence-Based Medicine" in July this year, Gøtzsche, Lars Jørgensen, and Tom Jefferson point out that Gardasil 9 was not included in the Cochrane review.

"Since many countries are shifting to Gardasil 9, it is unfortunate that the Gardasil 9 trial was not included in the Cochrane review," they wrote.

In their response to Jorgensen et al, published on September 3, Cochrane's editor in chief, David Tovey, and deputy editor in chief, Karla Soares-Weiser, said Cochrane had initiated an investigation in response to the criticisms, working with the review authors and editors and with independent researchers who had not been involved in the original publication.

They cited the following key findings:

- The Cochrane Review did not miss "nearly half of the eligible trials". A small number of studies were missed because the primary focus was on peer-reviewed reports in scientific journals, but addition of these data makes little or no difference to the review's main results.
    - The trial's comparators were unambiguously, transparently, and accurately described.
    - The "selection of outcomes for benefits" was appropriate and consistent with World Health Organisation guidance.
    - The review included published and unpublished data on serious harms, and the findings on mortality were reported transparently and responsibly.
    - The review was compliant with Cochrane's current conflict of interest policy.
    - Cochrane's media coverage was cautious and balanced, but Cochrane recognised that there could be improvements in relation to transparency where external experts are quoted.
- The article in BMJ Evidence-Based Medicine "substantially overstated its criticisms"

The editors said they concluded that "Jørgensen et al. made allegations that are not warranted and provided an inaccurate and sensationalised report of their analysis".

The researchers say that their analysis was appropriate and that the Cochrane editors substantially ignored several of their criticisms.

Quoted by Nigel Hawkes in an article published in the BMJ on August 9 this year, Tovey said: "We fully understand the severity and importance of the criticisms made, whose implications go well beyond this review in terms of systematic review methodology.

"For this reason, we have had a team of editors working with the author team to investigate the claims as a matter of urgency."

Tovey told Hawkes that work was ongoing on a second review that would tackle matters of comparative benefit and harms from the various HPV vaccines.

All 26 trials included in the Cochrane review used active comparators: adjuvants (aluminium hydroxide or amorphous aluminium hydroxyphosphate sulfate) or hepatitis vaccines).

Jørgensen, Gøtzsche, and Jefferson say the Cochrane authors mistakenly used the term placebo to describe the active comparators.

"They acknowledged that 'The comparison of the risks of adverse events was compromised by the use of different products (adjuvants and hepatitis vaccines) administered to participants in the control group'.

"Nevertheless, this statement can easily be overlooked, as it comes after 7,500 words about other issues in the discussion and under the heading 'Potential biases in the review process'."

Active comparators was not a bias in the review process, but a bias in the design of the HPV vaccine trials, Jørgensen, Gøtzsche, and Jefferson say.

"The use of active comparators probably increased the occurrence of harms in the comparator groups and thereby masked harms caused by the HPV vaccines."

Many women were excluded from the trials if they had received the adjuvants before or had a history of immunological or nervous system disorders, the three authors point out.

"These exclusion criteria lowered the external validity of the trials and suggest that the vaccine manufacturers were worried about harms caused by the adjuvants.

"The criteria are not listed as warnings on the package inserts of the HPV vaccines, which may have led to more vaccine-related harms in clinical practice than in the trials."

All trials included in the Cochrane review were funded by the HPV vaccine manufacturers, the authors point out.

"Most of the 14 Cochrane authors on the first published protocol for the Cochrane review had major conflicts of interest related to the HPV vaccine manufacturers.

"The Cochrane review only has four authors; three of whom had such conflicts of interest a decade ago. The review's first author currently leads EMA's 'post-marketing surveillance of HPV vaccination effects in non-Nordic member states of the European Union', which is funded by Sanofi-Pasteur-MSD that was the co-manufacturer of Gardasil."

The three authors say the announcement of the Cochrane review on Cochrane. org

In the 'News' section included a 'Science Media Centre roundup of third-party expert reaction to the review'.

"Six experts were cited – all from the UK, although the Cochrane Collaboration is an international organisation. Two of the experts had financial conflicts of interest with the HPV vaccine manufactures. A third expert was responsible for vaccinations in Public Health England (PHE) that promotes the HPV vaccines."

The experts highlighted the Cochrane analysis "that the HPV vaccine is the most effective way for young girls to protect themselves against cervical cancer" and that "the vaccine causes no serious side-effects".

Jørgensen, Gøtzsche, and Jefferson point out that no expert criticised the review.

"In our view, this is not balanced and people with conflicts of interest in relation to the manufacturers should not be quoted in relation to a Cochrane review."

The researchers say the Cochrane authors did not describe any cervical cancers in the 26 trials, although cancers did occur in the trials.

"Furthermore, the relationship between CIN2* and cervical cancer is not clear-cut. Most CIN2 lesions in women below age 30 regress spontaneously; an active surveillance approach has therefore been recommended for this group.

"The Cochrane review's 26 trials mainly included women below age 30 and used frequent cervical screening (often every six months) that did not reflect real-life practice (often every three to five years)."

The Cochrane authors concluded with 'high certainty' that the risk of serious adverse events was similar in the HPV vaccine groups and the comparator groups, Jørgensen, Gøtzsche, and Jefferson say.

"However, the authors failed to mention that several of the included trials did not report serious adverse events for the whole trial period."

The Cochrane authors found more deaths in the HPV vaccine groups than in the comparator groups and the death rate was significantly increased in women above age 25.

The total numbers of deaths were 51 in the HPV vaccine groups and 39 in the comparator groups.

“The Cochrane authors suggested that this was a chance occurrence since there was no pattern in the causes of death or in the time between vaccine administration and date of death,” Jørgensen, Gøtzsche, and Jefferson wrote.

“However, as the Cochrane review only included randomised trials, the authors cannot rule out that the increase could be caused by the HPV vaccines.”

The three researchers say the Cochrane review did not assess HPV vaccine-related safety signals.

The Cochrane authors did not mention a study from 2017 by the WHO UMC that found serious harms following HPV vaccination overlapping with two syndrome: POTS and CRPS.

As of May 2018, VigiBase listed 526 cases of POTS and 168 cases of CRPS reported as related to HPV vaccination.

“The Cochrane authors did not investigate whether the included trial data reported cases of POTS, CRPS or other safety signals,” Jørgensen, Gøtzsche, and Jefferson wrote.

“Instead, the authors cited EMA, which concluded that ‘No causal relation could be established’ between POTS or CRPS and the HPV vaccines’.

“EMA’s conclusion was based on the HPV vaccine manufacturers’ own unverified assessments that only included half of the eligible trials.

”Furthermore, the HPV vaccine manufacturers’ search strategies for POTS and CRPS were inadequate and led to cases being overlooked.”

HPV ‘a passenger virus’

In the “Sacrificial Virgins” documentary, released last year, Peter Duesberg, who is a professor of molecular biology at the University of California in Berkeley in the US, says that scientific studies have found that cervical cancers are not caused by HPV.

Duesberg says HPV doesn’t replicate in cervical cancer cells. He says that when HPV is found in some cervical cancer cells, it is a “passenger virus” that plays no role.

He says it is “fossils” of HPV DNA that are being detected and they come from previous infection that could date back decades.

HPV vaccination should be stopped, Duesberg says, until there is proof that it protects against cancer. It has, he says, more side-effects than any other vaccine.

“Other vaccines combined have less adverse effects than this one.”

Gérard Delépine points out that vaccination is a complex process with unpredictable clinical consequences that can vary depending on the antecedents of the person vaccinated and whether they already have the virus being targeted.

There are numerous studies about the decreases in HPV infection and genital warts since HPV vaccination began, but Delépine says this concentration on the reduction in HPV infection, which easily clears by itself, is a tactic by the pharmaceutical companies.

“The only justification for Gardasil vaccination would be if it is leading to a decrease in the incidence of invasive cervical cancer, and it is not.”

Media headlines are frequently extremely misleading. “HPV vaccine has led to ‘significant drop’ in cervical cancer rates among UK women, study reveals” was a recent headline in the Independent in Britain, but the article was actually about an apparent reduction in HPV infection.

‘Virtual-reality science’

Delépine says that an analysis of all the official data from cancer registries “allows us to establish an extremely probable causal link between HPV vaccination and an increased risk of invasive cervical cancer”.

He is highly critical of the many articles that use mathematical modelling and surrogate markers, or endpoints[9], to argue that a HPV vaccine take-up of more than 80 percent will reduce the incidence of cervical cancer and even eliminate it within thirty years.

"This virtual-reality science is completely at odds with what we can see happening clinically," he said.

Writing in the Journal of Epidemiology and Community Health in May 2010, Ansgar Gerhardus and Oliver Razum talk about how surrogate endpoints can be misleading.

They said that, in the FUTURE I and FUTURE II studies, the statistical analyses were conducted in subgroups comprising only of women who tested negative for HPV 16 or 18 at the beginning of the study.

Also, "a new population was defined retrospectively, consisting only of women who (also retrospectively) tested negative to almost all oncogenic HPV types at the onset of the study".

Applying this criterion led to the exclusion of about half of the original study population, Gerhardus and Razum say. "The remaining group is presumably less sexually active than average, so it is difficult to tell how sound the conclusions drawn from this surrogate population are."

The researchers say that, when presenting the results of the FUTURE studies, the European manufacturer of Gardasil, Sanofi-Pasteur MSD, simply claimed up to 100 percent protection against cervical cancer and other HPV-related diseases.

"More disturbingly," they added, "even the German Standing Vaccination Committee (STIKO) assumed a lifelong protection of 92.5 percent."

The researchers say that when the uncertainties related to surrogates are ignored decisions at health policy and individual levels might be misled.

> "Thus, the flawed estimate of the protective efficacy by STIKO influenced the decision to reimburse HPV vaccination in Germany, and probably led many physicians to recommend the vaccination under false assumptions."

Gerhardus and Razum say that such data will be inserted into models uncritically. "A review found that all cost-effectiveness studies on HPV vaccination at that time had invariably assumed a reduction of cervical cancer cases by 70 percent."

In addition, heterogeneity between different age groups can be overlooked, the researchers say. "Many countries issue recommendations for girls up to 17 years and assume the effectiveness to be 70 percent for the whole age span below."

In Germany, the researchers say, the resulting, but unwarranted, confidence in the new vaccines "led to the impression that there was no need to actually evaluate their effectiveness".

Delépine says that Gardasil was pushed rapidly on to the market after flawed trials and the warnings about the risks of HPV vaccination that were issued by scientists in numerous articles in major international journals were quite simply ignored.

Most of the experts are quite simply asking the wrong questions, Delépine says. "They should be doing all they can to really understand why there is such an increase in cervical cancer, not hiding the reality and declaring their faith in vaccines that are clearly dangerous.

> "Imagine the anguish and anxiety of a young woman who discovers that the vaccine she received that she had hoped would protect her from cervical cancer is actually increasing the incidence of that cancer.

"And more and more boys are now being vaccinated. What is going to be effect on them? We just don't know."

In a paper entitled "Motor and sensory clinical findings in girls vaccinated against the human papillomavirus from Carmen de Bolivar, Colombia", Pompilio Martinez, from the National University of Colombia describes HPV vaccination as a "crime against humanity".

In his paper, published in March 2016, Martinez describes the neurological symptoms of 62 girls who received HPV vaccination. Sixty-one of the girls were Colombian and received quadrivalent Gardasil and one girl from Mexico received the bivalent Cervarix vaccine. The average age was 14.5 years.

> "This survey reveals an overall pattern of peripheral nervous system damage as demonstrated by complaints of inflammatory and neuropathic pain syndromes in the head, back, chest, arms and legs," Martinez wrote.

"There were also sensory and motor syndromes with upper and lower limb numbness and tingling (paraesthesia), muscle weakness and difficulty walking (paresis) accompanied by tremors, muscle spasms and twitches (abnormal movements)."

Martinez says that most symptoms appeared after the second vaccine dose, "which agrees with greater antibody titers seen in booster dose immunisations".

He says the evidence leads him to suggest that an autoimmune hypersensitivity type II reaction is triggered by Gardasil.

The general disease pattern following HPV vaccination is consistent with a demyelinating disorder that might not apply to every girl, Martinez says. "Therefore every one of them should be diagnosed and treated individually."

One of the strongest findings of the survey in Colombia was the pattern of symptom onset after the first and second HPV vaccine doses, Martinez says.

A class action lawsuit against Merck and the Colombian government has been filed on behalf of seven hundred girls in Colombia who say they have been injured by quadrivalent Gardasil.

Media coverage about HPV vaccination increased in Uruguay in August this year, meanwhile, with reports about the 12-year-old daughter of Senator Verónica Alonso losing sight in one eye, and being unable to walk three weeks after undergoing HPV vaccination.

'A commercial success, but a global health catastrophe'

Delépine points out that, over the past 12 years, close to one billion dollars has been spent to vaccinate 200 million women.

> "HPV vaccination is a commercial success for the manufacturer, but a global health catastrophe," he said.

In 2011, Merck was sentenced in a criminal case to pay a fine of $321,636,000 after pleading guilty to violating the Food, Drug and Cosmetic Act for introducing a misbranded drug, Vioxx, into interstate commerce.

Merck made false statements about the drug's cardiovascular safety and promoted it for the treatment of rheumatoid arthritis before that use was approved by the FDA.

It is estimated that Vioxx may have caused between 88,000 and 139,000 heart attacks and between 26,000 and 42,000 deaths before it was withdrawn. Some have estimated the likely deaths to be much higher, reaching as many as 120,000.

> "We risk seeing a much larger number of victims of the HPV vaccination scandal than we saw in the case of Vioxx," Delépine says, "and the health authorities who have allowed and promoted HPV vaccination are massively responsible."

1. *Dysplasia is the presence of abnormal or enlarged cells, which may signify a stage preceding the development of cancer.*
2. *An oncogene is a gene that has the potential to cause cancer.*
3. *Syncope is better known as fainting. It is a temporary loss of consciousness, usually related to insufficient blood flow to the brain.*
4. *Heart arrhythmia, also known as irregular heartbeat or cardiac dysrhythmia, is a group of conditions in which the heartbeat is irregular, too slow, or too fast.*
5. *Cytokines are small secreted proteins released by cells that have a specific effect on the interactions and communications between cells.*
6. *A black triangle product is a medicine or vaccine that is new to the market or one that is being used for a new reason or by a new route of administration. The black triangle also highlights the need for surveillance of any adverse reactions that might arise from the use of a new medication. The black triangle generally stays on new drugs (or drugs being used for a new reason) for at least five years, at which stage the black triangle status is reviewed.*
7. *A prodrome is an early sign or symptom (or set of signs and symptoms), which often indicate the onset of a disease before more diagnostically specific signs and symptoms develop.*
8. *Deputy director of the Nordic Cochrane Centre Karsten Juhl Jørgensen; senior associate tutor at the Centre for Evidence-Based Medicine in Oxford, England, Tom Jefferson; MEP from the Group of the Greens/European Free Alliance, Margrete Auken; and Louise Brinth, previously at the Danish Syncope Unit, Frederiksberg.*
9. *In clinical trials, a surrogate endpoint is a measure of effect of a specific treatment that may correlate with a real clinical endpoint but does not necessarily have a guaranteed relationship.*

———————————————————————————————————————

Further findings from Murall et al.:

Murall et al. say there is considerable excitement surrounding the HPV vaccines because of their innovative virus-like-particle (VLP) technology and "the very high efficacy rates found in clinical trials", they write.

"The HPV vaccine is hailed as a very effective preventive measure against the several cancers (cervical, penile, anal and head-and-neck) that are caused by this very common sexually transmitted virus," they state.

However, the researchers cite the vaccine-induced evolution of Marek's disease virus (MDV), which is a double-stranded DNA (dsDNA) virus, like HPV.

"Unexpectedly, MDV has evolved increased virulence and escape mutants in response to several vaccination campaigns. Here, we heed this cautionary tale …", they say.

The researchers say that, when the vaccine-targeted virus types experience an unnaturally strong antibody response, "this drives the oncogene expression necessary for persistent circulation up further".

They say that effector cells induced by HPV vaccination invade faster, "and invasion can no longer be delayed through strategies using slow viral replication and signalling interference".

They also that that vaccine adaptive response now exclusively targets epitopes of the capsid protein L1, which is distinct from natural responses that target the early proteins, E2, E6 and E7, for clearance.

They say their findings indicate that "the novel vaccine immunity favours increased virulence in order to allow for transmission during the short window of time before vaccine-induced clearance".

The researchers say that the main form of vaccine "leakiness" that has been addressed in the HPV literature is that of type specificity and the focus is on whether it can result in type replacement.

"A 'leak' that has not been considered, and what we find here to be important, is what happens when the vaccine does not block infection and viral shedding.

"Given that challenge infections by vaccine-targeted types were detectable in vaccinated women during HPV vaccine trials, we argue that the vaccine does not always fully block viral shedding."

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2. ***Package insert* for Gardasil 9**

6.2 Post-Marketing Experience

"There is limited post-marketing experience following administration of GARDASIL 9. However, the post-marketing safety experience with GARDASIL is relevant to GARDASIL 9 since the vaccines are manufactured similarly and contain the same antigens from HPV types 6, 11, 16, and 18. Because these events were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or to establish a causal relationship to vaccine exposure. The following adverse experiences have been spontaneously reported during post-approval use of GARDASIL and may also be seen in post-marketing experience with GARDASIL 9:

Blood and lymphatic system disorders: Autoimmune hemolytic anemia, idiopathic thrombocytopenic purpura, lymphadenopathy.

Respiratory, thoracic and mediastinal disorders: Pulmonary embolus.

Gastrointestinal disorders: Nausea, pancreatitis, vomiting.

General disorders and administration site conditions: Asthenia, chills, death, fatigue, malaise.

Immune system disorders: Autoimmune diseases, hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria.

Musculoskeletal and connective tissue disorders: Arthralgia, myalgia.

Nervous system disorders: Acute disseminated encephalomyelitis, dizziness, Guillain-Barré syndrome, headache, motor neuron disease, paralysis, seizures, syncope (including syncope associated with tonic-10 clonic movements and other seizure-like activity) sometimes resulting in falling with injury, transverse myelitis.

Infections and infestations: Cellulitis.

Vascular disorders: Deep venous thrombosis."

Update 15/9/2018:

Peter Gøtzsche has been expelled from the Cochrane Collaboration.

Six of the 13 members of the collaboration's governing board voted for his expulsion.

Gøtzsche said in a statement: "No clear reasoned justification has been given for my expulsion aside from accusing me of causing 'disrepute' for the organisation.

> "This is the first time in 25 years that a member has been excluded from membership of Cochrane. This unprecedented action taken by a minority of the governing board is disproportionate and damaging to Cochrane, as well as to public health interests."

Gøtzsche added: "As a result of this decision, and a number of broader issues concerning the inadequate governance of Cochrane, in accordance with its principles and objectives, four other members of the board have resigned.

> "As a result, the Cochrane Collaboration has entered an unchartered territory of crisis and lack of strategic direction."

In just 24 hours, Gøtzsche said, the Cochrane governing board had lost five of its members, four of whom were centre directors and key members of the organisation in different countries.

Gøtzsche says that, in recent years, Cochrane has significantly shifted more to a profit-driven approach.

"Even though it is a not-for-profit charity, our 'brand' and 'product' strategies are taking priority over getting out independent, ethical and socially responsible scientific results," he said.

"Despite our clear policies to the contrary, my centre, and others, have been confronted with attempts at scientific censorship, rather than the promotion of pluralistic, open scientific debate about the merits of concrete Cochrane reviews of the benefits and harms of health care interventions."

Gøtzsche says the "hidden agenda" of his expulsion is a clear strategy for a Cochrane that moves further and further away from its original objectives and principles.

"This is not a personal question," he said. "It is a highly political, scientific and moral issue about the future of Cochrane. As most people know, much of my work is not very favourable to the financial interests of the pharmaceutical industry. Because of this Cochrane has faced pressure, criticism and complaints. My expulsion is one of the results of these campaigns.

> "What is at stake is the ability of producing credible and trustworthy medical evidence that our society values and needs."

In his statement Gøtzsche says Cochrane has been giving less and less priority to its civic and political commitment to promoting open access, open data, scientific transparency, and avoiding conflicts of interest.

> "There is stronger and stronger resistance to say anything that could bother pharmaceutical industry interests," he said.

Gøtzsche says that, a year ago, he proposed that there should be no Cochrane authors with financial conflicts of interests with companies related to the products considered in the reviews.

"This proposal was supported by other members of the board, but the proposal has not progressed at all," he said.

Update 24/9/2018:

On September 23, Jørgensen, Gøtzsche and Jefferson published a lengthy response to the Cochrane editors, in which they state that the editors substantially ignored several of their criticisms, "including the incomplete reporting of serious adverse events in several of the Cochrane HPV review's included studies".

In their response, published in in BMJ Evidence-Based Medicine, the researchers state: "The HPV vaccines are expensive blockbuster vaccines generating billions of dollars of revenue, and the Cochrane review ought, therefore, to have been independent of any financial conflicts of interests."

The Cochrane editors state that the review was compliant with Cochrane's current conflict of interest policy. "If that is the case," Jørgensen, Gøtzsche and Jefferson state, "we believe Cochrane should reconsider its policy."

The researchers add: "The Cochrane editors are confident that the Cochrane authors have no relevant conflicts of interest. We do not agree."

In their conclusion, they state that "the Cochrane HPV review is still incomplete and ignores important evidence of bias".

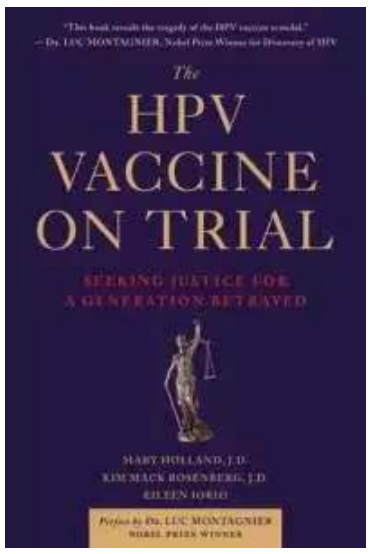
They add: "We found an additional 25,550 females (and possibly up to 30,195 for the Cochrane HPV review's serious adverse events meta-analyses) that are eligible for the Cochrane HPV review's meta-analyses."

It is not merely studies that the authors of the Cochrane review missed, the researchers state. "They also missed benefits and harms data from the studies they included."

The researchers added: "The Cochrane authors state that 'The deaths reported in the trials had an identified cause, and none were assessed to be due to vaccination', but such judgements are biased, particularly in industry sponsored trials, and the analysis of deaths should be based on all events."

They also say that the Cochrane editors' considerations of the trials' adjuvant and vaccine comparators were "ambiguous, opaque, inaccurate and ignored the fact that the studies only tested the vaccine antigens – not the vaccines".

Update 28/9/2018



"The HPV Vaccine on Trial: Seeking Justice for a Generation Betrayed" is due for release on October 2.

The book challenges the mainstream view of HPV vaccination and uncovers disturbing truths about the dangers and inefficacy of the Gardasil and Cervarix vaccines.

The French virologist Luc Montagnier, who was a joint recipient of the 2008 Nobel Prize in Physiology or Medicine for his discovery of the human immunodeficiency virus (HIV), says the book reveals "the tragedy of the HPV vaccine scandal".

He says in the preface: "The reader will see the truth: the side effects are underreported by medical personnel, while there are a growing number of parents suing manufacturers and governments for inducing lifelong handicaps, even death, of their loved ones.

> "In fact, this is the tragic example of various segments of our society, worldwide, placing economic interests before the health and protection of our younger generation."

The book's publisher, Skyhorse Publishing, says it paints a "devastating picture of corporate and government conflicts of interest, negligence, and malfeasance in approving and promoting human papillomavirus (HPV) vaccines, touted to prevent cervical and other cancers".

The authors point out that the three HPV vaccines bring in more than US$2.5 billion in annual sales for Merck and GlaxoSmithKline.

Holland, Rosenberg, and Iorio conclude that HPV vaccines have never been proven to prevent cancer of any kind and that the clinical trials never investigated the vaccines' possible effects on human fertility or their potential to cause cancer.

They point out that, although children aged 11 and 12 receive HPV vaccination, only a small fraction of clinical trial subjects were in this age range.

The new book talks about the lawsuits filed against HPV vaccine manufacturers and government health agencies around the world and the millions of dollars that the US government earns in royalties from Merck and GlaxoSmithKline for its role in the invention of HPV vaccine technology.

"Although the US government proclaims HPV vaccines safe and effective, it has paid out millions of dollars to compensate families for death, brain injury, multiple sclerosis, ulcerative colitis, and other severe, debilitating conditions," the authors state.

> "National and international health agencies are working hand in glove with the HPV vaccine manufacturers to promote, advertise, finance, recommend, and even compel children to get HPV vaccines."

Update 6/10/2018

The US Food and Drug Administration has approved a supplemental application for Gardasil 9, expanding its approved use to include women and men aged 27 to 45.

The FDA granted the Gardasil 9 application priority review status. (A priority review designation means the FDA aims to take action on an application within six months as compared to ten months under standard review.)

Approval of the supplement to the Gardasil 9 Biologics License Application was given to the Merck, Sharp & Dohme Corporation. a subsidiary of Merck & Co., Inc.

Update 7/10/2018

The authors of "The HPV Vaccine on Trial" have called for the retraction of all articles in the American Academy of Pediatrics' journal "Pediatrics" that are based on the Gardasil clinical trial Protocol 018.

Holland, Rosenberg, and Iorio point out that the articles are based on data presented in Protocol 018 that their research has shown to be unsound as a basis on which to claim vaccine safety.

The authors have discovered, "hidden in plain sight in an FDA document", evidence that the vaccinated children in Protocol 018 received half the dose of AAHS adjuvant that is present in the licensed vaccine.

"It is possible, although not likely, that this is a typographical error. But, if proven true through full disclosure, the implications are enormous," the authors state.

The FDA's 2006 clinical review shows evidence of this dose anomaly, Holland, Rosenberg, and Iorio point out. (See Table 210 below from "The HPV Vaccine on Trial".)

The vaccine formulation is indicated "per mL" (millilitre), but Gardasil is dosed by the half-millilitre, the authors state.

"Simple division shows that the 0.5 mL dose administered in the 018 study contained only 112.5 mcgs (micrograms) of AAHS, as well as the standard ratio of the four HPV L1 VLPs [virus-like particles]."

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]

The authors also point out that no other clinical trial described the vaccine formulation in this way. (See the excerpt from Table 26 below, also from "The HPV Vaccine on Trial".

The table shows the standard per 0.5 mL dose description used in Protocol 015.

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	"

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

Holland, Rosenberg, and Iorio point out that Protocol 018 is unique. "The FDA considered it important because it is the only study in the preteen target population comparing Gardasil to a non-aluminum-containing control (the carrier solution).

> "A lot was at stake, as it would provide the only long-term study cohort for this age group."

They also point out that none of the three articles about Protocol 018 published in "Pediatrics" addresses the AAHS dose anomaly.

They write: "A 2017 follow-up study based on Protocol 018 in Pediatrics confidently asserts that it 'should help to dismiss any lingering doubts about the safety and durability of HPV vaccine-induced protection'."

Clinicians around the world have been relying on the 2017 study to dismiss a connection between Gardasil and injuries, the authors state.

> "Pediatrics carries a lot of weight with pediatricians. But if the Protocol 018 data are based on a different vaccine formulation, Pediatrics should immediately retract both the 2014 and 2017 follow-up studies.
>
> "If Merck used a half AAHS dose, the data from that protocol do not support safety of the standard Gardasil formulation.
>
> "In fact, journals should retract *any* articles relying on Protocol 018 for the same reason."

Holland, Rosenberg, and Iorio also point out that HPV vaccination has never been proven to prevent cancer. Holland said in a recent interview: "The clinical trials did not require that. They used what were called surrogate endpoints and they showed in the cervical cancer context that lesions that *may* lead to cervical cancer were reduced."

She added: "That doesn't really tell us twenty to thirty years out are we going to have fewer cases of cervical cancer. It doesn't answer that question."

HPV vaccination has been "grossly oversold", Holland says.

The use of surrogate endpoints allowed Merck and GSK to shorten the clinical trials for their HPV vaccines, Holland, Rosenberg, and Iorio state.

> "Merck further took advantage of FDA fast tracking and priority review to shrink both Gardasil's and Gardasil 9's approval times. Based on the FDA's own criteria, the wisdom of its decision to accelerate Gardasil's approval is debatable."

This article was also updated with information from the AHVID on 14/09/2018 and was further updated to include information about the deaths of Joel Gomez and Maddie Moorman in the United States, and the story of Kesia Lyng from Denmark. There have also been updates to the cervical cancer statistics.

Update 11/12/2018:

Ireland's Minister for Health, Simon Harris, has annnounced that HPV vaccination will be extended to boys next year.

R.E.G.R.E.T. has produced a video about injury from HPV vaccination:

Update 12/3/2019

According to the World Health Organisation's pharmacovigilance database, VigiBase, 91,259 adverse reactions following HPV vaccination have now been reported.

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