HPV vaccination and cancer prevention

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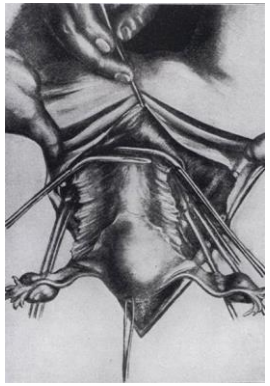
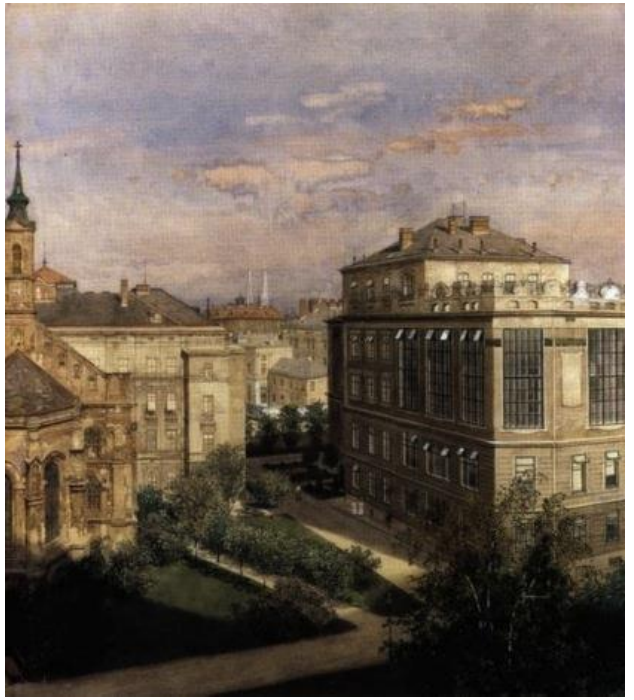
Disclosure

- Investigator for HPV vaccines (Merck)
  - Advisory board member
- Advisor for Roche Diagnostics

- Lectures for MSD, GSK, Roche

Vienna 1897
Ernst Wertheim: Radical Hysterectomy





Nobel Prize in Medicine 2008
Harald zur Hausen

Proc. Natl. Acad. Sci. USA
Vol. 80, pp. 560–563, January 1983
Medical Sciences

Human papillomavirus types 6 and 11 DNA sequences in genital and laryngeal papillomas and in some cervical cancers

(molecular cloning/blot hybridization/perinatal infection/genital cancer)

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Communicated by Gertrude Henle, October 13, 1982

ABSTRACT Human genital tumors as well as recurrent laryngeal papillomas were analyzed for the presence of human papillomavirus (HPV) 6 and HPV 11 sequences. HPV 11 DNA was found in 7 of 14 laryngeal papillomas; in the 7 other tumors no HPV DNA was demonstrated. HPV 11 DNA was also found in all five atypical condylomata of the cervix included in this study. Condylomata acuminata mainly contained HPV 6 DNA. From 63 biopsy specimens, 41 clearly harbored HPV 6 DNA and 13 harbored HPV 11 DNA. In three tumors accurate typing was impossible, and in six additional ones neither HPV 6 nor HPV 11 DNA could be demonstrated. The data support a genital origin of laryngeal papillomavirus infections. In 4 of 24 malignant tumors, HPV 11 DNA or related sequences were demonstrated; 2 of the 4 were biopsy specimens from invasive cancer, and the other 2 originated from carcinomata *in situ*. A possible role of this or related papillomavirus types in the induction of malignant genital tumors remains to be elucidated.

MATERIALS AND METHODS

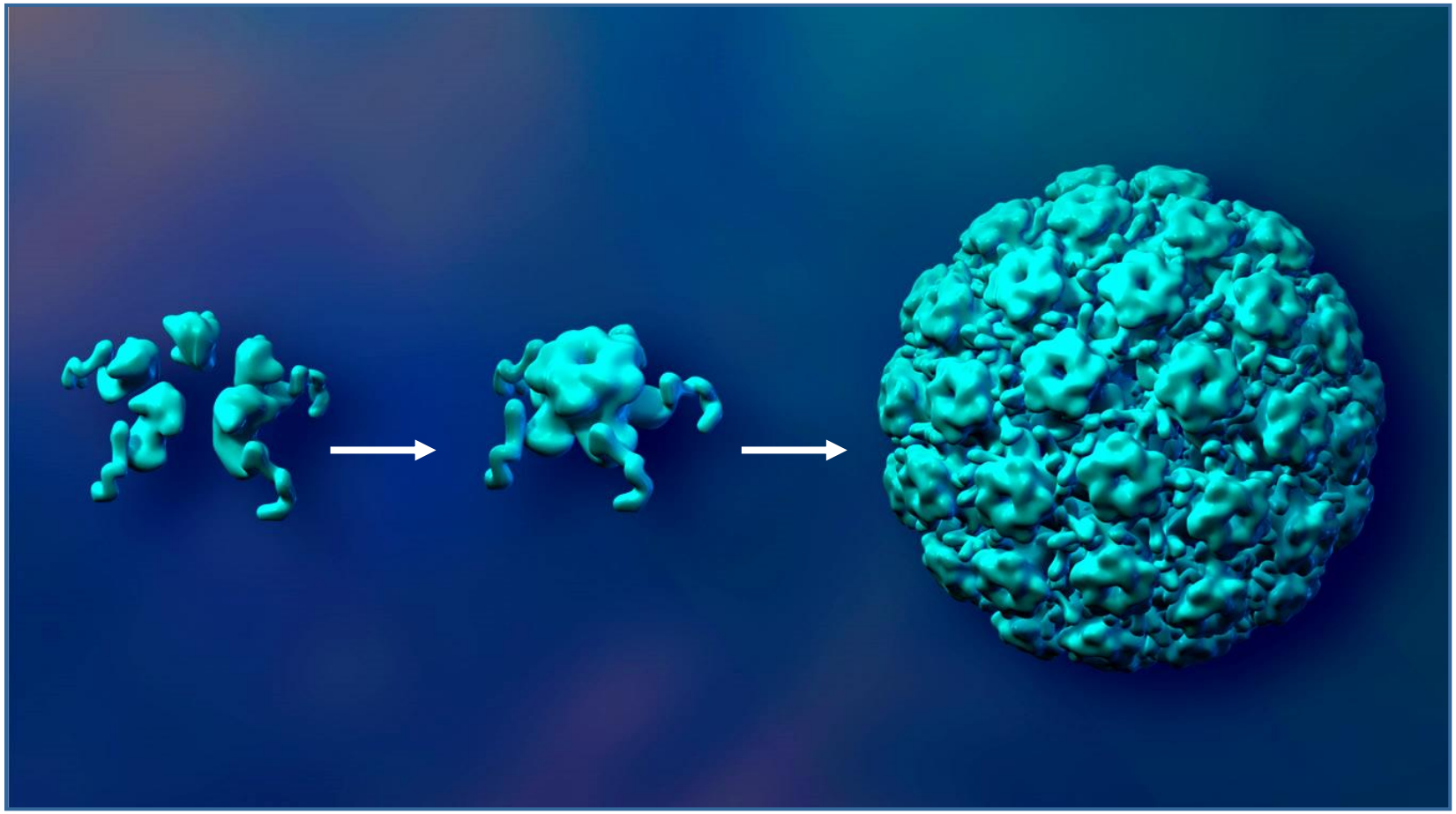
Extraction of Cellular DNA. Biopsy materials were examined histologically and stored at −20°C or −70°C until further processing. Extraction of cellular DNA was done as described (6).

Labeling of HPV DNA. HPV 6 DNA has been cloned into pBR322 in two fragments representing approximately one-third and two-thirds of the total genome, respectively (5). HPV 11 DNA, which has been identified from a genomic library of laryngeal papilloma constructed in λ L47 (7), was subcloned in pBR322 at the single *Bam*HI site.

Both DNAs were prepared as described (10) and labeled with deoxynucleotide [α-^{32}P]triphosphate by the nick-translation procedure to a specific activity of $>10^8$ cpm/μg (6).

Blot Hybridization. About 10 μg of papilloma DNA was cleaved with restriction enzyme; the products were separated

Virus-Like Particles (VLPs)



Bioengineered L1 Proteins (5)

L1 Pentamer

Self-Assembled Virus-Like Particle

Proof of principle

The New England
Journal of Medicine

VOLUME 347 NOVEMBER 21, 2002 NUMBER 21

A CONTROLLED TRIAL OF A HUMAN PAPILLOMAVIRUS TYPE 16 VACCINE

LAURA A. KOUTSKY, PH.D., KEVIN A. AULT, M.D., COSETTE M. WHEELER, PH.D., DARRON R. BROWN, M.D., ELIAV BARR, M.D., FRANCES B. ALVAREZ, R.N., LISA M. CHIACCHIERINI, PH.D., AND KATHRIN U. JANSEN, PH.D., FOR THE PROOF OF PRINCIPLE STUDY INVESTIGATORS

8 June 2006

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

News & Events

Home › News & Events › Newsroom › Press Announcements › 2006

FDA NEWS RELEASE

FOR IMMEDIATE RELEASE
P06-77
June 8, 2006

Media Inquiries:
Julie Zawisza, 301-827-6242
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888-INFO-FDA

FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus

Rapid Approval Marks Major Advancement in Public Health

The Food and Drug Administration (FDA) today announced the approval of Gardasil, the first vaccine developed to prevent cervical cancer, precancerous genital lesions and genital warts due to human papillomavirus (HPV) types 6, 11, 16 and 18. The vaccine is approved for use in females 9-26 years of age. Gardasil was evaluated and approved in six months under FDA's priority review process--a process for products with potential to provide significant health benefits.

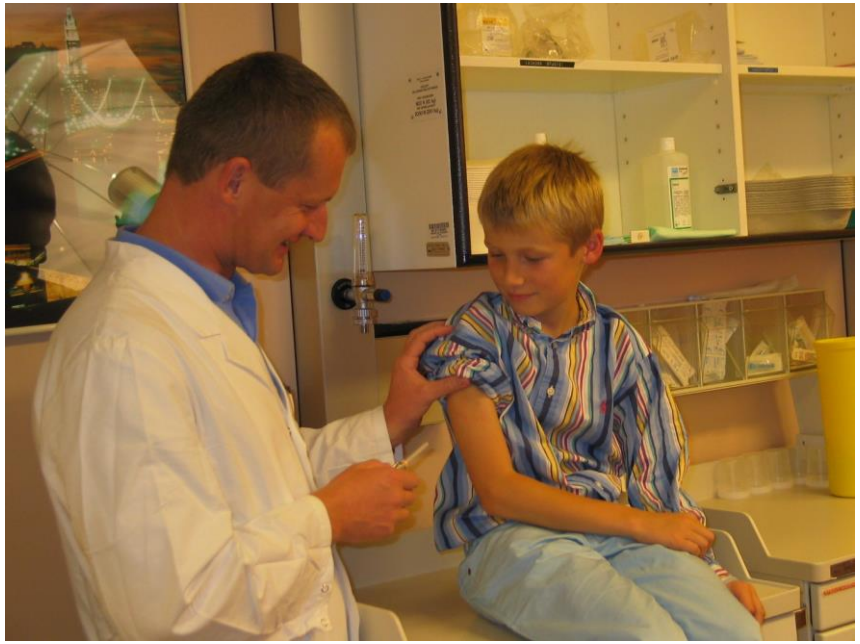
"Today is an important day for public health and for women's health, and for our continued fight against serious life-threatening diseases like cervical cancer," said Alex Azar, Deputy Secretary, U.S. Department of Health and Human Services (HHS). "HHS is committed to advancing critical health measures such as the development of new and promising vaccines to protect and advance the health of all Americans."

HPV is the most common sexually-transmitted infection in the United States. The Centers for Disease Control and Prevention estimates that about 6.2 million Americans become infected with genital HPV each year and that over half of all sexually active men and women become infected at some time in their lives. On average, there are 9,710 new cases of cervical cancer and 3,700 deaths attributed to it in the United States each year. Worldwide, cervical cancer is the second most common cancer in women; and is estimated to cause over 470,000 new cases and 233,000 deaths each year.

For most women, the body's own defense system will clear the virus and infected women do not develop related health problems. However, some HPV types can cause abnormal cells on the lining of the cervix that years later can turn into cancer. Other HPV types can cause genital warts. The vaccine is effective against HPV types 16 and 18, which cause approximately 70 percent of cervical cancers and against HPV types 6 and 11, which cause approximately 90 percent of genital warts.

"This vaccine is a significant advance in the protection of women's health in that it strikes at the infections that are the root cause of many cervical cancers," said Andrew C. von Eschenbach, MD, Acting Commissioner of Food and Drugs. "The development of this vaccine is a product of extraordinary work by scientists as well as by FDA's review teams to help facilitate the development of very novel vaccines to address unmet medical needs. This work has resulted in the approval of a number of new products recently, including Gardasil, which address significant public health needs."

First European HPV Vaccination
30.9.2006



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A 9-Valent HPV Vaccine against Infection and Intraepithelial Neoplasia in Women

E.A. Joura, A.R. Giuliano, O.-E. Iversen, C. Bouchard, C. Mao, J. Mehlsen, E.D. Moreira, Jr., Y. Ngan, L.K. Petersen, E. Lazcano-Ponce, P. Pitisuttithum, J.A. Restrepo, G. Stuart, L. Woelber, Y.C. Yang, J. Cuzick, S.M. Garland, W. Huh, S.K. Kjaer, O.M. Bautista, I.S.F. Chan, J. Chen, R. Gesser, E. Moeller, M. Ritter, S. Vuocolo, and A. Luxembourg, for the Broad Spectrum HPV Vaccine Study*

ABSTRACT

BACKGROUND

The investigational 9-valent viruslike particle vaccine against human papillomavirus (HPV) includes the HPV types in the quadrivalent HPV (qHPV) vaccine (6, 11, 16, and 18) and five additional oncogenic types (31, 33, 45, 52, and 58). Here we present the results of a study of the efficacy and immunogenicity of the 9vHPV vaccine in women 16 to 26 years of age.

METHODS

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Joura at the Department of Gynecology and Obstetrics, Medical University of Vienna, Währinger Gürtel 18-20, Vienna, Austria, or at elmar.joura@meduniwien.ac.at.

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

Mélanie Drolet, Élodie Bénard, Norma Pérez, Marc Brisson, on behalf of the HPV Vaccination Impact Study Group

Summary

Background More than 10 years have elapsed since human papillomavirus (HPV) vaccination was implemented. We did a systematic review and meta-analysis of the population-level impact of vaccinating girls and women against human papillomavirus on HPV infections, anogenital wart diagnoses, and cervical intraepithelial neoplasia grade 2+ (CIN2+) to summarise the most recent evidence about the effectiveness of HPV vaccines in real-world settings and to quantify the impact of multiple age-cohort vaccination.

Methods In this updated systematic review and meta-analysis, we used the same search strategy as in our previous paper. We searched MEDLINE and Embase for studies published between Feb 1, 2014, and Oct 11, 2018. Studies were eligible if they compared the frequency (prevalence or incidence) of at least one HPV-related endpoint (genital HPV infections, anogenital wart diagnoses, or histologically confirmed CIN2+) between pre-vaccination and post-vaccination periods among the general population and if they used the same population sources and recruitment methods before and after vaccination. Our primary assessment was the relative risk (RR) comparing the frequency (prevalence or incidence) of HPV-related endpoints between the pre-vaccination and post-vaccination periods. We stratified all analyses by sex, age, and years since introduction of HPV vaccination. We used random-effects models to estimate pooled relative risks.

Findings We identified 1702 potentially eligible articles for this systematic review and meta-analysis, and included 65 articles in 14 high-income countries: 23 for HPV infection, 29 for anogenital warts, and 13 for CIN2+. After 5–8 years of vaccination, the prevalence of HPV 16 and 18 decreased significantly by 83% (RR 0·17, 95% CI 0·11–0·25) among girls aged 13–19 years, and decreased significantly by 66% (RR 0·34, 95% CI 0·23–0·49) among women aged 20–24 years. The prevalence of HPV 31, 33, and 45 decreased significantly by 54% (RR 0·46, 95% CI 0·33–0·66) among girls aged 13–19 years. Anogenital wart diagnoses decreased significantly by 67% (RR 0·33, 95% CI 0·24–0·46) among girls aged 15–19 years, decreased significantly by 54% (RR 0·46, 95% CI 0.36–0.60) among women aged 20–24 years, and decreased significantly by 31% (RR 0·69, 95% CI 0·53–0·89) among women aged 25–29 years. Among boys aged 15–19 years anogenital wart diagnoses decreased significantly by 48% (RR 0·52, 95% CI 0·37–0·75) and among men aged 20–24 years they decreased significantly by 32% (RR 0·68, 95% CI 0·47–0·98). After 5–9 years of vaccination, CIN2+ decreased significantly by 51% (RR 0·49, 95% CI 0·42–0·58) among screened girls aged 15–19 years and decreased significantly by 31% (RR 0·69, 95% CI 0·57–0·84) among women aged 20–24 years.

Interpretation This updated systematic review and meta-analysis includes data from 60 million individuals and up to 8 years of post-vaccination follow-up. Our 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.

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Lancet 2019; 394: 497–509

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See Comment page 450

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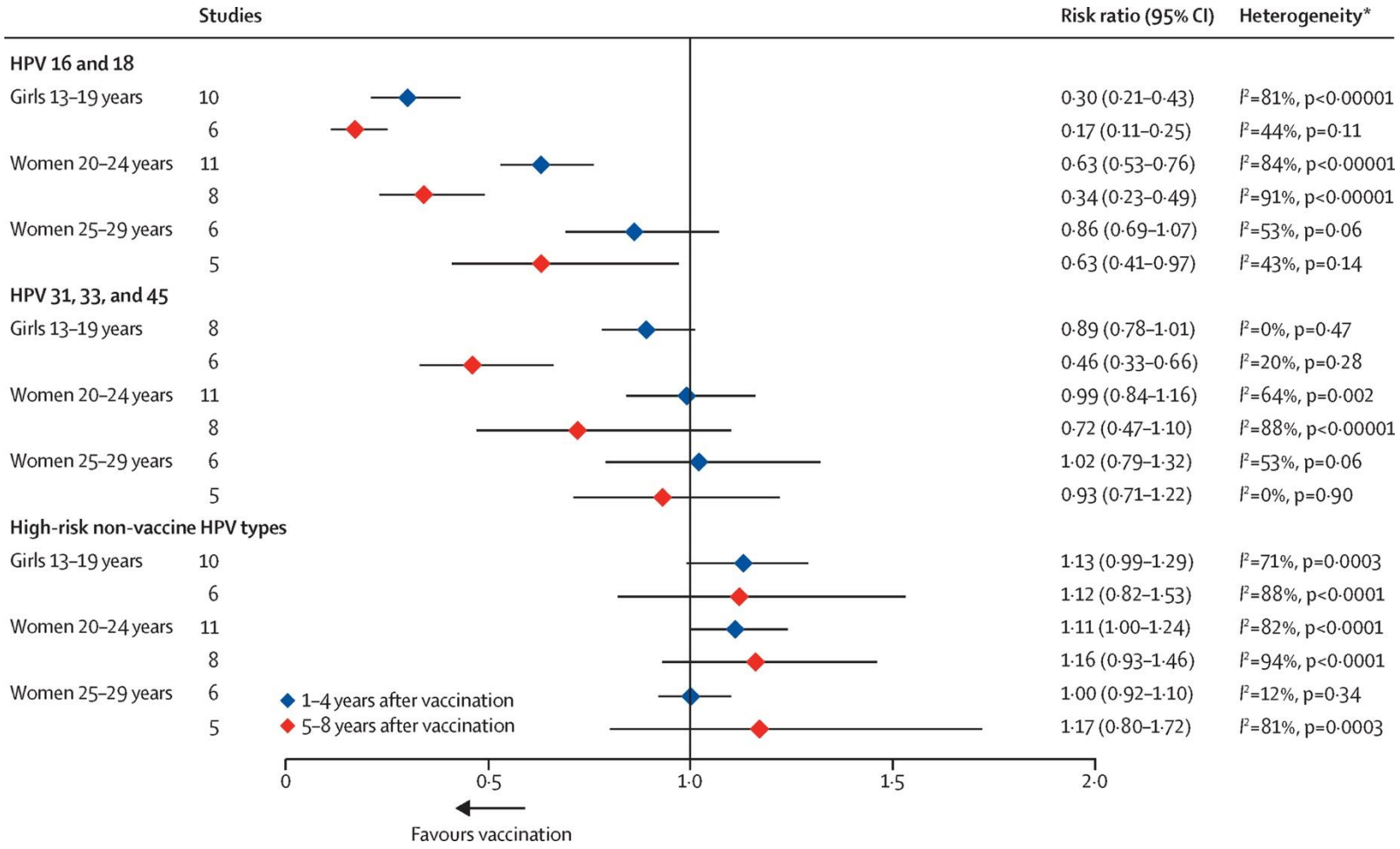
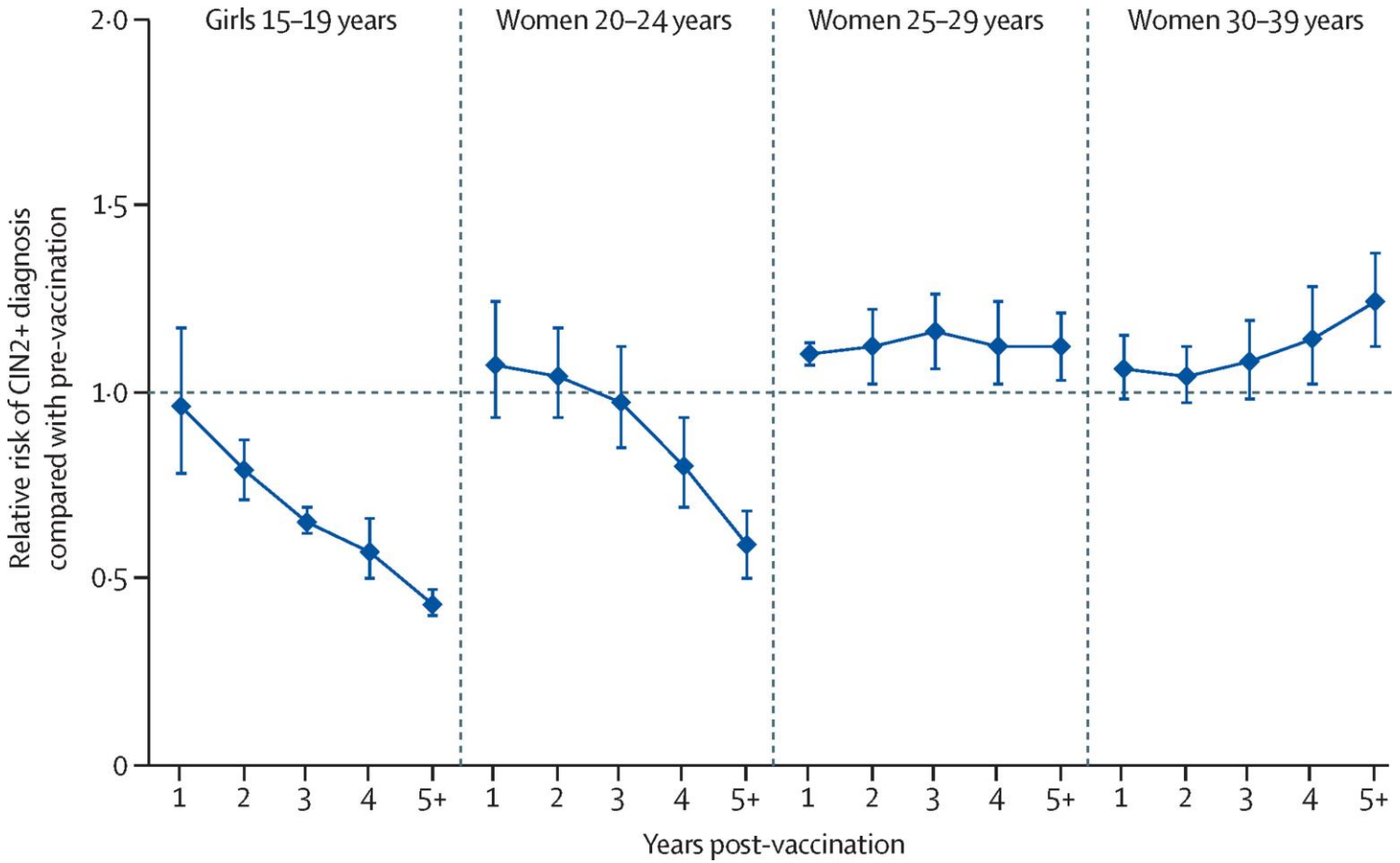
Population impact of HPV vaccine
HPV Infections



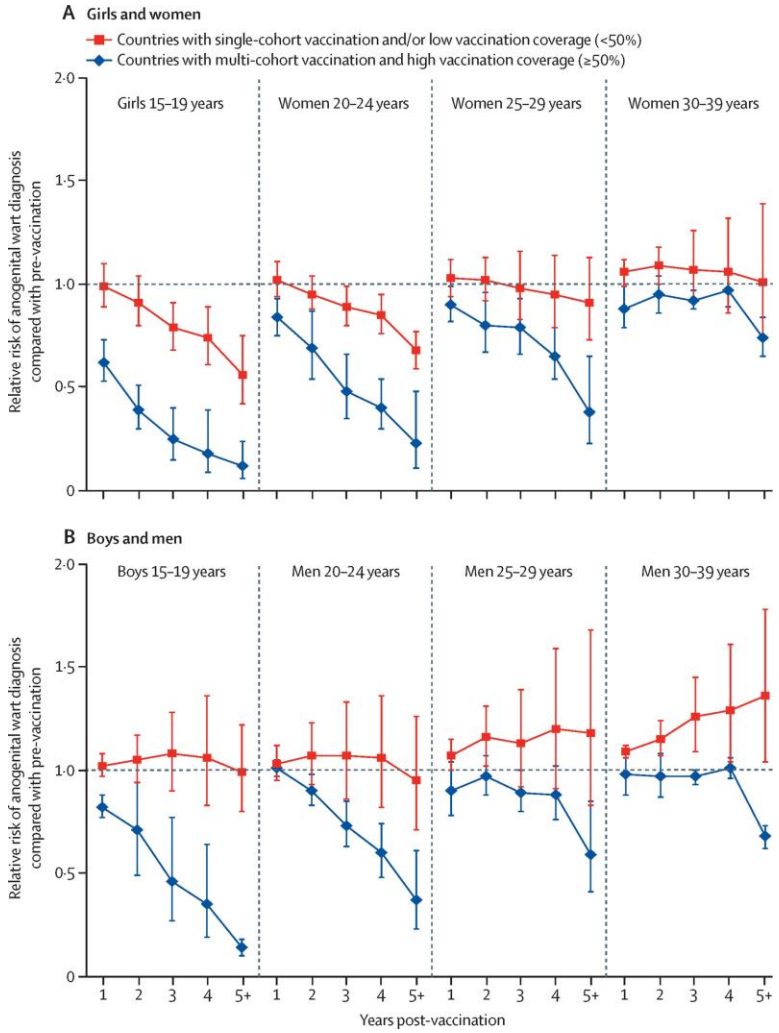
Drolet M, et al. Lancet 2019

Population impact of HPV vaccine
Cervical intraepithelial neoplasia 2+



Drolet M, et al. Lancet 2019

Population impact of HPV vaccine
Anogenital warts



Drolet M, et al. Lancet 2019

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

HPV Vaccination and the Risk of Invasive Cervical Cancer

Jiayao Lei, Ph.D., Alexander Ploner, Ph.D., K. Miriam Elfström, Ph.D., Jiangrong Wang, Ph.D., Adam Roth, M.D., Ph.D., Fang Fang, M.D., Ph.D., Karin Sundström, M.D., Ph.D., Joakim Dillner, M.D., Ph.D., and Pär Sparén, Ph.D.

1 October 2020

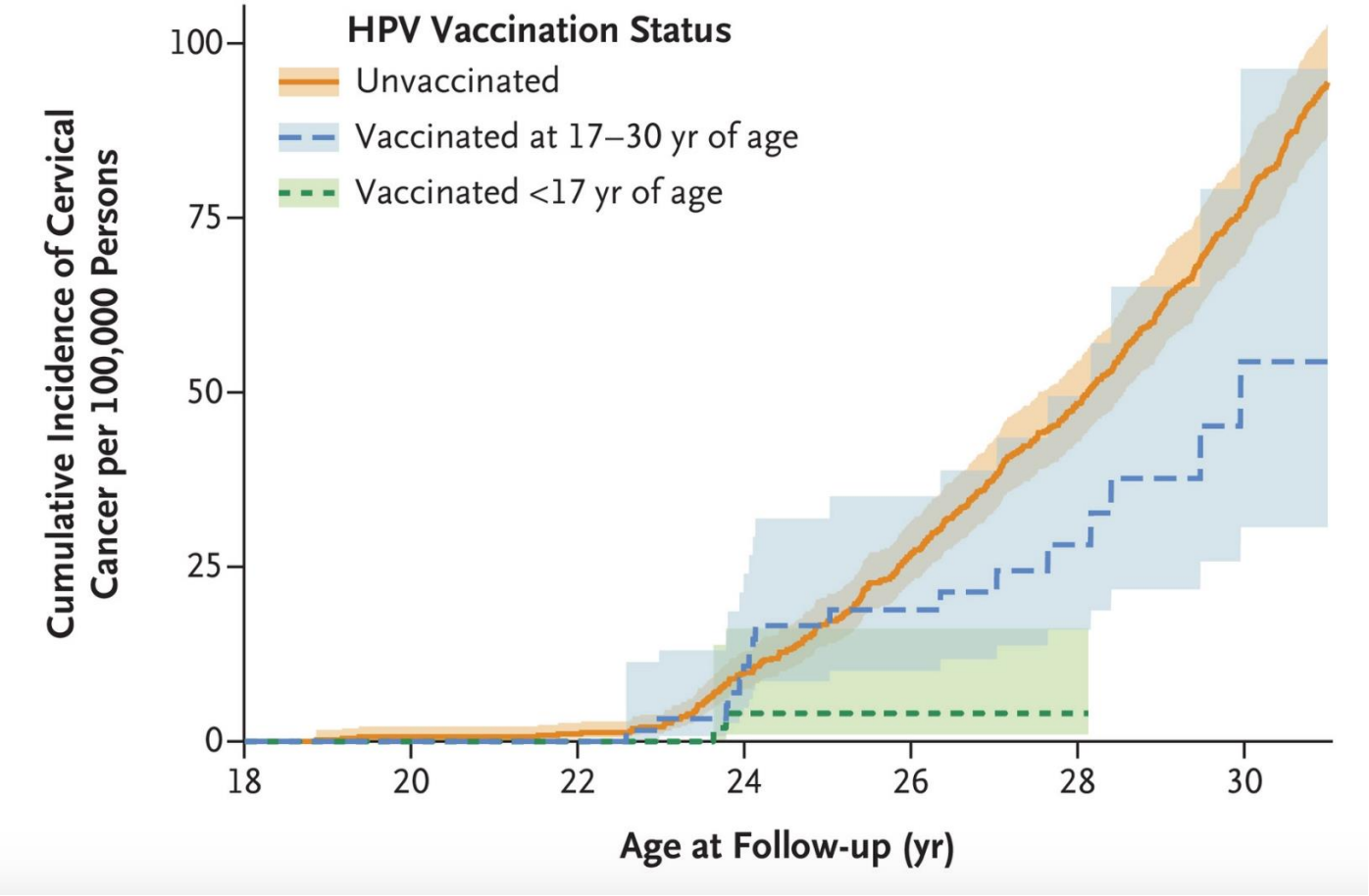
The NEW ENGLAND JOURNAL of MEDICINE

Table 2. HPV Vaccination and Invasive Cervical Cancer.

HPV Vaccination Status	No. of Cases of Cervical Cancer	Crude Incidence Rate per 100,000 Person-Yr (95% CI)	Age-Adjusted Incidence Rate Ratio (95% CI)	Adjusted Incidence Rate Ratio (95% CI)*
Unvaccinated	538	5.27 (4.84–5.73)	Reference	Reference
Vaccinated	19	0.73 (0.47–1.14)	0.51 (0.32–0.82)	0.37 (0.21–0.57)
Status according to age cutoff of 17 yr				
Vaccinated before age 17 yr	2	0.10 (0.02–0.39)	0.19 (0.05–0.75)	0.12 (0.00–0.34)
Vaccinated at age 17–30 yr	17	3.02 (1.88–4.86)	0.64 (0.39–1.04)	0.47 (0.27–0.75)
Status according to age cutoff of 20 yr				
Vaccinated before age 20 yr	12	0.49 (0.28–5.73)	0.52 (0.29–0.94)	0.36 (0.18–0.61)
Vaccinated at age 20–30 yr	7	5.16 (2.46–10.83)	0.50 (0.24–1.06)	0.38 (0.12–0.72)

* The adjusted incidence rate ratios were adjusted for age as a spline term with 3 degrees of freedom, county of residence, calendar year, mother's country of birth, highest parental education level, highest annual household income level, previous diagnosis in mother of CIN3+, and previous diagnosis in mother of cancers other than cervical cancer. The 95% confidence intervals were bias-corrected percentile confidence intervals that were estimated with the use of bootstrapping with a resampling frequency of 2000 times.

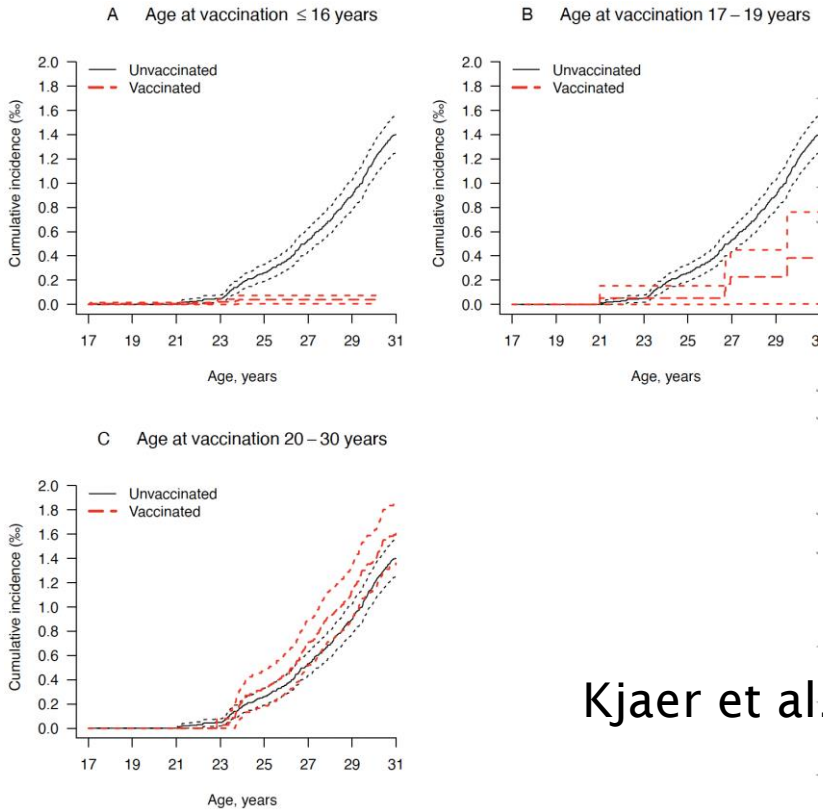
Cumulative Incidence of Invasive Cervical Cancer
According to HPV Vaccination Status



Lei J et al.
1 October 2020

The NEW ENGLAND JOURNAL of MEDICINE

Real world effectiveness of HPV vaccination against cervical cancer
Dänemark



Kjaer et al. JNCI 2021

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

Milena Falcaro, Alejandra Castañon, Busani Ndlela, Marta Checchi, Kate Soldan, Jamie Lopez-Bernal, Lucy Elliss-Brookes, Peter Sasieni

Summary

Background Human papillomavirus (HPV) immunisation with a bivalent vaccine (Cervarix) was introduced in England, UK, in Sept 1, 2008: routine vaccination was offered to girls aged 12–13 years with a catch-up programme for females aged 14–18 years in 2008–10. We quantified the early effect of this immunisation programme on cervical cancer and cervical carcinoma in situ, namely grade 3 cervical intraepithelial neoplasia (CIN3), registrations.

Methods In this observational study, we used an extension of the age-period-cohort Poisson model to estimate the relative risk of cervical cancer in three vaccinated cohorts compared with earlier cohorts that were not eligible for HPV vaccination. Data from a population-based cancer registry were extracted on Jan 26, 2021, and were assessed for diagnoses of cervical cancer and CIN3 from Jan 1, 2006 to June 30, 2019 in women aged 20–64 years and who were a resident in England. We used three vaccinated cohorts to account for differences in the school year in which the vaccine was offered and its national coverage. Adjustment for confounding was made using information on changes in cervical screening policy and historical events that affected cervical cancer incidence. Results were compared across models with different adjustments for confounders.

Findings We used data from a total of 13·7 million-years of follow-up of women aged 20 years to younger than 30 years. The estimated relative reduction in cervical cancer rates by age at vaccine offer were 34% (95% CI 25–41) for age 16–18 years (school year 12–13), 62% (52–71) for age 14–16 years (school year 10–11), and 87% (72–94) for age 12–13 years (school year 8), compared with the reference unvaccinated cohort. The corresponding risk reductions for CIN3 were 39% (95% CI 36–41) for those offered at age 16–18 years, 75% (72–77) for age 14–16 years, and 97% (96–98) for age 12–13 years. These results remained similar across models. We estimated that by June 30, 2019 there had been 448 (339–556) fewer than expected cervical cancers and 17 235 (15 919–18 552) fewer than expected cases of CIN3 in vaccinated cohorts in England.

Interpretation We observed a substantial reduction in cervical cancer and incidence of CIN3 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.

Funding Cancer Research UK.

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See **Online/Comment**
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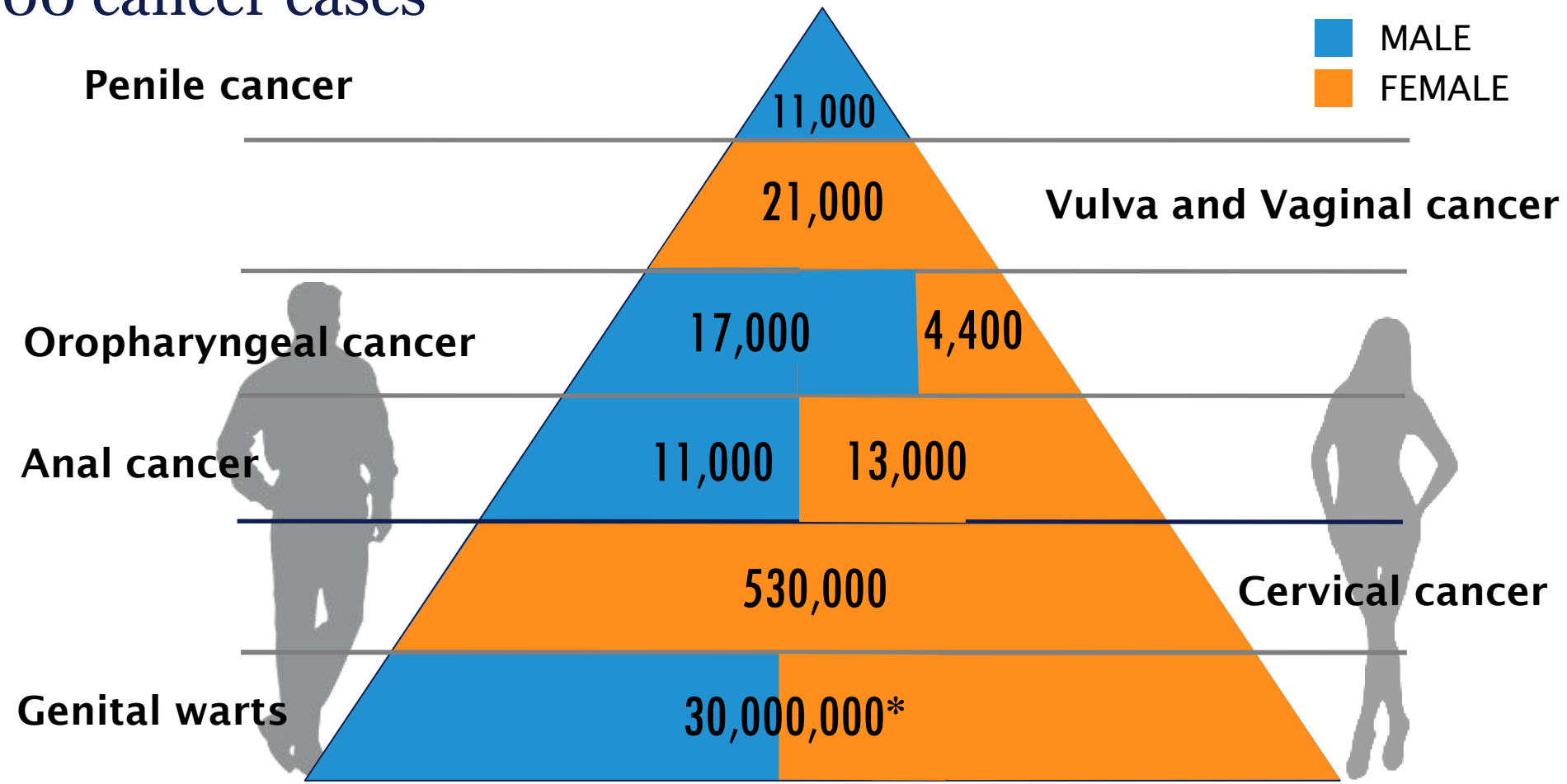
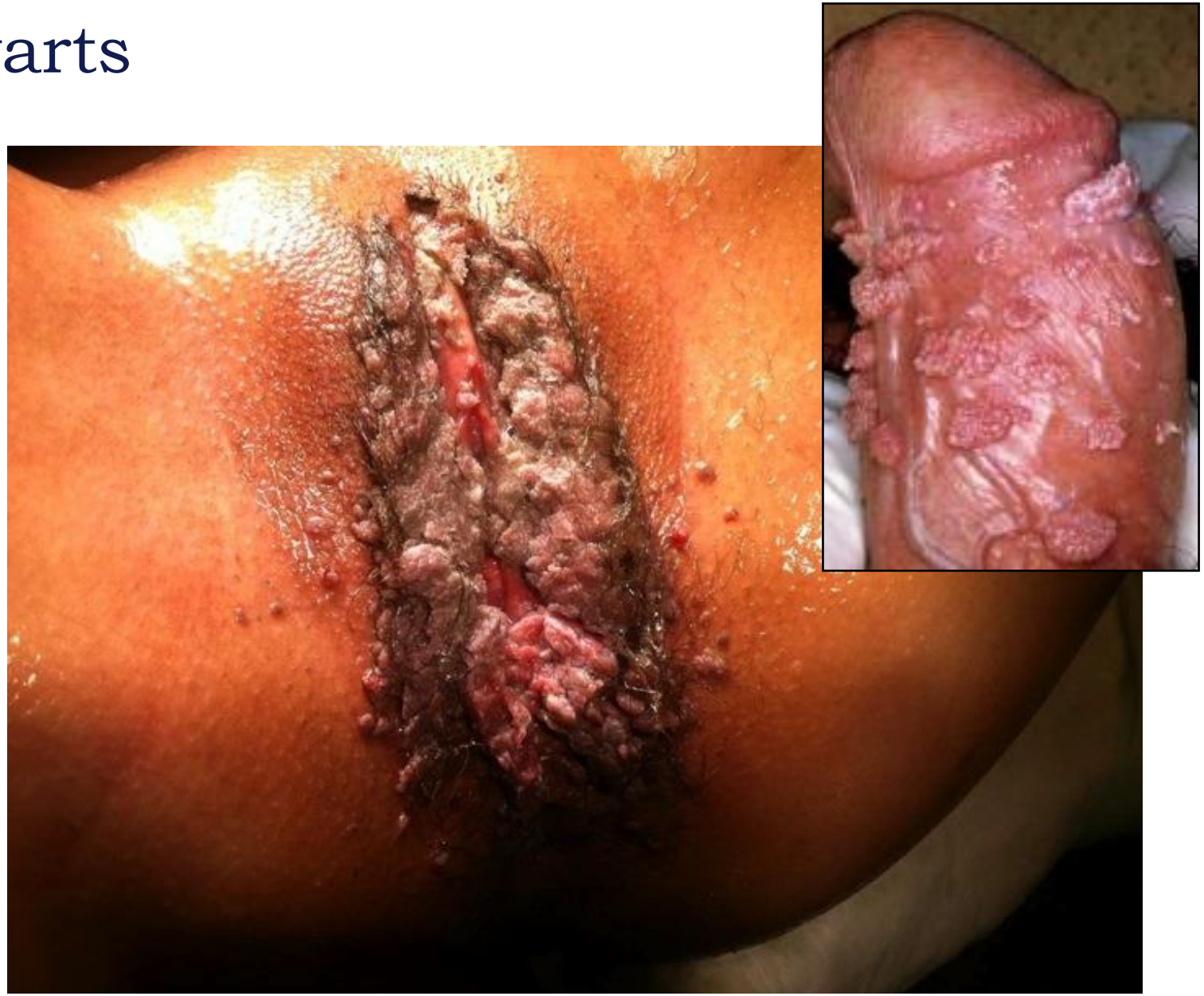
Global Burden of HPV lesions: 607,000 cancer cases



Oncol (cancers) and *2010 Dillner et al BMJ* (genital warts)
*Together with low-grade cervical intraepithelial neoplasia

Genital warts



Blomberg et al. JID 2012

Risk of cancer in nearly 50,000 patients with genital warts in Denmark

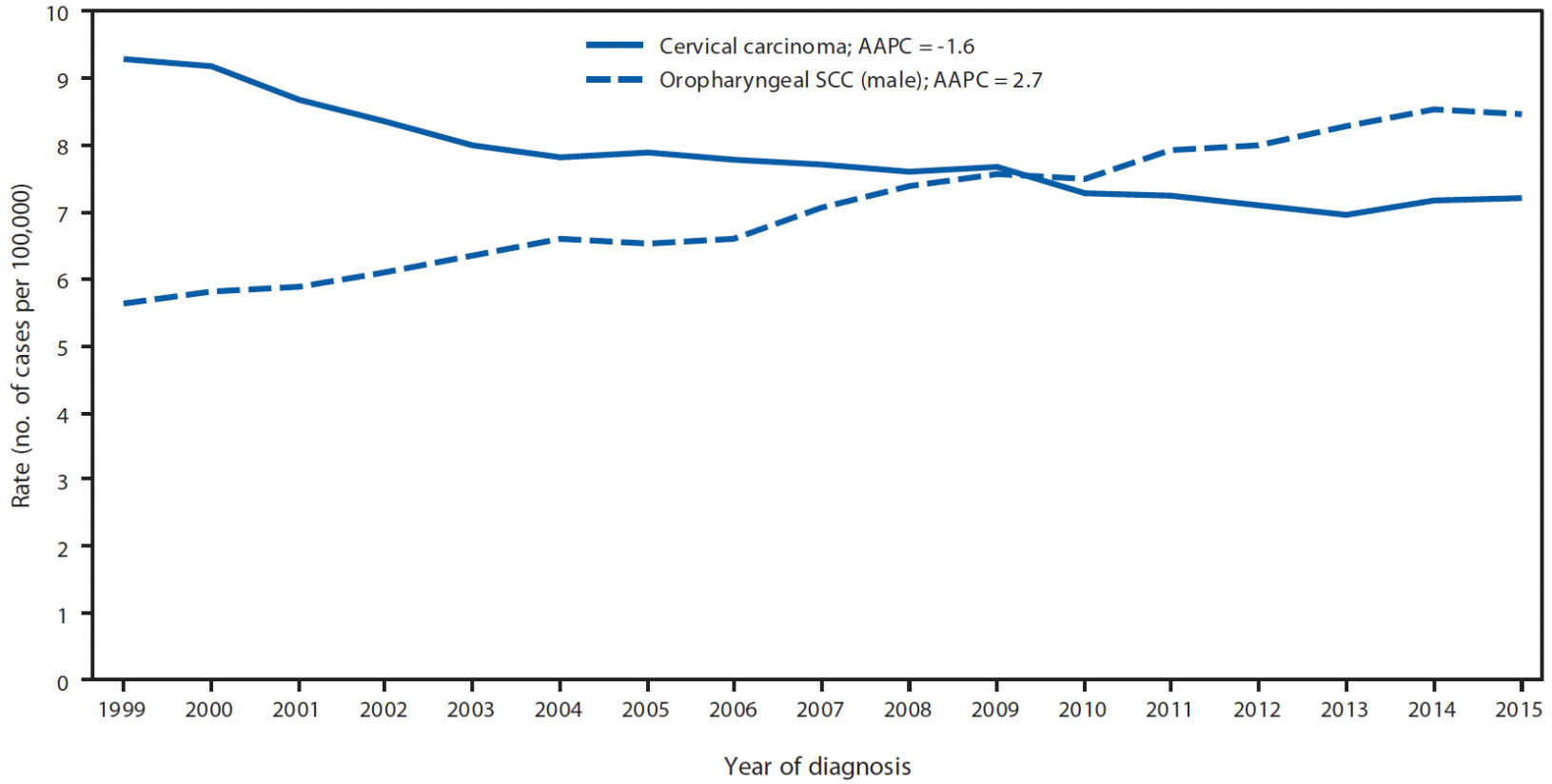
Anogenital	MEN			WOMEN		
	Observed	SIR	95 % CI	Observed	SIR	95 % CI
Cervix	-	-	-	117	1.5	1.3-1.8
Vagina	-	-	-	6	5.9	2.2-12.9
Vulva	-	-	-	74	14.8	11.7-18.6
Anus	29	21.5	14.4-30.9	33	7.8	5.4-11.0
Penis	11	8.2	4.1-14.6	-	-	-
Testis	43	1.1	0.8-1.5	-	-	-

SIR: Standardized incidence ratio

Oropharyngeal cancer in males surpassing cervical cancer

Morbidity and Mortality Weekly Report

FIGURE 1. Trends* in age-adjusted incidence of cervical carcinoma among females and oropharyngeal SCC among men,† — United States,§ 1999–2015



HPV 16

VOLUME 36 · NUMBER 3 · JANUARY 20, 2018

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Effect of Prophylactic Human Papillomavirus (HPV) Vaccination on Oral HPV Infections Among Young Adults in the United States

Anil K. Chaturvedi, Barry I. Graubard, Tatevik Broutian, Robert K.L. Pickard, Zhen-Yue Tong, Weihong Xiao, Lisa Kahle, and Maura L. Gillison

Author affiliations and support information (if applicable) appear at the end of this article.

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A.K.C., B.I.G., and T.B. contributed equally to this work.

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0732-183X/18/3603w-262w/$20.00

ABSTRACT

Purpose

The incidence of human papilloma virus (HPV)–positive oropharyngeal cancers has risen rapidly in recent decades among men in the United States. We investigated the US population–level effect of prophylactic HPV vaccination on the burden of oral HPV infection, the principal cause of HPV-positive oropharyngeal cancers.

Methods

We conducted a cross-sectional study of men and women 18 to 33 years of age (N = 2,627) within the National Health and Nutrition Examination Survey 2011 to 2014, a representative sample of the US population. Oral HPV infection with vaccine types 16, 18, 6, or 11 was compared by HPV vaccination status, as measured by self-reported receipt of at least one dose of the HPV vaccine. Analyses accounted for the complex sampling design and were adjusted for age, sex, and race. Statistical significance was assessed using a quasi-score test.

Results

Between 2011 and 2014, 18.3% of the US population 18 to 33 years of age reported receipt of at least one dose of the HPV vaccine before the age of 26 years (29.2% in women and 6.9% in men; $P < .001$). The prevalence of oral HPV16/18/6/11 infections was significantly reduced in vaccinated versus unvaccinated individuals (0.11% *v* 1.61%; $P_{adj} = .008$), corresponding to an estimated 88.2% (95% CI, 5.7% to 98.5%) reduction in prevalence after model adjustment for age, sex, and race. Notably, the prevalence of oral HPV16/18/6/11 infections was significantly reduced in vaccinated versus unvaccinated men (0.0% *v* 2.13%; $P_{adj} = .007$). Accounting for vaccine uptake, the population-level effect of HPV vaccination on the burden of oral HPV16/18/6/11 infections was 17.0% overall, 25.0% in women, and 6.9% in men.

Efficacy, immunogenicity, and safety of a quadrivalent HPV vaccine in men: results of an open-label, long-term extension of a randomised, placebo-controlled, phase 3 trial

Stephen E Goldstone, Anna R Giuliano, Joel M Palefsky, Eduardo Lazcano-Ponce, Mary E Penny, Robinson E Cabello, Edson D Moreira Jr, Ezio Baraldi, Heiko Jessen, Alex Ferenczy, Robert Kurman, Brigitte M Ronnett, Mark H Stoler, Oliver Bautista, Rituparna Das, Thomas Group, Alain Luxembourg, Hao Jin Zhou, Alfred Saah

Summary

Background The quadrivalent human papillomavirus (HPV) vaccine was shown to prevent infections and lesions related to HPV6, 11, 16, and 18 in a randomised, placebo-controlled study in men aged 16–26 years. We assessed the incidences of external genital warts related to HPV6 or 11, and external genital lesions and anal dysplasia related to HPV6, 11, 16, or 18, over 10 years of follow-up.

Lancet Infect Dis 2021

Published Online
November 12, 2021
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WHO Statement on Cervical Cancer Elimination Director-General Call to Action

World Health Organization

"Today I am calling for coordinated action globally to eliminate Cervical Cancer, one of the greatest threats to women's health. We have the tools and, crucially, the political commitment to achieve it"

www.who.int/reproductivehealth/DG_all-to-action.pdf

Dr Tedros Adhanom Ghebreyesus WHO Director General 19 May 2018

HPV vaccination programs 2020

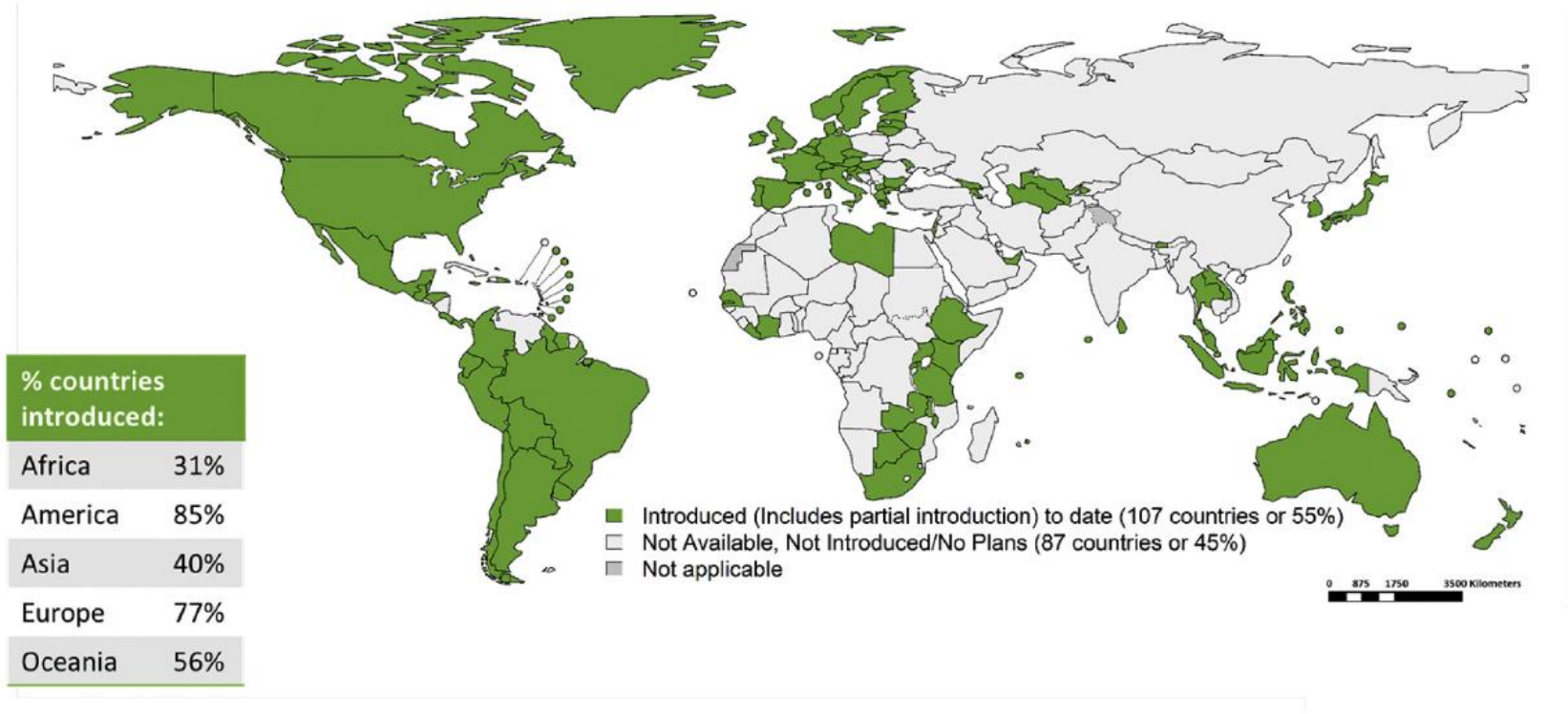


Fig. 1. WHO member states with HPV vaccination in their national immunization program, as of June 2020.
It does not include territories, state of free-association, or semi-autonomous regions. The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Vaccine hesitancy- a global problem

Vaccines prevent 3 millions deaths annually!

EUROPEAN
COMMISSION

Brussels, 3.2.2021
COM(2021) 44 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

Europe's Beating Cancer Plan

{SWD(2021) 13 final}

Europe´s Beating Cancer Plan 2021

Flagship initiatives on prevention

- Eliminate cancers caused by HPV
- EU support for Member States on vaccination
- **Vaccinate at least 90% of the EU target population of girls**
- Significantly increase the vaccination of **boys** by 2030

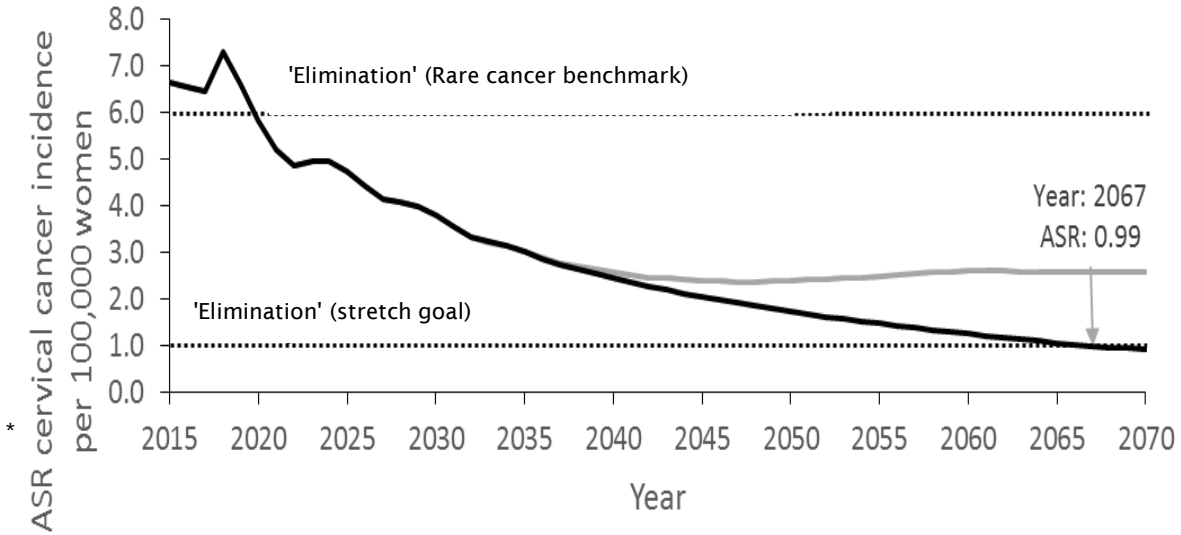
HPV Gender Neutral Vaccination in Europe

Access Maps

- Funded
- Recommended
- Not Funded

MSD-Data on File

Australian modelling. First candidate to elimination



Without screening HPV9 cohorts, the stretch goal elimination benchmark of 1 per 100,000 will never be reached.

With 5-yearly screening, the benchmark is reached by 2067

HPV9 vaccination from 2018 onwards, no cervical screening for cohorts offered HPV9 (pre-renewed NCSP from 1991-2017 and HPV4 vaccination from 2007-2017)

renewed NCSP and HPV9 vaccination from 2018 onwards (pre-renewed NCSP from 1991-2017 and HPV4 vaccination from 2007-2017)

^*The projected timeframe until cervical cancer elimination in Australia*, Michaela T Hall, Kate T Simms, Jie Bin Lew, Megan A Smith and Karen Canfell, (in prep)

Conclusion

- HPV causes cervical cancer
  - Vulvar/Vaginal cancer
  - Anal cancer
  - Oropharyngeal cancer
- HPV vaccination programs are effective
  - Young age
  - Good coverage

- HPV vaccines are safe!