HPV vaccine safety and effectiveness

Evidence for one dose and length of protection.

The Costa Rica Vaccine trial CVT Long Term Follow-Up Study (LTFU)

The Costa Rica Vaccine trial (CVT) was a blinded, randomized, phase III clinical trial. It used the bivalent HPV 16/18 virus-like particle (VLP) vaccine. The Costa Rica Vaccine trial (CVT) ended in 2010. The CVT Long Term Follow-Up Study (LTFU) commenced. This extended the follow-up of CVT participants to 10 years epidemiologic cohort study. The CVT study continues in a subset of the HPV-vaccinated women. Women are expected to be followed for a median of 20 years after the initial vaccination.

Results to date

- Three doses of the HPV vaccine may not be necessary. Similar vaccine efficacy against cervical HPV 16/18 infection was observed. This was among women who received two, and even a single dose. This included more than 10 years of follow-up.
- Demonstrated partial cross-protection against HPV 31, 33 and 45.
- High efficacy against HPV16/18-associated precancer. This was seen for more than a decade after initial vaccination,
- 10% HPV vaccine efficacy against carcinogenic HPV types excluding HPV 16, 18, 31, 33, 45.
- No vaccine efficacy against existing HPV infections.

CVT Long Term Follow-Up Study is available here

Costa Rica HPV Vaccine Trial (CVT) and Long-Term Follow-Up - NCI (cancer.gov)

With links below to publications from the CVT Long Term Follow-Up Study (LTFU):

- Shing JZ, et al. Precancerous cervical lesions caused by non-vaccine-preventable HPV types after vaccination with the bivalent AS04-adjuvanted HPV vaccine: an analysis of the long-term follow-up study from the randomised Costa Rica HPV Vaccine Trial. *Lancet Oncol* 2022.
- Porras C, Tsang SH, et al. Efficacy of the bivalent HPV vaccine against HPV 16/18- associated precancer: long-term follow-up results from the Costa Rica Vaccine Trial. *Lancet Oncol* 2020.
- Kreimer AR, Sampson JS, et al. Evaluation of Durability of a Single Dose of the Bivalent HPV Vaccine: The CVT Trial. *JNCI* 2020.
- Tsang SH, Sampson JS, et al. Durability of Cross-Protection by Different Schedules of the Bivalent HPV Vaccine: The CVT Trial. *JNCI* 2020.

- Herrero R, Wacholder S, Rodriguez AC, et al. Prevention of persistent human papillomavirus infection by an HPV16/18 vaccine: a community-based randomized clinical trial in Guanacaste, Costa Rica. *Cancer Discov* 2011.
- Herrero R, Hildesheim A, Rodriguez AC, et al. Rationale and design of a community-based double-blind randomized clinical trial of an HPV 16 and 18 vaccine in Guanacaste, Costa Rica. *Vaccine* 2008.

Institutional Agency for Research on Cancer [IARC] India trial.

A systematic 10-year follow-up of a cohort of about 17,000 female participants who received the quadrivalent HPV vaccine at age 10–18 years. This study demonstrated that the protection offered by a single dose of quadrivalent vaccine against persistent infection with HPV16 and HPV18 (the types responsible for nearly 80% of cervical cancers in low- and middle-income countries) was as high as that offered by two doses or three doses of the vaccine. The vaccine efficacy of a single dose against persistent HPV16/18 infection was 95.4%. This was not significantly different from the efficacy of two doses or three doses of the vaccine.

Reference: Basu Pet al. Vaccine efficacy against persistent human papillomavirus (HPV) 16/18 infection at 10 years after one, two, and three doses of quadrivalent HPV vaccine in girls in India: a multicentre, prospective, cohort study. Lancet Oncol. 2021 Nov;22(11):1518-1529. doi: 10.1016/S1470-2045(21)00453-8. Epub 2021 Oct 8. Erratum in: Lancet Oncol. 2022 Jan;23(1):e16. doi: 10.1016/S1470-2045(21)00700-2. PMID: 34634254; PMCID: PMC8560643.

Reduction Immunobridging and Safety Study (DoRIS), compared antibody responses after one dose of HPV vaccine. This was a randomised trial of different HPV vaccine schedules in Tanzania. Using two observational HPV vaccine trials as comparators. Researchers found high efficacy of one dose up to 11 years against HPV16 and HPV18 (Costa Rica Vaccine Trial [CVT] and Institutional Agency for Research on Cancer [IARC] India trial).

References:

Watson-Jones at al. Immunogenicity and safety of one-dose human papillomavirus vaccine compared with two or three doses in Tanzanian girls (DoRIS): an open-label, randomised, non-inferiority trial. Lancet Glob Health. 2022 Oct;10(10):e1473-e1484. doi: 10.1016/S2214-109X(22)00309-6. PMID: 36113531; PMCID: PMC9638030.

2022

April 2022

The April convening of the **WHO Strategic Advisory Group of Experts on Immunization (SAGE)** evaluated the evidence that has been emerging over past

years that single-dose HPV vaccination schedules provide comparable efficacy to the two or three-dose regimens.

SAGE's review concluded that a single-dose of HPV vaccine delivers solid protection against HPV, comparable to that delivered by two-dose schedules.

SAGE considered the evidence from an updated systematic review on the immunogenicity, efficacy, and effectiveness of single-dose vaccination schedules compared with no vaccination and multidose schedules. The review included 55 studies, 20 of which were new studies not included in a previous review conducted in 2019. The review showed comparable efficacy and effectiveness between single- and multidose schedules in preventing persistent infection with HPV serotypes 16 and 18, lasting up to 10 years following vaccination.

Further evidence on single-dose schedules from efficacy trials, including trials for which interim results were reviewed by SAGE, will become available during the next three years.

The report from the April 2022 WHO SAGE meeting is available here: https://www.who.int/publications/i/item/who-wer9724-261-276 (you will be directed to the WHO website)

HPV Vaccine Safety and Effectiveness 2006 - 2024

Since HPV vaccine was licensed in 2006 research has been conducted all over the world that demonstrates that the vaccine is safe and prevents pre-cancers. The evidence has been steadily growing since 2006 and now a large bank of research exists which proves the safety and effectiveness of this vaccine.

Over 140 countries and territories now have a HPV vaccine programme, with more than 50 of these giving the vaccine to boys and girls.

We have been asked if the HPV vaccine is linked to chronic fatigue like conditions. A number of studies have been conducted that show there is no link between the HPV vaccine and chronic fatigue like conditions. You can read these studies here.

2024

Linkage studies, conducted in Scotland, Sweden, Denmark, and England, have demonstrated effectiveness against cervical cancer by vaccinating with HPV vaccine.

June 2024

Scottish study:

The Scottish study by Palmer et al linking vaccination files with cervical cancer screening data and the national cancer registry, demonstrates excellent protection against invasive cervical cancer among girls immunized at the age of 12 to 13 years with the bivalent human papillomavirus (HPV) vaccine (Cervarix). The study completes and strengthens the evidence of the high level of effectiveness of primary cervical cancer prevention by HPV vaccination based on intervention trials and population-based surveillance of real-world data built up over the last two decades.

This study showed girls who were vaccinated at the age of 12 to 13 years, irrespective of the number of doses, the incidence of invasive cancer was zero (effectiveness of 100%).
Women from the most deprived areas showed a significant reduction in incidence following 3 doses of vaccine (13.1/100 000 [95% CI = 9.95 to 16.9] vs 2.29 [95% CI = 0.62 to 5.86]).

Conclusion: findings confirm that the bivalent vaccine prevents the development of invasive cervical cancer and that even 1 or 2 doses 1 month apart confer benefit if given at 12-13 years of age.
At older ages, 3 doses are required for statistically significant vaccine effectiveness. Women from more deprived areas benefit more from vaccination than those from less deprived areas.

Reference:
Invasive cervical cancer incidence following bivalent human papillomavirus vaccination: a population-based observational study of age at immunization, dose, and deprivation. J Natl Cancer Inst. 2024 Jun 7;116(6):857-865. doi: 10.1093/jnci/djad263. PMID: 38247547.

Linkage of individual-patient data confirm protection of prophylactic human papillomavirus vaccination against invasive cervical cancer

Marc Arbyn, PhD, Pegah Rousta, MSc, Laia Bruni, PhD, Lina Schollin Ask, PhD, Partha Basu, PhD

JNCI: Journal of the National Cancer Institute, Volume 116, Issue 6, June 2024, Pages 775–778, https://doi.org/10.1093/jnci/djae042

Vaccination Efficacy (VE) of HPV vaccine from linkage studies to cancer register and cervical screening.

Vaccination efficacy is 81% in under 17 years vaccinated in Sweden (Lei et al) and falls to 36% in 17–30-year-olds.

Reference: Lei J et al. HPV Vaccination and the Risk of Invasive Cervical Cancer. N Engl J Med. 2020 Oct 1;383(14):1340-1348. doi: 10.1056/NEJMoa1917338. PMID: 32997908.

In the Danish, study VE was found to be 87% if given at aged 16 years or under and falls to 69% aged 17-19 years and falling further to 14% for 20 -30-year-olds. (Kjaer)

Reference: Kjaer SK et al. Real-World Effectiveness of Human Papillomavirus Vaccination Against Cervical Cancer. J Natl Cancer Inst. 2021 Oct 1;113(10):1329-1335. doi: 10.1093/jnci/djab080. PMID: 33876216; PMCID: PMC8486335.

Falcro et al found a VE of 87% for 12–13-year-olds and 14–16-year-old of 62% in England.

It should be noted that vaccine effectiveness estimated from the four linkage studies were adjusted for various socioeconomic, demographic, time, age, and other factors. However, bias due to residual confounding, inherent to observational data, cannot be excluded.

These four studies support early vaccination in first year.

Reference: Falcaro M, et al. The effects of the national HPV vaccination programme in England, UK, on cervical cancer and grade 3 cervical intraepithelial neoplasia incidence: a register-based observational study. Lancet. 2021 Dec 4;398(10316):2084-2092. doi: 10.1016/S0140-6736(21)02178-4. Epub 2021 Nov 3. PMID: 34741816.

databases with cancer registries

Reference (Country)	Age at vaccination (years)	VE (95% CI)	Cofactors adjusted for adjusted for
Lei, 2020 (14)	<17	81% (35% to 95%)	Age, county, calendar year, birth country of mother, education and income of parents, occurrence of (pre)cancer in mother
(Sweden)	17-30	36% (0% to 61%)	
Kjaer, 2021 (15)	≤16	87% (59% to 96%)	VE adjusted for attained age and education of parent(s)
(Denmark)	17-19	69% (−7% to 91%)	
	20-30	−14% (-49% to 13%)	
Falcaro, 2021 (16)	12-13	87% (72% to 94%)	VE adjusted for age-cohort interactions, screening campaign and J Goody campaign[b] effect
(England)	14-16	62% (52% to	

Open in a separate window

[a]Completely vaccinated (2 doses at least 5 months apart or 3 doses). CI = confidence interval; VE = vaccine

May 2024

Effect of the HPV vaccination programme on incidence of cervical cancer and grade 3 cervical intraepithelial neoplasia by socioeconomic deprivation in England: population based observational study

Annual update on an ongoing study showing continued reduction of CIN 3 in vaccinated cohorts
Design Observational study.
Setting England, UK.
Participants Women aged 20-64 years resident in England between January 2006 and June 2020 including 29 968 with a diagnosis of cervical cancer and 335 228 with a diagnosis of CIN3. In England, HPV vaccination was introduced nationally in 2008 and was offered routinely to girls aged 12-13 years, with catch-up campaigns during 2008-10 targeting older teenagers aged <19 years.
Results: In the birth cohort of women offered vaccination routinely at age 12-13 years, adjusted age standardised incidence rates of cervical cancer and CIN3 in the additional 12 months of follow-up (1 July 2019 to 30 June 2020) were, respectively, 83.9% (95% confidence interval (CI) 63.8% to 92.8%) and 94.3% (92.6% to 95.7%) lower than in the reference cohort of women who were never offered HPV vaccination. The high effectiveness of the national HPV vaccination programme previously seen in England continued during the additional 12 months of follow-up. HPV vaccination was associated with a substantially reduced incidence of cervical cancer and CIN3 across all five deprivation groups, especially in women offered routine vaccination.

BMJ 2024; 385 doi: https://doi.org/10.1136/bmj-2023-077341 (Published 15 May 2024)Cite this as: *BMJ* 2024;385:e077341

WHO 3rd July 2024

Vaccines to treat human papillomavirus could be a significant innovation in the fight against cervical cancer

Innovative vaccines are being developed that could potentially treat dangerous human papillomavirus (HPV) infections in adults and therefore reduce risks of cervical cancer, according to a new report released today by the World Health Organization (WHO).

Eliminating cervical cancer – which kills one woman every 90 seconds – is a major public health initiative for WHO.

Reference: WHO webpage 3rd July 2024 available ta this link

https://www.who.int/news/item/03-07-2024-vaccines-to-treat-human-papillomavirus-could-be-a-significant-innovation-in-the-fight-against-cervical-cancer#:~:text=%E2%80%9CTherapeutic%20HPV%20vaccines%20could%20be,threatening%20cancer%20in%20the%20future.%E2%80%9D

2023

October

The effect of HPV vaccination on the rate of high-grade cytology in 25-year-old women attending cervical screening in Ireland

In Ireland, women vaccinated through the initial catch-up HPV vaccination programme from 2011/12 to 2013/14 first became eligible for cervical screening in

2019 at age 25. This study examined the changes in detection of high-grade cytology outcomes in 25-year-olds screened from 2010 to 2022 compared to population data on HPV vaccination in this group.

Vaccination rates in the catch-up programme were lower (44-70%) than for routine HPV immunisation at age 12/13 in 2010/11 (81%). The rate of high-grade cytology in 25-year-olds in 2015–2018 was 3.7% of all cytology tests taken in this age group. For the corresponding period from 2019 to 2022 (when vaccinated women were attending screening), the average percentage of high-grade cytology in 25-year-olds was 1.5%, representing a significant reduction in high-grade cytology proportions.

This research shows the importance of HPV vaccine on the journey to the elimination of cervical cancer in Ireland and highlights the importance of increasing HPV vaccine uptake for further reduction in high grade cervical abnormalities to prevent cervical cancer.

Micheal Rourke, Patricia Fitzpatrick, Olalekan Popoola, Rewhandamzi Boms, Therese Mooney, Laura Heavey, Caroline Mason Mohan, Cara M. Martin, Lucy Jessop & Noirin E. Russell

https://link.springer.com/article/10.1007/s11845-023-03551-y (you will be directed to the Irish Journal of Medical Science website)

Irish Journal of Medical Science, published: 19th October 2023

September

Ten-Year Follow-up of 9-Valent Human Papillomavirus Vaccine: Immunogenicity, Effectiveness, and Safety

This study assessed the immunogenicity and effectiveness of 9-valent HPV vaccine through 10 years post vaccination.

1272 participants (males and females aged 9-15 years in the base study), who had received 3 doses of 9-valent HPV vaccine (day 1, months 2 and 6) enrolled in this long term follow up study. The study was carried out in 40 sites across 13 countries including Belgium, Brazil, Colombia, Costa Rica, Peru, Poland, South Africa, South Korea, Spain, Sweden, Taiwan, Thailand, and the United States.

In this study, the 9-valent HPV vaccine elicited sustained antibody responses to the 9 vaccine-targeted HPV types through 10 years post dose 3 in girls and boys 9 to 15 years of age. There were also no cases of high-grade cervical, vulvar, or vaginal intraepithelial neoplasia in female participants, of high-grade penile, perineal, or perianal intraepithelial neoplasia in male participants, or of genital warts in all participants related to vaccine-targeted HPV types through end of the long term follow up post dose 3. Incidence rates of HPV6/11/16/18/31/33/45/52/58-related 6-month persistent infection in males and females were low and within ranges expected in vaccinated cohorts, based on previous human papillomavirus vaccine efficacy trials. In addition, no vaccine-related serious adverse events were reported during long term follow up through 10 years postvaccination.

The authors concluded that the 9-valent HPV vaccine demonstrated sustained immunogenicity and effectiveness through ~10 years, post 3 doses, in boys and girls aged 9 to 15 years.

Restrepo J, Herrera T, Samakoses R, Reina JC, Pitisuttithum P, Ulied A, et al. Ten-Year Follow-up of 9-Valent Human Papillomavirus Vaccine: Immunogenicity, Effectiveness, and Safety. Pediatrics. 2023 Sep 5;e2022060993. (you will be directed to the PubMed website)

2021

December

Human papillomavirus vaccine efficacy against invasive, HPV-positive cancers: population-based follow-up of a cluster randomised trial.

During a follow-up time of up to 11 years, this Finnish study identified no invasive cancer cases in the HPV-vaccinated cohorts. However there were 17 HPV-positive invasive cancer cases (14 cervical cancers, 1 vaginal cancer, 1 vulvar cancer and 1 tongue cancer) in the non-HPV-vaccinated cohorts.

Matti Lehtinen et al.

BMJOPEN December 2021

https://bmjopen.bmj.com/content/bmjopen/11/12/e050669.full.pdf (you will be directed to the BMJ website)

November

The effects of the National HPV immunisation programme in England, UK on cervical cancer and grade 3 cervical intraepithelial neoplasia incidence: a register based observational study

A study from England observed a substantial reduction in cervical cancer and incidence of CIN3 (severe cervical abnormality) in young women after the introduction of the HPV immunisation programme in England, especially in individuals who were offered the vaccine at age 12–13 years.

The HPV immunisation programme has successfully almost eliminated cervical cancer in women born since Sept 1, 1995".

Milena Falcaro Phd et al. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02178-4/fulltext (you will be directed to the Lancet website)

May

Cancer Incidence and Prevalence in Scotland (2019) - published 2021 May

Rates of cervical cancer were much lower in 2019 in 20 to 29-year-old women compared to previous years while rates of histologically verified CIN3 (the most serious pre-cancerous form of cervical intraepithelial neoplasia) have been falling for several years and are significantly different over the last ten years.

Together, these findings suggest that the HPV vaccination programme introduced in Scotland in 2008 has been effective in reducing cervical cancer.

2020

September

HPV Vaccination and the Risk of Invasive Cervical Cancer

Among Swedish girls and women aged 10 to 30 years old, quadrivalent HPV vaccination (Gardasil vaccine which protects against 70% of cervical cancers) was associated with a substantially reduced risk of invasive cervical cancer at the population level.

In the study from Sweden, cervical cancer was diagnosed in 19 women who had received the Gardasil vaccine and in 538 women who had not received the vaccine.

After adjustment for all covariates, the incidence rate ratio was 0.12 (95% CI, 0.00 to 0.34) among women who had been vaccinated before the age of 17 years and 0.47 (95% CI, 0.27 to 0.75) among women who had been vaccinated at the age of 17 to 30 years.

(Funded by the Swedish Foundation for Strategic Research and others.)

Jiayao Lia et al

N Engl J Med 2020; 383:1340-1348 DOI: 10.1056/NEJMoa1917338

Association between quadrivalent human papillomavirus vaccination and selected syndromes with autonomic dysfunction in Danish females: population based, self-controlled, case series analysis.

This study from Denmark did not find a causal association between quadrivalent human papillomavirus vaccination and chronic fatigue syndrome, complex regional pain syndrome, or postural orthostatic tachycardia syndrome, either individually or as a composite outcome.

Hviid Anders, Thorsen Nicklas M , Valentiner-Branth Palle, Frisch Morten, Mølbak Kåre

https://www.bmj.com/node/1033205.full (you will be directed to the BMJ website)

June

Final analysis of a 14-year long-term follow-up study of the effectiveness and immunogenicity of the quadrivalent human papillomavirus vaccine in women from four nordic countries

No case of high-grade precancerous changes of the cervix caused by the HPV types16 and 18, which Gardasil vaccine provides protection from, were seen among 2121 women who were followed up for more than 12 years after Gardasil vaccination.

Vaccine effectiveness of 100% (95% CI 94·7–100) was demonstrated for ≥12 years for these women. There is evidence also to suggest a trend toward continued protection in the future through 14 years.

There was no evidence of waning immunity, suggesting no need for a booster dose during that period.

Suzanne K Kjaer, Mari Nygård, Karin Sundröm, Joakim Dillner, Laufey Tryggvadottir, Christin Munk et al.

https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(20)30145-0/fulltext (you will be directed to the Lancet website)

April

"No association between HPV vaccination and infertility in U.S. females 18–33 years old"

A new US study shows there was no evidence of increased infertility among women who received the HPV vaccine.

These results provide further evidence of HPV vaccine safety and should give providers confidence in recommending HPV vaccination.

Further research should explore protective effects of HPV vaccines on female and male fertility.

https://www.sciencedirect.com/science/article/pii/S0264410X2030414X (you will be directed to the Science Direct website)

January

The World Health Organization (WHO) Global Advisory Committee for Vaccine Safety (GACVS) has reviewed the evidence on the safety of HPV vaccines in 2007, 2008, 2009, 2013, 2014, 2015, 2017 and most recently in January 2020.

In January 2020, the World Health Organization (WHO) Global Advisory Committee for Vaccine Safety (GACVS) reported

"Since the first marketing authorization in 2006, post-licensure monitoring and research have been conducted for the 3 vaccines (bivalent by GlaxoSmithKline, quadrivalent and 9-valent by Merck and Co.), with over 160 studies completed in several countries. HPV vaccines were found to have a favourable safety profile, with no confirmed clinically serious signals about safety. Anaphylaxis and syncope are known AEs."

Surveillance of type-specific HPV in sexually active young females in England, to end 2018

In England ten years after the introduction of the national HPV vaccination programme in adolescent females, population-based data continue to show dramatic declines in infections with HPV vaccine-types and closely related HPV types.

Public Health England. HPR Volume 14 Number 2 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attac

hment_data/file/858872/hpr0220_HPV_2018.pdf (you will be directed to the Gov.UK website)

2019

December

Immunogenicity and safety of human papillomavirus vaccine co-administered with other vaccines in individuals aged 9–25 years: A systematic review and meta-analysis

Giving other vaccines at the same time as HPV vaccine is acceptable and there is no interference with the effectiveness of response to HPV vaccine.

https://www.sciencedirect.com/science/article/pii/S0264410X19314811 (you will be directed to the Science Direct website)

November

Safety of the 9-Valent Human Papillomavirus Vaccine

Data obtained post-licensure safety monitoring support the safety of Gardasil 9 human papillomavirus vaccine, finding no evidence of health risks associated with the human papillomavirus (HPV) vaccine.

“No new or unexpected safety concerns or reporting patterns of 9vHPV with clinically important AEs were detected. The safety profile of 9vHPV is consistent with data from prelicensure trials and from post marketing safety data of its predecessor, the quadrivalent”.

Shimabukuro T, Su J, Marquez P, Mba-Jonas A, Arana J and Cano M

Pediatrics November
2019, e20191791 https://pubmed.ncbi.nlm.nih.gov/31740500/ (you will be directed to the PubMed website)

Near Real-Time Surveillance to Assess the Safety of the 9-Valent Human Papillomavirus Vaccine

"After 2 years of near real-time surveillance of 9vHPV and several prespecified adverse events, no new safety concerns were identified."

Donahue J, Kieke B, Lewis E, Weintraub E, Hanson K, McClure D, Vickers E, Gee J, Daley M, DeStefano F, Hechter R, Jackson L, Klein N, Naleway A, Nelson J, Belongia E

Pediatrics November
2019, e20191808 https://pediatrics.aappublications.org/content/early/2019/11/14/peds.2019-1808 (you will be directed to the AAP website)

September

The American Autonomic Society finds that there are no data to support a causal relationship between HPV vaccination and CRPS, chronic fatigue, and postural tachycardia syndrome to other forms of dysautonomia.

Certain conditions are prevalent in the same populations that are vaccinated with the HPV vaccine (peri-pubertal males and females). This association, however, is an insufficient proof of causality.

Human papillomavirus (HPV) vaccine and autonomic disorders: a position statement from the American Autonomic Society

Barboi, A., Gibbons, C.H., Axelrod, F. et al. Clin Auton Res (2019).

https://doi.org/10.1007/s10286-019-00608-w (you will be directed to the Springer Link website)

August

Population-level impact and herd effects following the introduction of human papillomavirus vaccination programmes: updated systematic review and meta-analysis

An updated systematic review and meta-analysis includeding data from 60 million individuals and up to 8 years of post-vaccination follow-up.

The results show compelling evidence of the substantial impact of HPV vaccination programmes on HPV infections and CIN2+ among girls and women, and on anogenital warts diagnoses among girls, women, boys, and men. Additionally, programmes with multi-cohort vaccination and high vaccination coverage had a greater direct impact and herd effects.

Mélanie Drolet, PhD, Élodie Bénard, MSc, Norma Pérez, MSc, Prof Marc Brisson, PhD

https://doi.org/10.1016/S0140-6736(19)30298-3 (you will be directed to the Lancet website)

April

Prevalence of cervical disease at age 20 after immunisation with bivalent HPV vaccine at age 12-13 in Scotland: retrospective population study

'In Scotland routine vaccination of 90% of all girls aged 12-13 years with the HPV vaccine since 2008 has led to a dramatic reduction in cervical precancers'.

Younger age at immunisation was associated with increasing vaccine effectiveness.

Tim Palmer, Lynn Wallace, Kevin G Pollock, Kate Cuschieri, Chris Robertson, Kim Kavanagh, Margaret Cruickshank.

BMJ 2019;365:l1161 https://www.bmj.com/content/365/bmj.l1161 (you will be directed to the BMJ website)

February

Widespread coverage of both HPV vaccination and cervical screening from 2020 onwards has the potential to avert up to12·5–13·4 million cervical cancer cases by 2069. A draft global strategy to accelerate cervical cancer elimination, with goals and targets for the period 2020–30, will be considered at the World Health Assembly in 2020.

Impact of scaled up human papillomavirus vaccination and cervical screening and the potential for global elimination of cervical cancer in 181 countries, 2020–99: a modelling study

Kate T Simms, Julia Steinberg, Michael Caruana, Megan A Smith, Jie-Bin Lew, Isabelle Soerjomataram, Philip E Castle, Freddie Bray, Karen Canfell

Lancet Oncol 2019; 20: 394–407, https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(18)30836-2/fulltext (you will be directed to the Lancet website)

2018

October

The International Federation of Obstetricians and Gynaecologists (FIGO) representing Obstetricians and Gynaecologists from 130 countries issue a Global Declaration on Cervical Cancer Elimination.

FIGO Global Declaration on Cervical Cancer Elimination

https://www.figo.org/Declaration-Cervical-Cancer2018 (you will be directed to the Figo website)

Dutch research shows no causal link between the HPV vaccine and chronic fatigue symptoms in girls. Current findings of epidemiological research in the Netherlands correspond with the results of previous international studies.

No evidence found for an increased risk of long-term fatigue following human papillomavirus vaccination of adolescent girls

T M Schurink-Van't Klooster, J M Kemmeren, N A T van der Maas, E M van de Putte, M Ter Wolbeek, S L Nijhof, A M Vanrolleghem, J A van Vliet, M Sturkenboom, H E de Melker

https://www.sciencedirect.com/science/article/pii/S0264410X18312684 (you will be directed to the Science Direct website)

September

HPV16 and HPV18 antibody levels remained stable and above natural infection-related antibody levels for up to 12 years for most vaccine recipients.

Long-Term Antibody Response to Human Papillomavirus Vaccines: up to 12 Years Follow-Up in the Finnish Maternity Cohort

Hanna Artemchuk, Tiina Eriksson, Mario Poljak, Heljä-Marja Surcel, Joakim Dillner, Matti Lehtinen, Helena Faust

The Journal of Infectious Diseases, jiy545, https://doi.org/10.1093/infdis/jiy545 (you will be directed to the Oxford Academic website)

July

Researchers in Norway have shown a significant 90% drop in HPV vaccine types in girls who were vaccinated with HPV vaccine.

"Substantial Decline in Prevalence of Vaccine-Type and Nonvaccine-Type Human Papillomavirus (HPV) in Vaccinated and Unvaccinated Girls 5 Years After Implementing HPV Vaccine in Norway"

Berit Feiring, Ida Laake, Irene Kraus Christiansen, Mona Hansen, Jeanette Stålcrantz, Ole Herman Ambur, Per Magnus, Christine Monceyron Jonassen, Lill Trogstad

The Journal of Infectious Diseases, jiy432, https://doi.org/10.1093/infdis/jiy432 (you will be directed to the Oxford Academic website)

June

Research published from England shows that 8 years after the introduction of HPV vaccine cancer causing HPV infections have fallen 86% among women aged 16 to 21 who were eligible for the vaccine.

"The Impact of the National HPV Vaccination Program in England Using the Bivalent HPV Vaccine: Surveillance of Type-Specific HPV in Young Females, 2010–2016"

David Mesher, Kavita Panwar, Sara L Thomas, Claire Edmundson, Yoon Hong Choi, Simon Beddows Kate Soldan

The Journal of Infectious Diseases, jiy249, https://doi.org/10.1093/infdis/jiy249 (you will be directed to the Oxford Academic website)

May

A study published in the Canadian Medical Association Journal shows no increased risk of autoimmune disorders in girls who received quadrivalent human papillomavirus (HPV4) vaccination, adding to the body of evidence for the safety of GARDASIL vaccine

"Quadrivalent human papillomavirus vaccination in girls and the risk of autoimmune disorders: the Ontario Grade 8 HPV Vaccine Cohort Study"

Erin Y. Liu, Leah M. Smith, Anne K. Ellis, Heather Whitaker, Barbara Law, Jeffrey C. Kwong, Paddy Farrington and Linda E. Lévesque

CMAJ May 28, 2018 190 (21) E648-E655;
DOI: https://doi.org/10.1503/cmaj.170871 (you will be directed to the CMAJ Group website)

Evidence published in the Cochrane Library shows that human papilloma virus (HPV) vaccines protect against cervical lesions in young women.

The evidence also shows the risk of serious adverse events is similar between control and HPV vaccines in women of all ages

Prophylactic vaccination against human papillomaviruses to prevent cervical cancer and its precursors

Marc Arbyn, Lan Xu, Cindy Simeons, Pierre PL Martin Hirsch

Cochrane Library: http://cochranelibrary-wiley.com/doi/10.1002/14651858.CD009069.pub3/abstract (you will be directed to the Cochrane Library website)

February

This study, reporting the longest surveillance follow-up to date, shows the HPV infection rate among women aged 18 to 24 dropped from 22.7% to 1.1% between 2005 and 2015. A substantial fall also occurred in women aged 25–35, despite lower vaccine coverage. Very Low Prevalence of Vaccine Human Papillomavirus Types Among 18- to 35-Year Old Australian Women 9 Years Following Implementation of Vaccination

Dorothy A Machalek, Suzanne M Garland, Julia M L Brotherton, Deborah Bateson, Kathleen McNamee, Mary Stewart, S Rachel Skinner, Bette Liu, Alyssa M Cornall , John M Kaldor, Sepehr N Tabrizi

The Journal of Infectious Diseases, jiy075, https://doi.org/10.1093/infdis/jiy075 (you will be directed to the Oxford Academic website)

January

11 years after HPV vaccine introduction, study shows significant decreases in vaccine-type HPV in vaccinated women. The decrease in 4-valent vaccine-type HPV indicates Gardasil vaccine effectiveness.

9-Valent and 4-Valent HPV Vaccine Effectiveness and Herd Protection among Young Women, 11 Years after Vaccine Introduction

Spinner Chelse, Lili Ding, David Bernstein, Darron R. Brown, Eduardo L.Franco, Jessica A. Kahn,

https://www.sciencedirect.com/science/article/pii/S1054139X17307012 (you will be directed to the Science Direct website)

2017

December

World Health Organization released an information sheet – Observed rate of vaccine reactions human papilloma virus vaccine

There is a large volume of evidence on the safety of the human papillomavirus (HPV) vaccine. This paper has identified robust scientific evidence that supports the safety of the HPV vaccine.

Safety of Human Papillomavirus Vaccines: An Updated Review

Anastasia Phillips, Cyra Patel, Alexis Pillsbury, Julia Brotherton, Kristine Macartney

Drug Saf https://doi.org/10.1007/s40264-017-0625-z (you will be directed to the Springer Link website)

November

4-Valent Human Papillomavirus (4vHPV) Vaccine in Preadolescents and Adolescents After 10 Years

Daron G. Ferris, Rudiwilai Samakoses, Stanley L. Block, Eduardo Lazcano-Ponce, Jaime Alberto Restrepo, Jesper Mehlsen, Archana Chatterjee, Ole-Erik Iversen, Amita Joshi, Jian-Li Chu, Andrea Likos Krick, Alfred Saah, Rituparna Das

http://pediatrics.aappublications.org/content/early/2017/11/20/peds.2016-3947 (you will be directed to the AAP website)

October

Another published study shows no evidence that the HPV vaccine increases risk of autoimmune and neurological diseases in adult women aged 18-44 years.

Human papillomavirus vaccination of adult women and risk of autoimmune and neurological diseases

Hviid, A, Svanström, H, Scheller, N. M., Grönlund, O., Pasternak, B., Arnheim-Dahlström, L.

Journal of Internal Medicine, 1365-2796, UR

A study following 2084 women in Denmark, Iceland, Norway, and Sweden shows that the HPV vaccine provides continued protection in women for at least 10 years, with a trend for continued protection through 12 years of follow-up.

A 12-Year Follow-up on the Long-Term Effectiveness of the Quadrivalent Human Papillomavirus Vaccine in 4 Nordic Countries

Susanne K Kjaer Mari Nygård Joakim Dillner J Brooke Marshall David Radley Meng Li Christian Munk Bo T Hansen Lara G Sigurdardottir Maria Hortlund.

Clinical Infectious Diseases, cix797, https://doi.org/10.1093/cid/cix797 (you will be directed to the Oxford Academic website)

July

The World Health Organisation (WHO) has again reported in July 2017 that HPV vaccines are considered to be extremely safe. The World Health Organization (WHO) Global Advisory Committee for Vaccine Safety (GACVS) has reviewed the evidence on the safety of Gardasil vaccine in 2007, 2008, 2009, 2013, 2014 and 2015. WHO has never reported safety concerns with HPV vaccines.

WHO Safety Update of HPV vaccines (you will be directed to the WHO website)

A large Norwegian study aimed to ascertain if any association existed between HPV vaccination and chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME). Over 176,000 girls who were eligible for HPV vaccination were included in the study. No indication of increased risk of CFS/ME following HPV vaccination was observed among girls who were vaccinated.

Feiring B, Laake I et al. HPV vaccination and risk of chronic fatigue syndrome/myalgic encephalomyelitis: A nationwide register-based study from Norway. HPV vaccination and risk of chronic fatigue syndrome/myalgic encephalomyelitis: A nationwide register-based study from Norway. Vaccine Volume 35, Issue 33, (you will be directed to the Science Direct website) , Pages 4203-4212

http://www.sciencedirect.com/science/article/pii/S0264410X17308083 (you will be directed to the Science Direct website)

In Scotland research has shown there has been a 90% fall in HPV infections in vaccinated girls which is even better than expected. In Scotland 90% of girls have accepted HPV vaccination.

Scottish Microbiological Society https://www.microbiologysociety.org/news/hpv-immunisation-campaign-causes-massive-reduction-in-prevalence-of-cancer-causing-virus-in-scottish-women.html (you will be directed to the Microbiology Society website)

June

A British study based upon two large population-based probability sample surveys found that fewer women, aged 18 to 20 years who were vaccinated against HPV 16/18 tested positive for HPV 16/18 (5.8% versus 11.2% in those unvaccinated).

Tanton C, Mesher D et al Human papillomavirus (HPV) in young women in Britain: Population-based evidence of the effectiveness of the bivalent immunisation programme and burden of quadrivalent and 9-valent vaccine types. Papillomavirus Res. (you will be directed to the Oxford Academic website) 2017 Jun;3:36-41

Please note you will be leaving www.immunisation.ie when you click the research author links above.

https://www.ncbi.nlm.nih.gov/pubmed/28626810 (you will be directed to the PubMed website)

May

The World Health Organization updated their position statement on HPV vaccines. They state that adverse events following HPV vaccination are generally non-serious and of short duration. Data from all sources continue to be reassuring regarding the safety profile of all 3 HPV vaccines in use. Concerns have been raised about complex regional pain syndrome (CRPS) and postural orthostatic tachycardia syndrome (POTS) following HPV vaccination. Despite the difficulties in diagnosing both disorders, reviews of pre- and post-licensure data have provided no evidence that these syndromes are a direct effect of the HPV vaccines. The WHO Global Advisory Committee for Vaccine Safety has stated that policy decisions based on weak evidence, leading to lack of use of safe and effective vaccines, can result in significant harm.

Human papillomavirus vaccines: WHO position paper, May 2017 http://apps.who.int/iris/bitstream/10665/255353/1/WER9219.pdf?ua=1 (you will be directed to the WHO website)

March

An English study examined girls aged 11 to 20 years who were admitted to hospital with Guillain-Barre syndrome. The study found no evidence of an increased risk of GBS in the first 3, 6 or 12 months following a dose of HPV vaccination.

Andrews N, Stowe J, Miller E No increased risk of Guillain-Barre syndrome after human papilloma virus vaccine: A self-controlled case-series study in England Vaccine. (you will be directed to the PubMed website) 2017 Mar 23;35(13):1729-1732.

Please note you will be leaving www.immunisation.ie when you click the research author links above.

https://www.ncbi.nlm.nih.gov/pubmed/28245941 (you will be directed to the PubMed website)

A French based study of over 3,700 sexually active young women found that the prevalence of HPV strains contained in vaccines (vaccine type HPV prevalence) was significantly lower among confirmed vaccinated women than among those women who were unvaccinated. This study showed the effectiveness of HPV prophylactic vaccines at an individual level.

Heard I, Tondeur L Effectiveness of Human Papillomavirus Vaccination on Prevalence of Vaccine Genotypes in Young Sexually Active Women in France J Infect Dis. (you will be directed to the PubMed website) 2017 Mar 1;215(5):757-763.

https://www.ncbi.nlm.nih.gov/pubmed/28011911 (you will be directed to the PubMed website)

February

A French based follow-up study assessed if any association existed between HPV vaccine exposure and autoimmune diseases in French adolescents and young adults in the first 6 and a half years of vaccination in France. They found that exposure to HPV vaccines was not associated with an increased risk of autoimmune diseases, specifically central demyelination/multiple sclerosis, connective tissue disease, type 1 diabetes, autoimmune thyroiditis or idiopathic thrombocytopenic purpura.

Grimaldi-Bensouda L, Rossignol M et al Risk of autoimmune diseases and human papilloma virus (HPV) vaccines: six years of case-referent surveillance

J Autoimmun. (you will be directed to the PubMed website) *2017 May;79:84-90. doi: 10.1016/j.jaut.2017.01.005. Epub 2017 Feb 9*

https://www.ncbi.nlm.nih.gov/pubmed/28190705 (you will be directed to the PubMed website)

2016

December 2016

A study examined if any potential risk of new onset autoimmune disease in women aged 9 to 25 years in the United Kingdom after administration of the AS04-HPV 16/18 vaccine, existed. This found no evidence of an increased risk of autoimmune disease in women aged 9 to 25 years after vaccination.

Willame C, Rosillon D et a. Risk of new onset autoimmune disease in 9- to 25- year old women exposed to human papillomavirus – 16/18 AS04-adjuvanted vaccine in the United Kingdom

Hum Vaccin Immunother. (you will be directed to the PubMed website) 2016 Nov;12(11):2862-2871. Epub 2016 Jul 18

https://www.ncbi.nlm.nih.gov/pubmed/27428517 (you will be directed to the PubMed website)

A US study examined a group of sexually active, inner-city adolescent women receiving the 3-dose quadrivalent vaccine. Compared to unvaccinated women, those who were vaccinated had significantly lower incidence of cervical infection with HPV6/11/16/18. Among adolescents immunized at 15 years of age or older, a longer time to complete the 3-dose schedule was associated with an increased risk of anogenital HPV6/11/16/18 infection and an increased incidence of associated cervical cytological abnormalities.

Schlecht N F,Diaz A et al. Risk of Delayed Human Papillomavirus Vaccination in Inner-City Adolescent Women The Journal of Infectious Diseases, 214. 12,1952–1960,

https://academic.oup.com/jid/article-abstract/214/12/1952/2194444 (you will be directed to the Oxford Academic website)

November 2016

A literature review focused upon 13 randomized controlled trials which compared HPV vaccines to controls. Of the 11,189 people in seven publications reporting cumulative, all-type adverse events, the vaccinated group was higher than the control group, although the most common adverse events were injection-sire reactions. There was no significant difference in systemic symptoms. The authors concluded with the finding that the vaccination was a safe preventative measure for both men and women.

Mohamed Macki and Ali A. Dabaja Literature review of vaccine-related adverse events reported from HPV vaccination in randomized controlled trials. Basic Clin Androl. 2016; 26: 16

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October

CDC and American Advisory Committee on Immunization Practices recommend a two dose HPV vaccine and states this schedule would ensure more Americans are protected from cancer.

http://www.cdc.gov/media/releases/2016/p1020-hpv-shots.html (you will be directed to the CDC website)

A large clinical trial recruited women from Europe, North and Latin Americas and the Asia Pacific region. Women older than 25 years who were vaccinated with the HPV 16/18 vaccine were protected against infections, cytological cervical abnormalities and lesions associated with HPV 16/18 and cervical intraepithelial neoplasia as well as infection with non-vaccine types HPV 31 and 45 over a seven year period.

Wheeler Cosette M et al. Efficacy, safety and immunogenicity of the human papillomavirus 16/18 AS04-adjuvanted vaccine in women older than 25 years: 7-year follow-up of the phase3, double-blind, randomised controlled VIVIANE study The Lancet infectious Disease Volume 16, No. 10, (you will be directed to the Lancet website) p1154–1168, October 2016

September

Danish study finds that compared to controls, women reporting severe adverse reactions to HPV vaccine had increased care-seeking in the 2 years before receiving the first HPV vaccine.

Mølbak K, Hansen N, Valentiner-Branth P.Pre-Vaccination Care-Seeking in Females Reporting Severe Adverse Reactions to HPV Vaccine. A Registry Based Case-Control Study. PLoS One. (you will be directed to the PubMed website) 2016 Sep 9;11(9):e0162520.

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August

CDC US Department of Health and Human Services, American Academy of Family Physicians, and American Academy of Pediatrics declare that Gardasil is safe.

https://www.cdc.gov/vaccinesafety/pdf/data-summary-hpv-gardasil-vaccine-is-safe.pdf (you will be directed to the CDC website)

Irish Cancer Society Decoding Cancer public talks entitled: 'The HPV Vaccine – Warts and all' were held in Galway on August 23rd and in Cork, August on 24th. The talks outlined the significance of HPV as a cause of cancer and the facts about the safety and effectiveness of the vaccine in cervical and other cancer prevention.

July

American Cancer Society updated its guideline for HPV vaccination to include males.

http://www.cancer.org/cancer/news/news/american-cancer-society-updates-hpv-vaccine-recommendations-to-include-males (you will be directed to the American Cancer Society website)

Swedish study finds Gardasil vaccination was not associated with increased incidence of new-onset autoimmune disease in girls and women with pre-existing autoimmune disease. Gardasil vaccination was associated with a slightly reduced risk (0.77, 95% CI 0.65-0.93) of new onset autoimmune disease.

Grönlund O, Herweijer E, Sundström K, Arnheim-Dahlström L Incidence of new-onset autoimmune disease in girls and women with pre-existing autoimmune disease after quadrivalent human papillomavirus vaccination: a cohort study.J Intern Med. (you will be directed to the PubMed website) 2016 Jul 31. [Epub ahead of print]

Please note you will be leaving www.immunisation.ie when you click the research author links above.

https://www.ncbi.nlm.nih.gov/labs/articles/27478093/ (you will be directed to the National Library of Medicine website)

May

Australian review finds that implementation of HPV vaccination programmes resulted in reductions of HPV 6, 11,16 & 18 infection (90%), genital warts (90%), low-grade cytological cervical abnormalities (45%) and high-grade histologically proven cervical abnormalities (85%). Ensuring broad coverage of appropriate populations can provide a major advancement in global public health.

Garland S, Kjaer S, Munoz N et al. Impact and Effectiveness of the Quadrivalent Human Papillomavirus Vaccine: A Systematic Review of 10 Years of Real-world Experience - on the benefits of the HPV vaccine. Clinical Infectious Diseases, first published online May 26, 2016

http://cid.oxfordjournals.org/content/early/2016/06/14/cid.ciw354.full (you will be directed to the Oxford Academic website)

Irish Cancer Society states that a combination of a HPV vaccination and cervical screening programme, has the potential to reduce the incidence of cervical cancers by 90%. The Society also states that the HPV Vaccine is safe and that there is no scientific evidence to suggest otherwise.

April

American Society of Clinical Oncology strongly recommends the need to increase the proportion of adolescent boys and girls receiving the HPV vaccine which could lead to complete eradication of HPV-related cancers in men and women.

January

EMA concludes that there is zero evidence that HPV vaccines cause CRPS or POTS or chronic fatigue like conditions. They conclude that the benefits of HPV vaccines continue to outweigh their risks and that use of these vaccines is expected to prevent many cases of cervical cancer as well as various other cancers and conditions caused by HPV.

European Medicines Agency HPV vaccines: EMA confirms evidence does not support that they cause CRPS or POTS 12 January 2016

https://www.ema.europa.eu/documents/referral/hpv-vaccines-article-20-procedure-review-concludes-evidence-does-not-support-hpv-vaccines-cause-crps_en.pdf *(you will be directed to the European Medicines Agency website)*

US National Cancer Institute (NCI) designated Cancer Centers declare that low uptake rates of HPV vaccination constituted a serious public health threat. They further state that HPV vaccination represents a rare opportunity to prevent many cases of cancer and save lives.

https://www.mdanderson.org/content/dam/mdanderson/documents/prevention-and-screening/NCI_HPV_Consensus_Statement_012716.pdf (you will be directed to the MD Anderson website)

European Commission endorses the conclusion of the EMA stating that there is no need to change the way HPV vaccines are used or to amend the product information. This final outcome by the Commission is now binding in all member states.

https://www.kildarestreet.com/wrans/?id=2016-10-26a.374 (you will be directed to the Kildare Street website)

2015

December

WHO reports there are no safety issues with the use of HPV vaccines.

Global Advisory Committee on Vaccine safety Statement on Safety of HPV vaccines 17 December 2015

September

Multinational study finds no increase in the incidence of serious adverse events associated with HPV vaccination compared with background rates.

Vichnin M, Bonanni P, Klein N et al. An Overview of Quadrivalent Human Papillomavirus Vaccine Safety: 2006 to 2015. Pediatr Infect Dis J. (you will be directed to the PubMed website) 2015 Sep;34(9):983-91.

Please note you will be leaving www.immunisation.ie when you click the research author links above.

https://www.ncbi.nlm.nih.gov/pubmed/26107345 (you will be directed to the PubMed website)

August

Nordic region study finds that Gardasil provides protection for at least 9 years following vaccination.

Nygård M, Saah A, Munk C, Tryggvadottir L, Enerly E, Hortlund M, Sigurdardottir LG, Vuocolo S, Kjaer SK, Dillner J. Evaluation of the Long-Term Anti-Human Papillomavirus 6 (HPV6), 11, 16, and 18 Immune Responses Generated by the Quadrivalent HPV Vaccine. Clin Vaccine Immunol. (you will be directed to the PubMed website) 2015 Aug;22(8):943-8.

Please note you will be leaving www.immunisation.ie when you click the research author links above.

Japanese Society of Obstetrics and Gynecology demands the resumption of recommendations for HPV vaccination with the aim of eradicating cervical cancer.

Australian review concludes that HPV vaccines are highly efficacious (>90%) at preventing infection and related cervical intraepithelial neoplasia and has proven efficacy in both sexes and against HPV16/18/6/11 related vulvar, vaginal, penile and anal intraepithelial neoplasia and genital warts. There are no safety concerns.

Brotherton JHPV prophylactic vaccines: lessons learned from 10 years experience Future Virology (you will be directed to the Future Medicine website) August 2015 ,Vol. 10, No. 8, Pages 999-1009

http://www.futuremedicine.com/doi/abs/10.2217/fvl.15.60?journalCode=fvl (you will be directed to the Future Medicine website)

June

EMA approves Gardasil 9 vaccine for use in males and females from nine years to protect against precancerous lesions (growths) and cancers in the cervix, vulva or vagina and anus and genital warts caused by nine types of the human papillomavirus (HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58).

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003852/human_med_001863.jsp&mid=WC0b01ac058001d124 (you will be directed to the European Medicines Agency website)

May

Australian study confirms there was a decline in the diagnosis of genital warts 7 years following the introduction of the national Gardasil vaccination programme

Chow EP, Read TR, Wigan R, Donovan B, Chen MY, Bradshaw CS, Fairley CK.

Please note you will be leaving www.immunisation.ie when you click the research author links above.

Ongoing decline in genital warts among young heterosexuals 7 years after the Australian human papillomavirus (HPV) vaccination programme. Sex Transm Infect. (you will be directed to the PubMed website) 2015 May;91(3):214-9.

http://sti.bmj.com/content/91/3/214.full.pdf+html (you will be directed to the BMJ website)

January

Scandinavian study finds vaccinated girls were no more likely than unvaccinated girls to develop multiple sclerosis (MS) or other similar diseases.

Scheller NM, Svanström H, Pasternak B, Arnheim-Dahlström L, Sundström K, Katharina Fink K, et al. Quadrivalent HPV vaccination and risk of multiple sclerosis

and other demyelinating diseases of the central nervous system. JAMA. 2015 Jan; 313(1):54-61.

http://jamanetwork.com/journals/jama/fullarticle/2088853 (you will be directed to the JAMA Netwrok website)

Australian study confirms that the introduction of the national Gardasil vaccination Programme led to a reduction in the diagnoses of genital warts nationally among females (89.9%) and had indirect benefits to males (38.3%).

Smith MA, Liu B, McIntyre P, Menzies R, Dey A, Canfell K. Fall in genital warts diagnoses in the general and indigenous Australian population following implementation of a national human papillomavirus vaccination program: analysis of routinely collected national hospital data. J Infect Dis. (you will be directed to the PubMed website) 2015 Jan 1;211(1):91-9.

Please note you will be leaving www.immunisation.ie when you click the research author links above.

http://jid.oxfordjournals.org/content/211/1/91.full.pdf+html (you will be directed to the Oxford Academic website)

A US study finds no safety concerns for pregnant women who received Gardasil, or for their babies. ****Gardasil is not recommended during pregnancy. However, some women may receive the Gardasil shot before realising they are pregnant.*

Moro PL, Zheteyeva Y, Lewis P, Shi J, Yue X, Museru OI, et al. Safety of quadrivalent human papillomavirus vaccine (Gardasil®) in pregnancy: Adverse events among non-manufacturer reports in the Vaccine Adverse Event Reporting System, 2006-2013. Vaccine. 2015 Jan; 33(4): 519-22.

http://www.sciencedirect.com/science/article/pii/S0264410X14016041 (you will be directed to the Science Direct website)

2014

December

FDA approves Gardasil 9 for the prevention of cervical, vulvar, vaginal and anal cancers caused by HPV types 16, 18, 31, 33, 45, 52 and 58, and for the prevention of genital warts caused by HPV types 6 or 11. FDA states that Gardasil 9 has the potential to prevent approximately 90% of cervical, vulvar, vaginal and anal cancers.

https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm426445.htm *(you will be directed to the FDA website)*

Multinational study finds that after 4 years follow up, Gardasil is protective against HPV infections and cervical abnormalities associated with HPV 16/18 and infections with the non-vaccine HPV types 31 and 45.

Skinner SR, Szarewski A, Romanowski B, et al.Efficacy, safety, and immunogenicity of the human papillomavirus 16/18 AS04-adjuvanted vaccine in women older than 25 years: 4-year interim follow-up of the phase 3, double-blind, randomised controlled VIVIANE study.Lancet. (you will be directed to the PubMed website) 2014 Dec 20;384(9961):2213-27

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http://www.sciencedirect.com/science/article/pii/S014067361460920X (you will be directed to the Science Direct website)

September

US study finds Gardasil protects boys and girls aged 9 to 15 years for at least 8 years following vaccination.

Ferris D, Samakoses R, Block, S.L, et al, Long Term Study of a Quadrivalent Human Papilloma Virus Vaccine, Pediatrics 2014, 134: e657-e665

http://pediatrics.aappublications.org/content/134/3/e657.long (you will be directed to the AAP website)

August

Brazilian study finds Cervarix vaccine (HPV 16&18) protected women against HPV 16 and 18 after 9.4 years of follow up. There were no safety concerns.

Naud PS, Roteli-Martins CM, De Carvlho NS et al. Sustained efficacy, immunogenicity and safety of the HPV-16/18 ASO4 adjuvanted vaccine: Final analysis of a long-term follow-up study up to 9.4 years post-vaccination. Human Vaccines & Immunotherapeuthics 2014; 10(8)

US experts call on healthcare providers to provide the same strong recommendation for HPV vaccination as they do for other adolescent vaccines in order to play an active role in HPV-related cancers prevention.

July

Danish study finds Gardasil was not associated with venous thromboembolism (blood clots).

Scheller NM, Pasternak B, Svanström H, Hviid A. Quadrivalent human papillomavirus vaccine and the risk of venous thromboembolism. JAMA. 2014 Jul;312(2):187-8.

http://jamanetwork.com/journals/jama/fullarticle/1886177 (you will be directed to the JAMA Network website)

May

German study finds that antibody responses to a 2 dose schedule of Gardasil vaccine in girls aged 9-14 years is comparable to the standard 3 dose schedule.

Romanowski B, Schwarz T, Ferguson L, et al. Immune response to the HPV-16/18 AS04-adjuvanted vaccine administered as a 2-dose or 3-dose schedule up to 4 years after vaccination: results from a randomized study.Hum Vaccin Immunother. (you will be directed to the PubMed website) 2014;10(5):1155-65.

Please note you will be leaving www.immunisation.ie when you click the research author links above.

Danish study finds the incidence of anogenital warts reduced among med (50%0 and women (67%) following introduction of the national HPV vaccine programme.

Sando N, Kofoed K, Zachariae C, Fouchard J. A reduced national incidence of anogenital warts in young Danish men and women after introduction of a national quadrivalent human papillomavirus vaccination programme for young women--an ecological study.Acta Derm Venereol. (you will be directed to the PubMed website) 2014 May;94(3):288-92.

Please note you will be leaving www.immunisation.ie when you click the research author links above.

https://www.medicaljournals.se/acta/content/abstract/10.2340/00015555-1721 (you will be directed to the ActaDV website)

April

European Commission grants marketing authorisation for a 2-dose schedule of Gardasil vaccine for children aged from 9 -13 years.

French study finds there is no evidence of an increase in the risk of autoimmune disorders following Gardasil vaccination.

Grimaldi-Bensouda L, Guillemot D, Godeau B, et al. Autoimmune disorders and quadrivalent human papillomavirus vaccination of young female subjects. J Intern Med. 2014 Apr; 275(4):398-408. Epub 2013 Nov 22.

March

WHO evidence review concludes that there are no safety issues with Gardasil vaccine. WHO states that allegations of harm based on weak evidence can lead to real harm when, as a result, safe and effective vaccines cease to be used.

2013

December

Columbian study finds that Gardasil vaccination of 24-45 year-old women protects against HPV 6-, 11-, 16-, and 18-related genital warts and cervical dysplasia for 6 years.

Luna J, Plata M, Gonzalez M, Correa A, Maldonado I, Nossa C, Radley D, Vuocolo S, Haupt R, Saah A.Long-term follow-up observation of the safety, immunogenicity, and effectiveness of Gardasil in adult women.PLoS One. (you will be directed to the PubMed website) 2013 Dec 31;8(12)

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Brazilian study finds that HPV prevalence was much lower among vaccinated compared to unvaccinated women four years after Cervarix vaccination, suggesting protection against oral HPV infection, and associated oropharyngeal cancer.

Herrero R, Quint W, Hildesheim A, Gonzalez P, Struijk L, Katki H, Porras C, Schiffman M, Rodriguez A, Solomon D, Jimenez S, Schiller J, Lowy D, van Doorn L, Wacholder S, Kreimer A,CVT Vaccine Group Reduced Prevalence of Oral Human Papillomavirus (HPV) 4 Years after Bivalent HPV Vaccination in a Randomized Clinical Trial in Costa Rica

November

UK study finds that the HPV vaccine programme had led to a reduction in genital wart diagnoses at Genitourinary medicine clinics.

Howell-Jones R, Soldan K, Wetten S, Mesher D, Williams T, Gill ON, Hughes G.

Please note you will be leaving www.immunisation.ie when you click the research author links above.

Declining genital Warts in young women in England associated with HPV 16/18 vaccination: an ecological study.J Infect Dis. (you will be directed to the PubMed website) 2013 Nov 1;208(9):1397-403.

http://jid.oxfordjournals.org/content/208/9/1397.full.pdf+html (you will be directed to the Oxford Academic website)

October

Scandinavian study finds that Gardasil was not associated with blood clots or adverse events related to the autoimmune and brain systems.

Arnheim-Dahlström L, Pasternak B, Svanström H, Sparén P, Hviid A. Autoimmune, neurological, and venous thromboembolic adverse events after immunisation of adolescent girls with quadrivalent human papillomavirus vaccine in Denmark and Sweden: Cohort study. BMJ. 2013 Oct;347:f5906.

http://www.bmj.com/content/bmj/347/bmj.f5906.full.pdf (you will be directed to the BMJ website)

Australian study finds that population-based HPV vaccination program in schools significantly reduced cervical abnormalities for vaccinated women within five years of implementation.

Gertig D, Brotherton J, Budd A, Drennan K, Chappell G, Saville A.Impact of a population-based HPV vaccination program on cervical abnormalities: a data linkage study. BMC Med. (you will be directed to the PubMed website) 2013 Oct 22;11:227.

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August

US study finds that increased uptake of HPV vaccine among adolescent females coincided with a reduction in the annual rate of high-grade cervical and adenocarcinoma in situ in females ages 21 to 24 years.

Niccolai L, Julian P, Meek J, McBride V, Hadler J, Sosa L. Declining rates of high-grade cervical lesions in young women in Connecticut, 2008-2011. Cancer Epidemiol Biomarkers Prev. (you will be directed to the PubMed website) 2013 Aug;22(8):1446-50.

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http://cebp.aacrjournals.org/content/22/8/1446.long (you will be directed to the AACR website)

US study finds that vaccine-type HPV prevalence decreased by 56% among females aged 14-19 years within 4 years of vaccine introduction.

Markowitz L, Hariri S, Lin C, Dunne E, Steinau M, McQuillan G, Unger E. Reduction in human papillomavirus (HPV) prevalence among young women following HPV vaccine introduction in the United States, National Health and Nutrition Examination Surveys, 2003-2010. J Infect Dis. (you will be directed to the PubMed website) 2013 Aug 1;208(3):385-93.

Please note you will be leaving www.immunisation.ie when you click the research author links above.

http://jid.oxfordjournals.org/content/208/3/385.full.pdf+html (you will be directed to the Oxford Academic website)

July

American Academy of Pediatrics (AAP) and US CDC states that HPV vaccine is an anti-cancer vaccine and that preteen and teens are relying on the adults in their lives to help protect them and that no serious safety concerns have been identified. *http://www.cdc.gov/media/releases/2013/p0725-HPV-vaccine.html (you will be directed to the CDC website)*

The International Federation of Gynecology and Obstetrics (FIGO) supports the continued administration of the HPV vaccines and states the vaccines are safe.

June

WHO states that following review of evidence from all sources there were no HPV vaccine safety concerns.

2012

February

US study finds girls who received Gardasil were not more likely to develop autoimmune disorders than those who were unvaccinated.

Chao C, Klein NP, Velicer CM, Sy LS, Slezak JM, Takhar H, et al. Surveillance of autoimmune conditions following routine use of quadrivalent human papillomavirus vaccine. J Intern Med. 2012 Feb; 271(2):193-203. Epub 2011 Nov.

Multicentre (US, Canada and Brazil) study demonstrates that women aged 15-25 years were protected against HPV types 16 and 18 cervical changes 8.4 years after Cervarix vaccination.

Roteli-Martins, C.M., Naud, P., De Borba, P. et al. Sustained immunogenicity and efficacy of the HPV-16/18 AS04-adjuvanted vaccine: up to 8.4 years of follow-up. Human Vaccin Immunother. 2012; 8: 390–397

2011

October

US study finds women and girls who received Gardasil were no more at risk of allergic reactions, anaphylaxis (severe allergic reaction), Guillain–Barré Syndrome (GBS), stroke, blood clots, appendicitis, or seizures than those who were unvaccinated or who received other vaccines.

Gee J, Naleway A, Shui I, Baggs J, Yin R, Li R, et al. Monitoring the safety of quadrivalent human papillomavirus vaccine: Findings from the Vaccine Safety Datalink. Vaccine. 2011

http://www.sciencedirect.com/science/article/pii/S0264410X11013831 (you will be directed to the Science Direct website)

Costa Rican study finds that Cervarix resulted in complete protection HPV16 and HPV18 infections and partial protection against HPV31, 33, and 45 in HPV-naïve young women.

Bosch F, de Sanjose S, Castellsague X.The prospects of HPV vaccination in cervical cancer prevention: results of a new independent trial. Cancer Discov. (you will be directed to the PubMed website) 2011 Oct;1(5):377-80

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http://cancerdiscovery.aacrjournals.org/content/1/5/377.long (you will be directed to the AACR website)

September

Catch-up programme is introduced, with all girls in sixth year or equivalent from 2011 to 2014 offered Gardasil.

Immunisation Guidelines for Ireland (RCPI)

July

US review finds that Cervarix has the potential to reduce the incidence of cervical cancer from the current 50–80/100,000 women to 9.5/100,000 women.

Harper, D. M., & Vierthaler, S. L. (2011). Next Generation Cancer Protection: The Bivalent HPV Vaccine for Females. ISRN Obstetrics and Gynecology, 2011, 457204. http://doi.org/10.5402/2011/457204 (you will be directed to the HINDAWI website)

June

Australian study finds a reduction in the number of high grade cervical lesions within 3 years of the introduction of the national HPV vaccination programme.

Brotherton J, Fridman M, May CL, Chappell G, Saville AM, Gertig DM.Early effect of the HPV vaccination programme on cervical abnormalities in Victoria, Australia: an ecological study. Lancet. (you will be directed to the PubMed website) 2011 Jun 18;377(9783):2085-92.

Please note you will be leaving www.immunisation.ie when you click the research author links above.

http://www.sciencedirect.com/science/article/pii/S0140673611605515 (you will be directed to the Science Direct website)

February

US study finds that Gardasil prevents infection with HPV-6, 11, 16, and 18 and the development of related external genital lesions in males 16 to 26 years of age.

Giuliano A, Palefsky J, Goldstone S, Moreira E, Penny M, Aranda C, Vardas E, Moi H, Jessen H, Hillman R, Chang Y, Ferris D, Rouleau D, Bryan J, Marshall J, Vuocolo S, Barr E, Radley D, Haupt R, Guris D. Efficacy of quadrivalent HPV vaccine against

HPV Infection and disease in males. N Engl J Med. (you will be directed to the PubMed website) 2011 Feb 3;364(5):401-11.

Please note you will be leaving www.immunisation.ie when you click the research author links above.

January

Australian study finds diagnoses of genital warts reduced by 59% for young female residents after the introduction of Gardasil vaccination programme.

Donovan B, Franklin N, Guy R, Grulich AE, Regan DG, Ali H, Wand H, Fairley CK. Quadrivalent human papillomavirus vaccination and trends in genital warts in Australia: analysis of national sentinel surveillance data.Lancet Infect Dis. (you will be directed to the PubMed website) 2011 Jan;11(1):39-44.

Please note you will be leaving www.immunisation.ie when you click the research author links above.

http://www.sciencedirect.com/science/article/pii/S1473309910702255 (you will be directed to the Science Direct website)

2010

September

HPV Vaccine school programme is introduced in Ireland.

Immunisation Guidelines for Ireland (RCPI)

2009

October

FDA approves Cervarix for the prevention of cervical cancer, and precancerous lesions by HPV types 16 and 18.

August

U.S. Centers for Disease Control and Prevention (CDC) and FDA confirms that Gardasil is safe, effective and that benefits outweigh risks.

WHO states that the evidence on the safety of HPV vaccines is reassuring.

WHO Weekly Epidemiological Record No. 32, 2009, 84, 325–332

February

EMA recommends continued vaccination with Gardasil and concludes that the benefits of Gardasil outweigh the risks.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2009/11/news_detail_000113.jsp&mid=WC0b01ac058004d5c1 (you will be directed to the European Medicines Agency website)

2008

September

FDA extends Gardasil licence indication to include prevention of vaginal and vulvar cancers related to HPV types 16 and 18.

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111274.pdf (you will be directed to the FDA website)

2007

September

WHO concludes that HPV vaccine reduces the risk of cervical cancer.

Bulletin of the World Health Organization V olume 85: Number 9, September 2007

July

WHO Global Advisory Committee on Vaccine Safety (GACVS) states that the current evidence on the safety of HPV vaccines is reassuring.

WHO Weekly Epidemiological Record Nos. 28/29, 2007, 82, 245–260

2006

September

European Medicines Agency (EMA) grants a marketing authorisation for Gardasil vaccine throughout the European Union, including Ireland.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000703/human_med_000805.jsp (you will be directed to the European Medicines Agency website)

June

US Food and Drug Administration (FDA) approves Gardasil for the prevention of cervical cancer, and precancerous lesions by HPV types 6, 11, 16 and 18.

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