

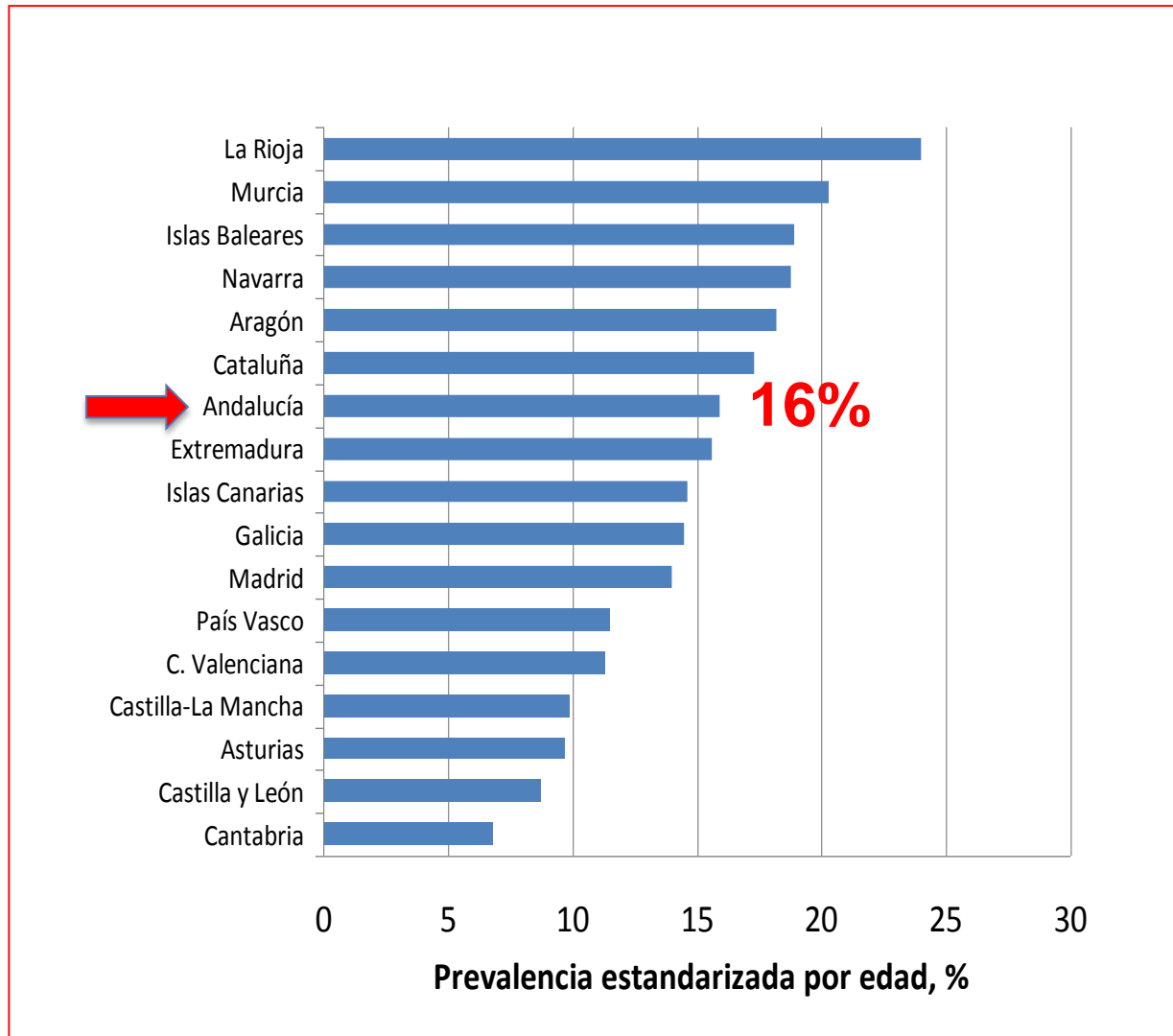
Vacunación frente a VPH, y tosferina

Vacunación VPH

**Donde estamos y hacia
donde vamos...**

- 1. Esquemas con 2 dosis a los 12 años**
- 2. Datos recientes: efectividad y seguridad**
- 3. VPH-9**

Prevalencia de infección VPH en mujeres (18-65) según CC. AA.

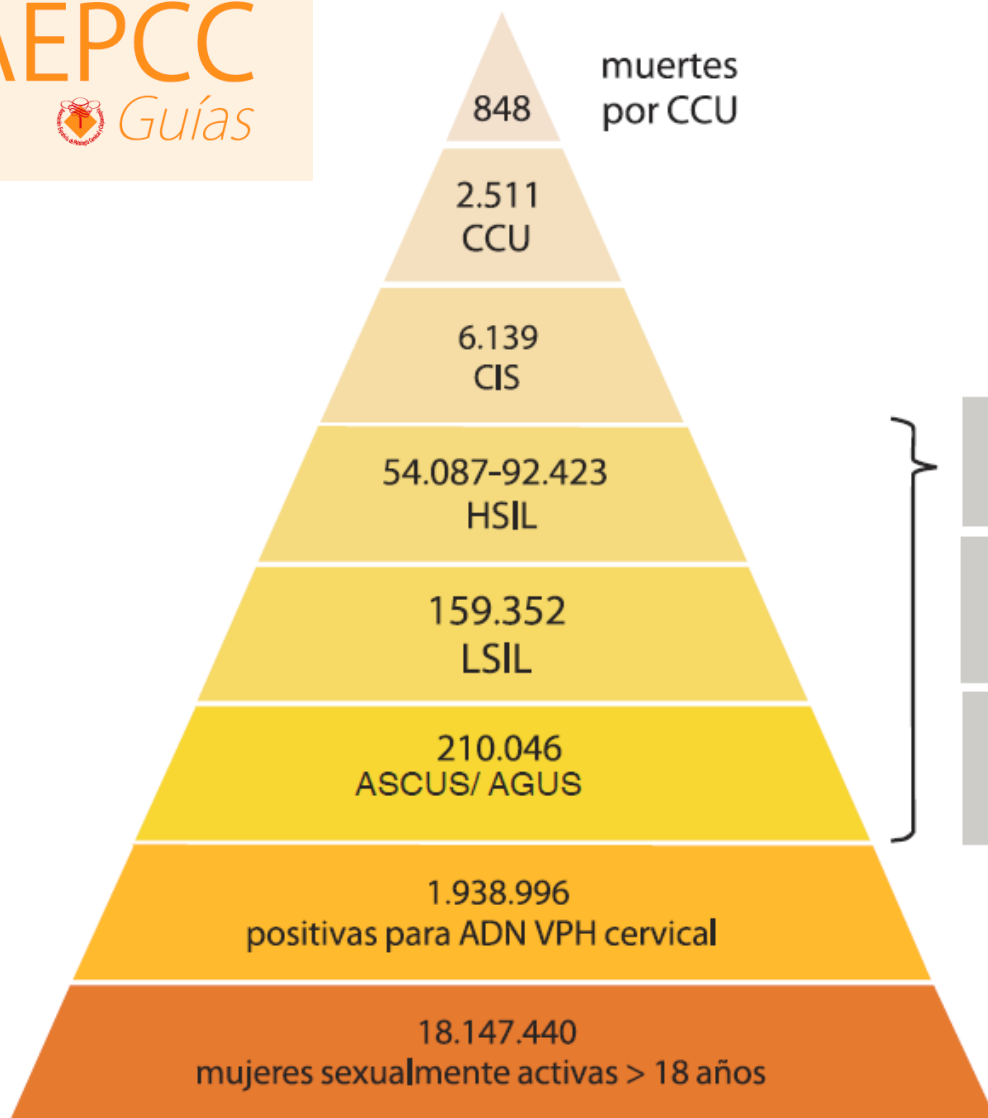


Cánceres atribuibles al VPH en España

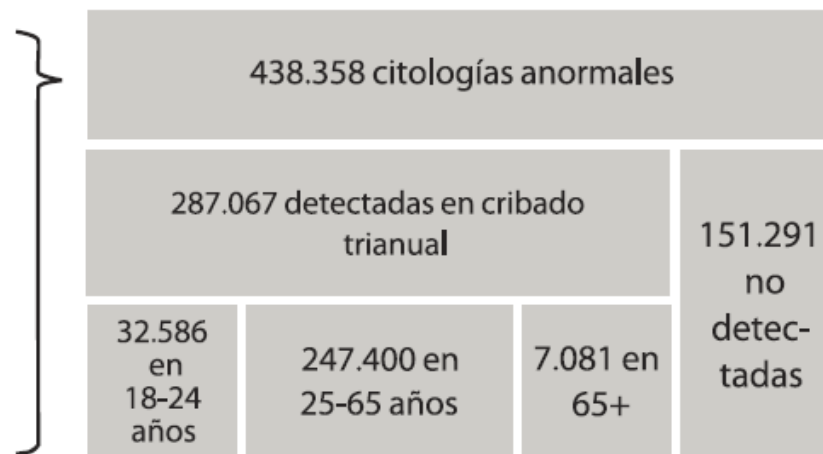
Tabla 1. Impacto de los cánceres asociados al VPH en España (2012-2013)

	CERVIX	VAGINA	VULVA	ANO	PENE	OROFARINGE	Total
Casos Incidentes	2511	115	664	372	294	951	4907
Muertes	848	50	344	94	118	570	2024
Fracción atribuible a VPH	1	0,74	0,29	0,88	0,33	7,1% (Hombres) 27,5% (Mujeres)	
Casos atribuibles a VPH	2511	85	193	327	97	95	3308

Fuentes: Incidencia: Globocan 2012; Mortalidad: WHO mortality database (2013); Fracciones atribuibles al VPH: Cáncer de cérvix: Walboomers et al., J Pathol 1999; De Sanjosé et al., Lancet Oncol 2010; Cáncer de vagina: Alemany et al., Eur J Cancer 2014; Cáncer de vulva: De Sanjosé et al., Eur J Cancer 2013; Cáncer de ano: Alemany et al., Int J Cancer 2015; Cáncer de pene: Alemany et al., Eur Urol 2016; Cáncer de orofaringe (incluye base de lengua): Castellsagué et al., JNCI 2016 (datos específicos de España según sexo facilitados por los autores).



Estimaciones de la carga de enfermedades por infección cervical por VPH en España



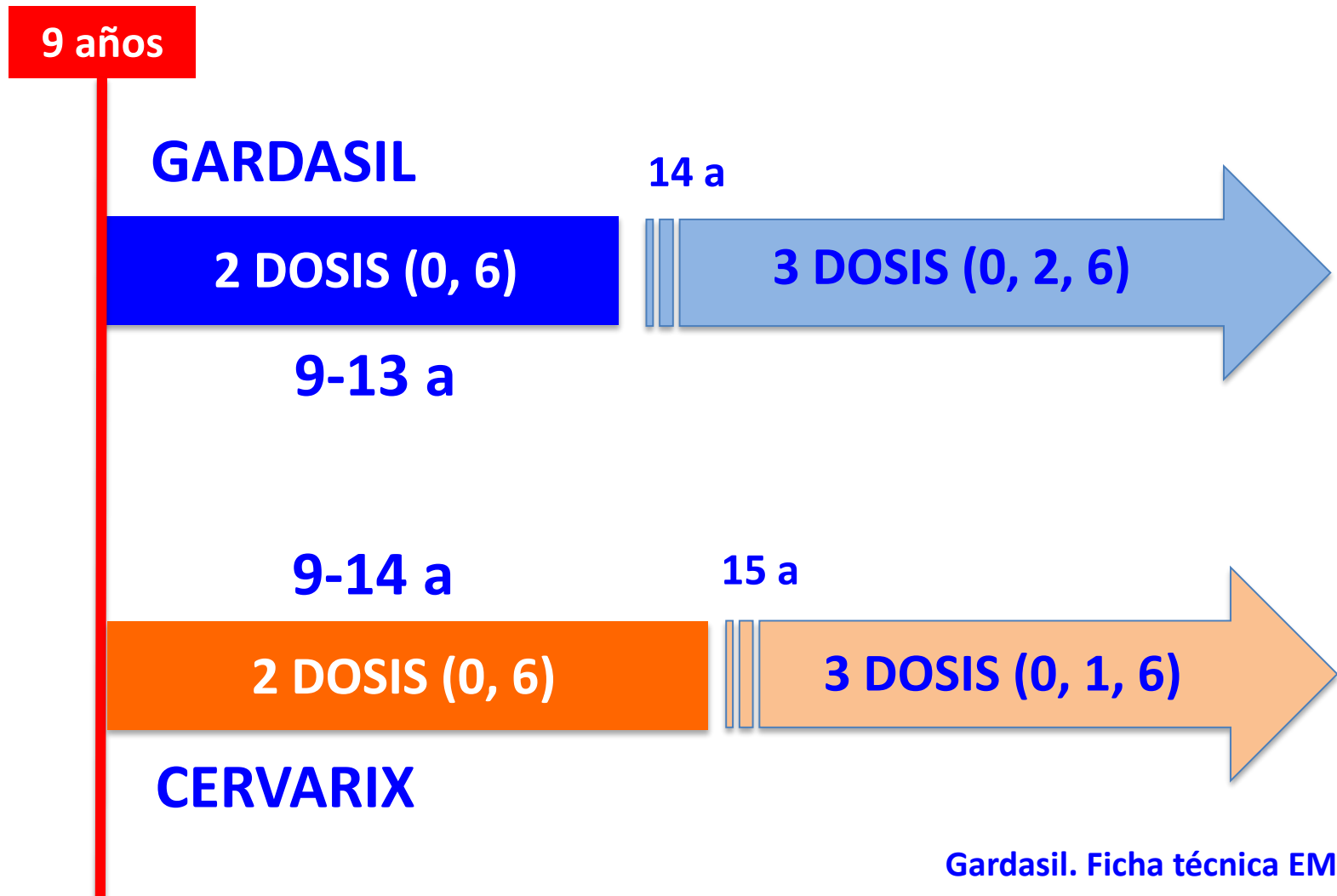
Vacunas frente al VPH

Tabla 2. Principales características de las tres vacunas profilácticas frente a VPH.

	Cervarix ® ^{Z3} - GSK	Gardasil ® ^{Z4} - Merck/SPMSD	Gardasil 9 ® ^{Z5} - Merck/SPMSD
Tipos de VLP	16/18	6/11/16/18	6/11/16/18/ 31/33/45/52/58
Contenido	20/20 mcg	20/40/40/20 mcg	30/40/60/40 mcg 20/20/20/20/20 mcg
Adyuvante	AS04 (hidróxido de aluminio, MPL)	Hidroxifosfato sulfato de aluminio (AAHS)*	Hidroxifosfato sulfato de aluminio (AAHS)**
Pautas***	0, 6 meses (9-14 años) 0, 1, 6 meses (>=15 años)	0, 6 meses (9-13 años) 0, 2, 6 meses (>=14 años)	0, 6 meses (9-14 años) 0, 2, 6 meses (>=15 años)
Indicaciones	Lesiones precancerosas cervicales, vulvares, vaginales y anales, y cáncer de cérvix y ano	Lesiones precancerosas cervicales, vulvares, vaginales y anales, y cáncer de cérvix y ano; verrugas genitales	Lesiones precancerosas y cáncer de cuello uterino, vulva, vagina y ano; verrugas genitales

MPL: monofosforil lípido A; VLP: *virus-like particles*

VACUNAS VPH: 2 dosis en adolescentes



Gardasil. Ficha técnica EMA 2015

Cervarix. Ficha técnica EMA 2015

OMS – Documento VPH 2014

- Pauta de 2 dosis (0, 6 meses) para niñas <15 años
- Pauta de 3 dosis para niñas ≥ 15 años
- Pauta de 3 dosis para **INMUNOCOMPROMETIDAS**

A 3-dose schedule (0, 1–2, 6 months) is recommended for females aged 15 years and older, and for those known to be immunocompromised and/or HIV-infected (regardless of whether they are receiving antiretroviral therapy). It is not necessary to screen for HPV infection or HIV infection prior to HPV vaccination.

¿POR QUÉ ES MEJOR VACUNAR ANTES DE LOS 14 AÑOS?

**ASEGURAR QUE
NINGUNA
ADOLESCENTE HAYA
INICIADO ACTIVIDAD
SEXUAL**

**PARA QUE SUBAN
LAS COBERTURAS**

Mayor aceptabilidad
Mayor cumplimiento
Menos efectos adversos

TABLA 8: COBERTURAS DE VACUNACIÓN FRENTE A VIRUS DEL PAPILOMA HUMANO (VPH). PAUTA COMPLETA NIÑAS DE 11-14 AÑOS. COMUNIDADES AUTÓNOMAS 2015 O CURSO ESCOLAR 2014-2015

CC.AA	Población objeto	Fuente	nº dosis	%
Andalucía	43.031	BDU	28.243	65,6
Aragón*	5.600	IAE	4.946	88,3
Asturias	3.520	SIPRES Cohorte 2001	2.606	74,0
Baleares*	5.185	Padrón	3.726	71,9
Canarias	10.237	TIS	9.373	91,6
Cantabria	2.619	INE	2.005	76,6
Castilla y León	9.524	Censo escolar curso 2014-2015 nacidas 2001	8.704	91,4
Castilla La Mancha	9.762	Tarjeta sanitaria	7.166	73,4
Cataluña	36.259	Vacunación escolar	30.026	82,8
C. Valenciana	23.391	Tarjeta sanitaria	18.700	79,9
Extremadura	5.489	CIVITAS	4.408	80,3
Galicia	10.188	IGE. Padrón 2015	8.076	79,3
Madrid	30.611	Padrón 2014	24.899	81,3
Murcia	8.054	Censo escolar nacidos 2004	6.618	82,2
Navarra	3.086	TIS	2.659	86,2
P. Vasco	9.186	Departamento Educación	8.422	91,7
La Rioja	1.478	Censo escolar	1.380	93,4
Ceuta	500	INE	465	93,0
Melilla	581	Padrón municipal	474	81,6
TOTAL	218.301		172.896	79,2



Commentary

HPV vaccine: Less is more

Rachel Caskey*, Steven Andes, Surrey M Walton

Departments of Pediatrics and Internal Medicine, University of Illinois at Chicago, 840 S. Wood St., Clinical Sciences North, 440 M/C 718, Chicago, IL 60612, United States

about virus transmission and disease prevention, by discussing the HPV vaccine separately from the other adolescent vaccines we are sending the wrong message to parents: *this vaccine is different*.

We propose a 'less is more' strategy when recommending the HPV vaccine, namely less talking and more recommending. Given the overwhelming evidence regarding safety and efficacy for the HPV vaccine, a more direct and consistent recommendation is warranted and could lead to an increase in vaccination rates by eliminating this unintentional signal of clinical uncertainty to parents [9]. In some cases, education may increase resistance to vaccines and extended explanations may confuse more than facilitate an informed choice [10]. Giving a single uniform recommendation for all adolescent vaccines can be achieved with little investment and can have important cost and health implications moving forwards. Others have discussed the fact that discussing

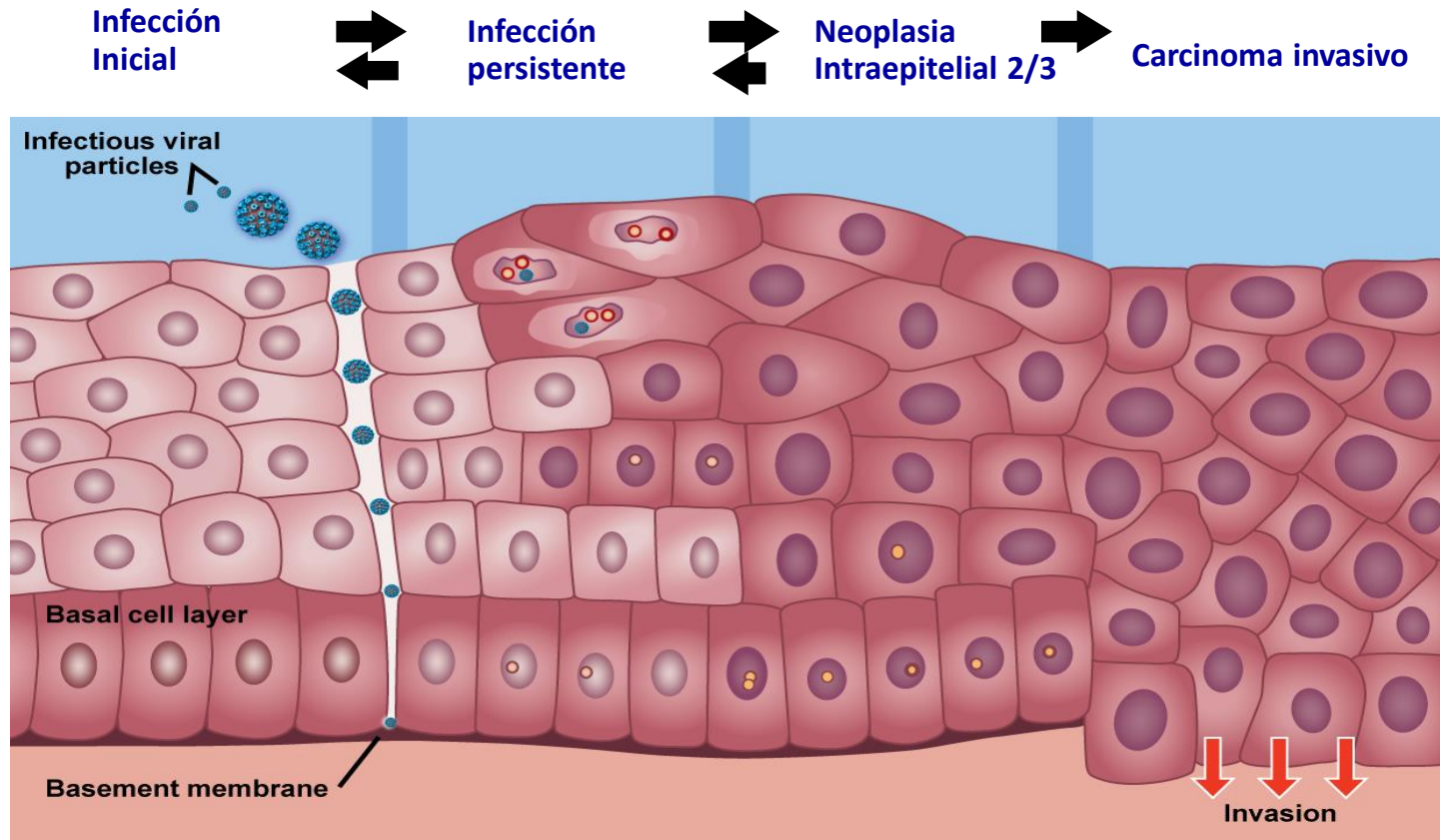
Vacunación VPH

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3. VPH en varones
4. VPH-9

Cánceres relacionados con VPH tienen un vía de desarrollo similar

Desarrollo de la enfermedad^{1,5,*}



La infección inicial transcurre después de la transmisión desde un compañero sexual o autoinoculación desde otro sitio anatómico^{2,3}

*The pathogenetic process of disease development is similar in all affected epithelial tissues of the anogenital tract and oral cavity¹. HPV = human papillomavirus

1. Alani RM et al. J Clin Oncol 1998
2. Bruchell A et al. Epidemiol 2010
3. Hernandez BY et al Emerg Infect Dis 2008
4. D'Souza G et al. J Infect Dis. 2009
5. Zandberg et al. Cancer J Clin 2013

VACUNAS VPH: eficacia

Human Papillomavirus Vaccination Recommendations of the Advisory Committee on Immunization Practices (ACIP)

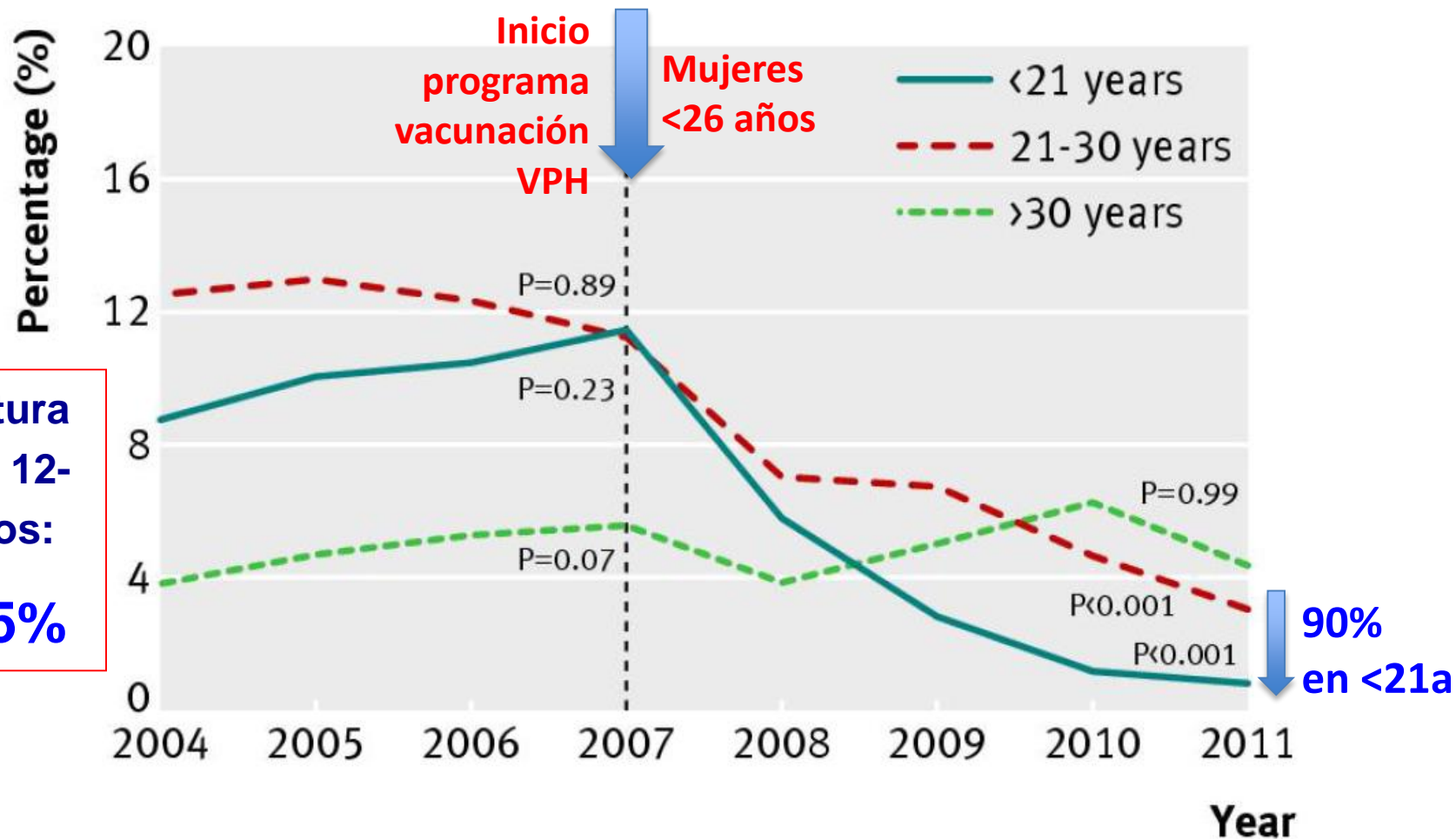
TABLE 4. Per-protocol efficacy for prevention of human papillomavirus vaccine-type disease outcomes among females in trials of the bivalent and quadrivalent human papillomavirus vaccines, end-of-study analyses

Vaccine/Endpoint related type	Vaccine		Control		Vaccine efficacy	
	No.	Cases	No.	Cases	%	(95% CI)
Quadrivalent vaccine*						
<u>CIN2/3 or AIS[†]</u>						
HPV 6, 11, 16, 18	7,864	2	7,865	110	98.2	(93.3–99.8)
HPV 16	6,647	2	6,455	81	97.6	(91.1–99.7)
HPV 18	7,382	0	7,316	29	100.0	(86.6–100.0)
<u>VIN/VaIN2/3[†]</u>						
HPV 6, 11, 16, 18	7,900	0	7,902	23	100.0	(82.6–100.0)
HPV 16	6,654	0	6,467	17	100.0	(76.5–100.0)
HPV 18	7,414	0	7,343	2	100.0	(<0–100.0)
<u>Genital warts[§]</u>						
HPV 6 and/or 11	6,718	2	6,647	186	98.9	(96.1–99.9)
Bivalent vaccine[¶]						
<u>CIN2/3 or AIS</u>						
HPV 16 and/or 18	7,338	5	7,305	97	94.9	(87.7–98.4)
HPV 16	6,296	2	6,160	81	97.6	(91.0–99.7)
HPV 18	6,789	3	6,739	23	87.1	(57.2–97.5)

A corto plazo: **verrugas** genitales

VPH-4: verrugas genitales

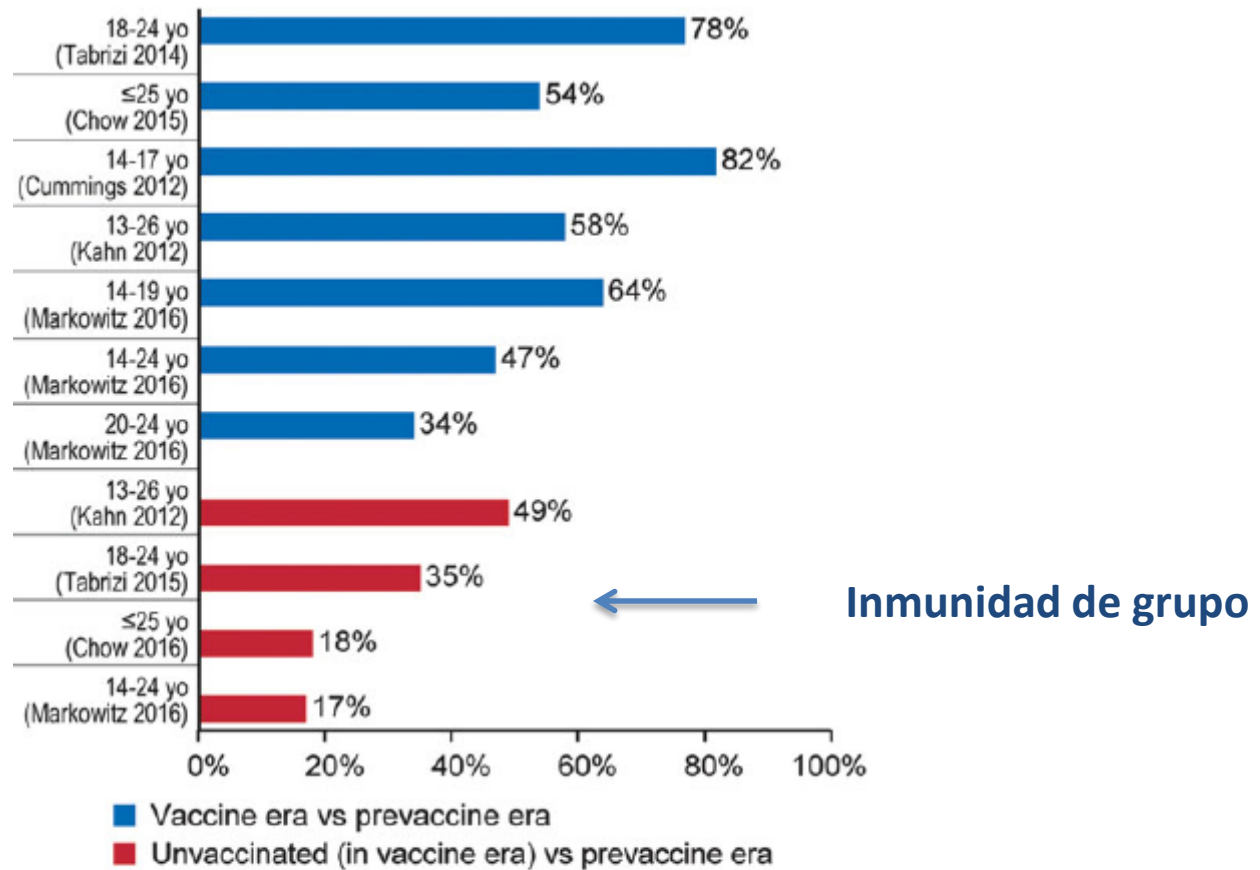
Mujeres < 30 años



Ali H, et al. BMJ 2013

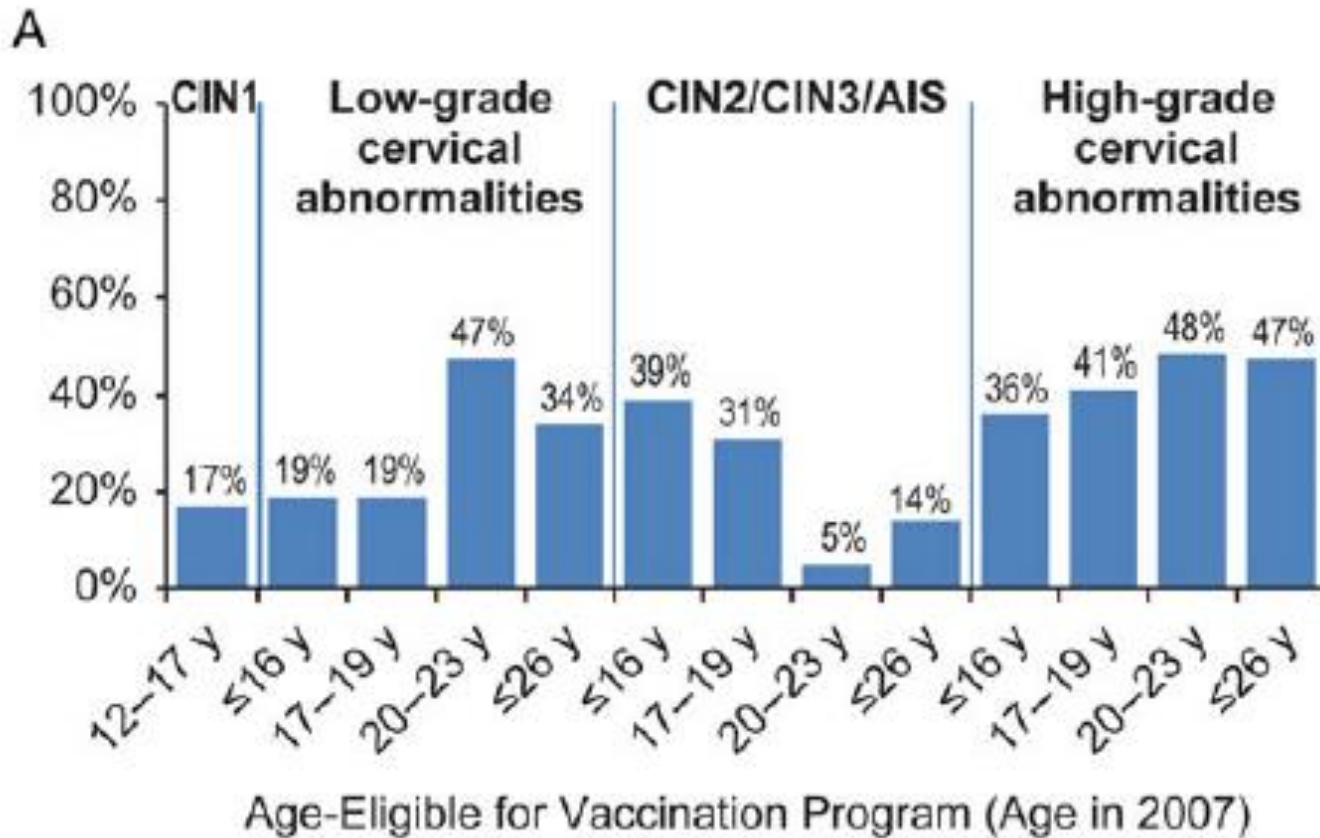
A medio plazo: lesiones **preneoplásicas**

Prevalencia de infección por VPH 6 -11 en periodos pre y vacunal

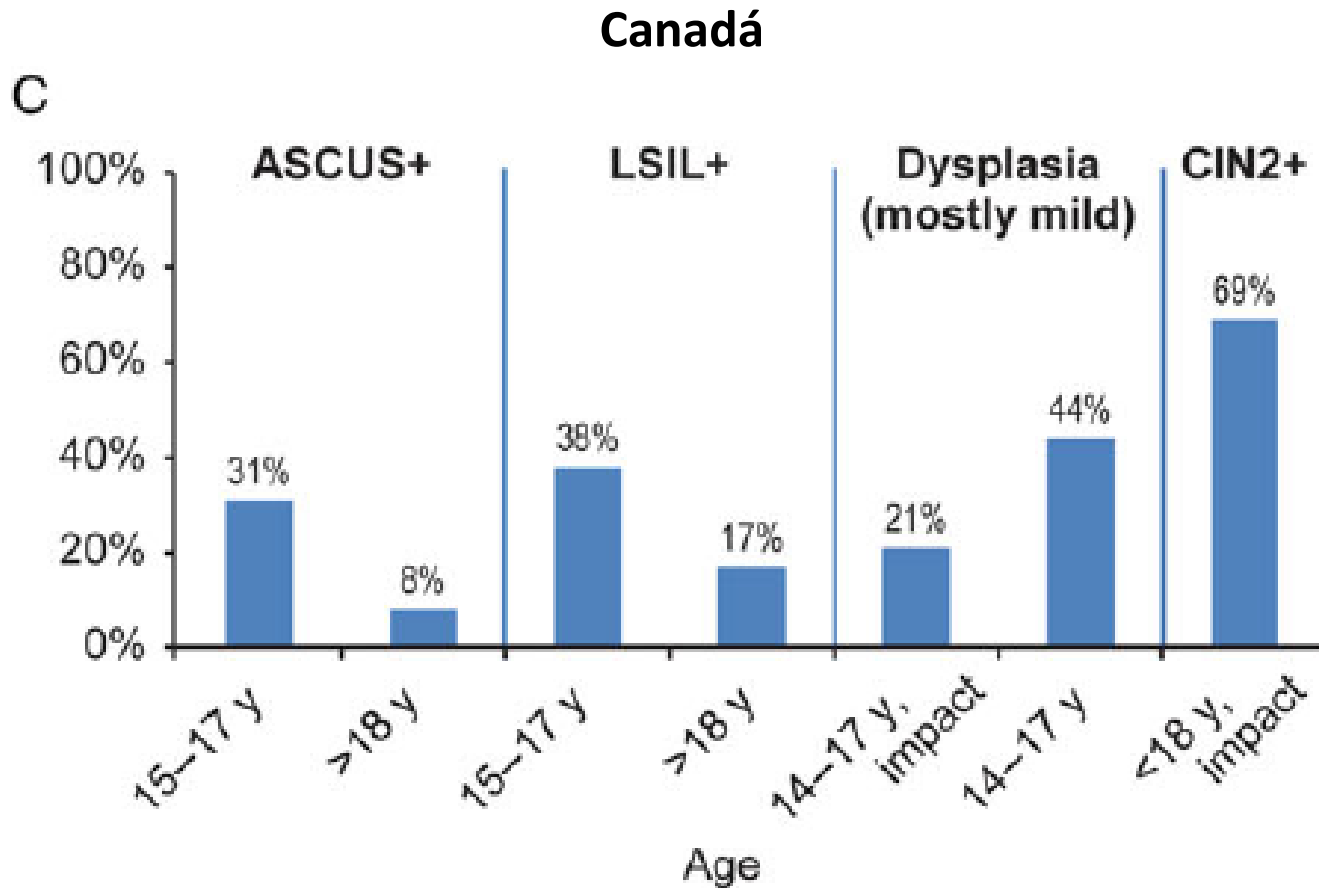


Reducción de lesiones cervicales en vacunadas vs no vacunadas

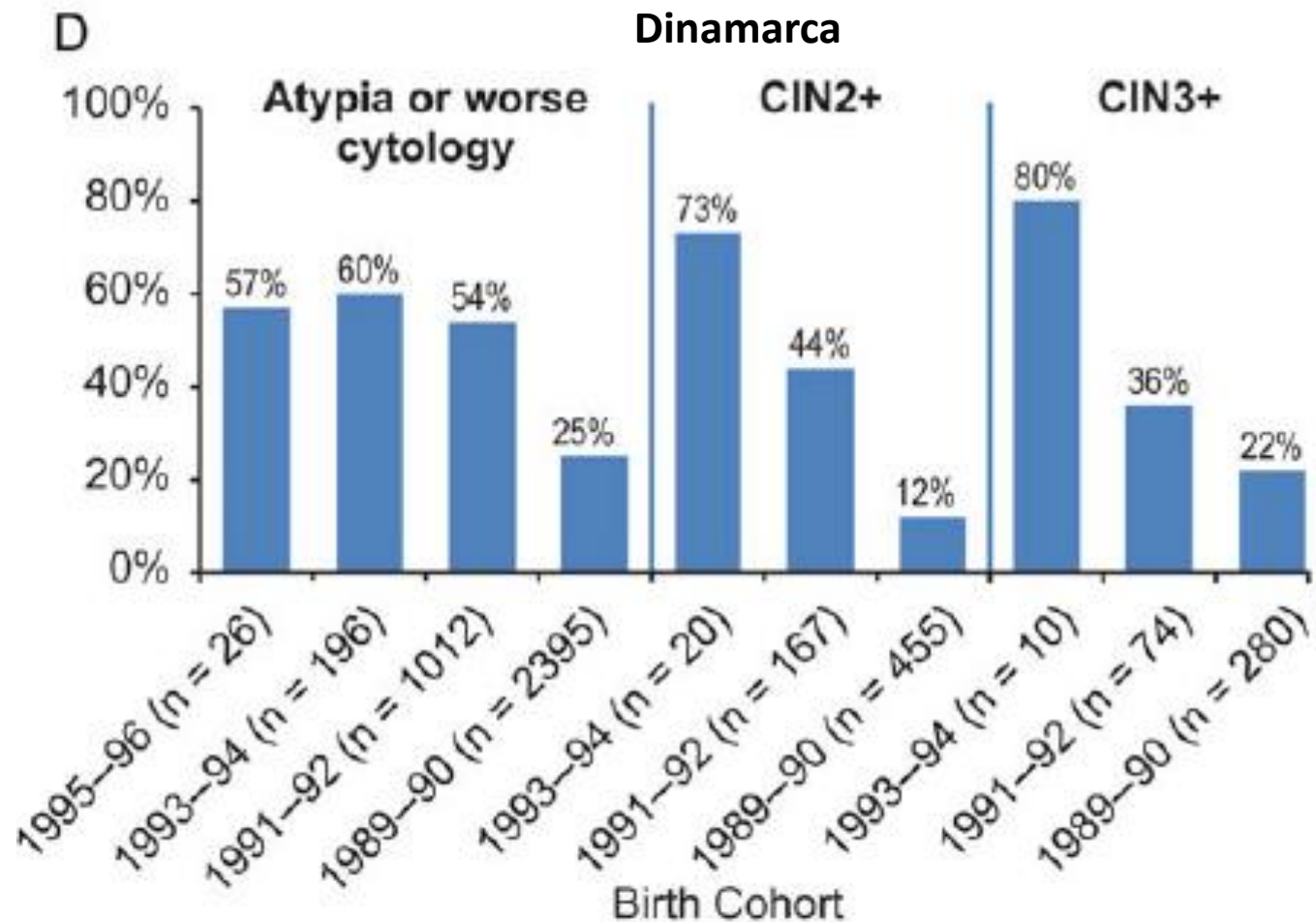
Australia



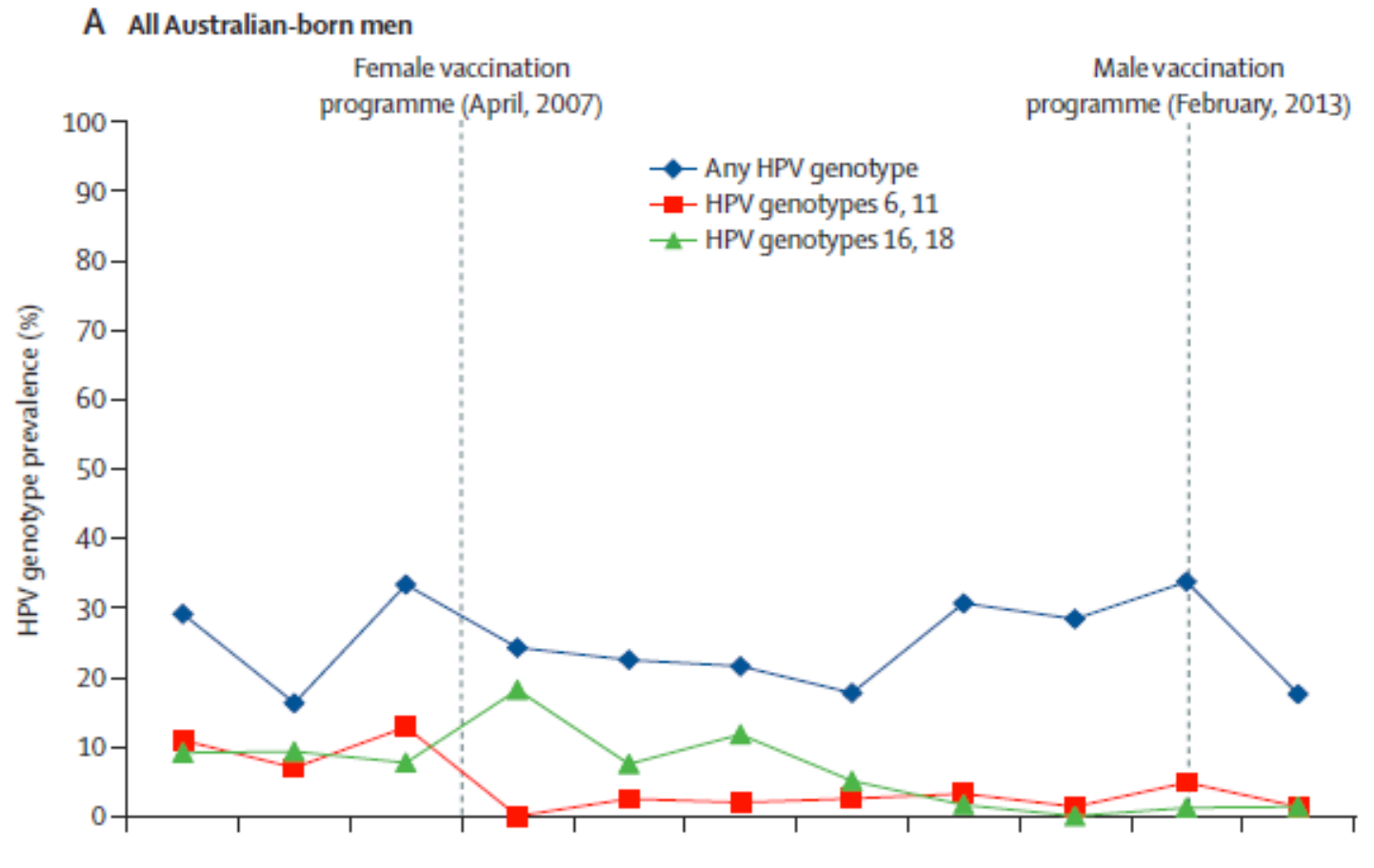
Reducción de lesiones de cérvix en mujeres vacunadas en la era vacunal vs no vacunadas y mujeres de la era prevacunal



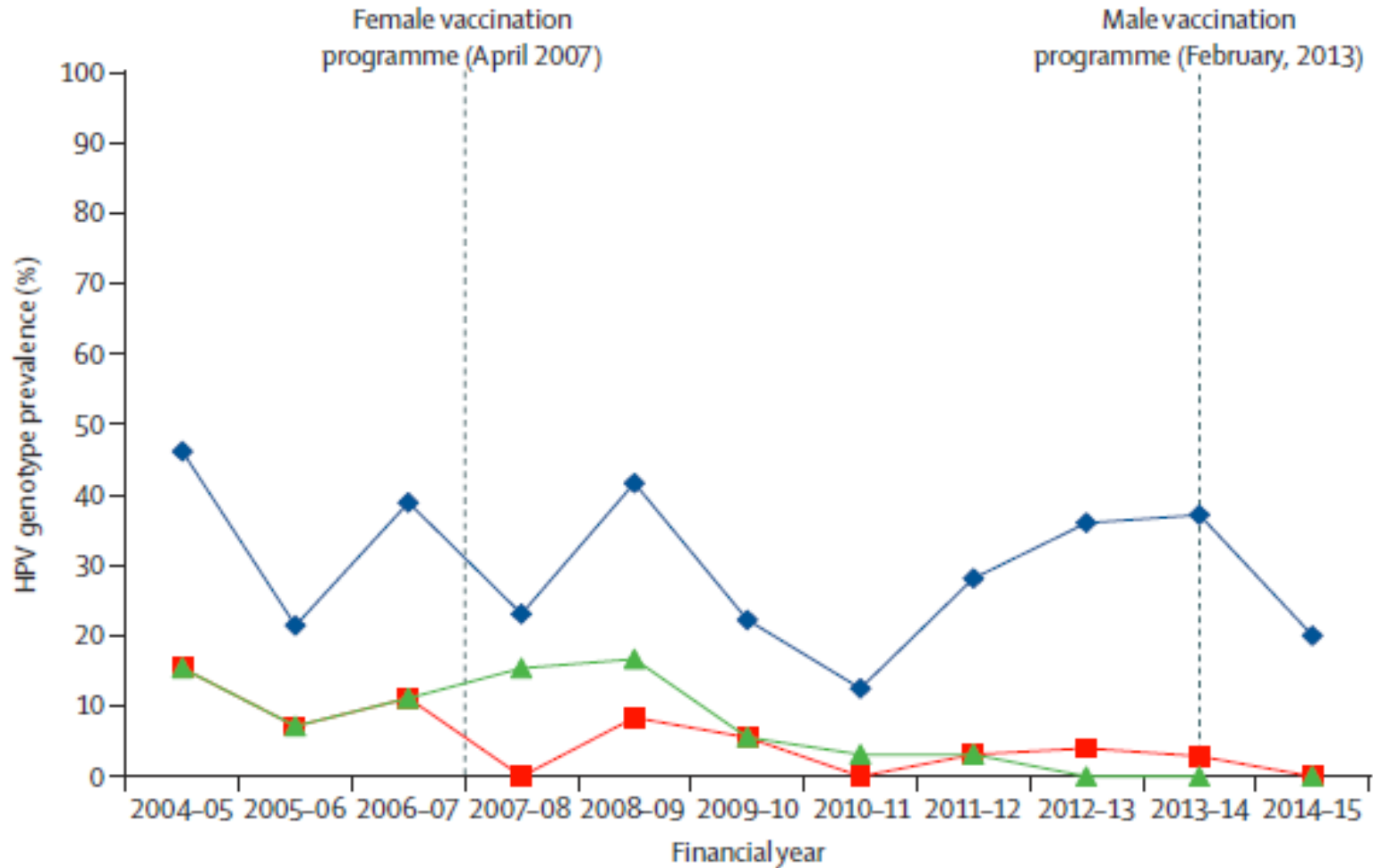
Reducción de lesiones en mujeres vacunadas vs no vacunadas (por cohortes de nacidas)



Inmunidad de Grupo. Infección por VPH en hombres. (Australia)



Inmunidad de Grupo. Infección por VPH en hombres. (Australia)



Infecciones por VPH en Ohio

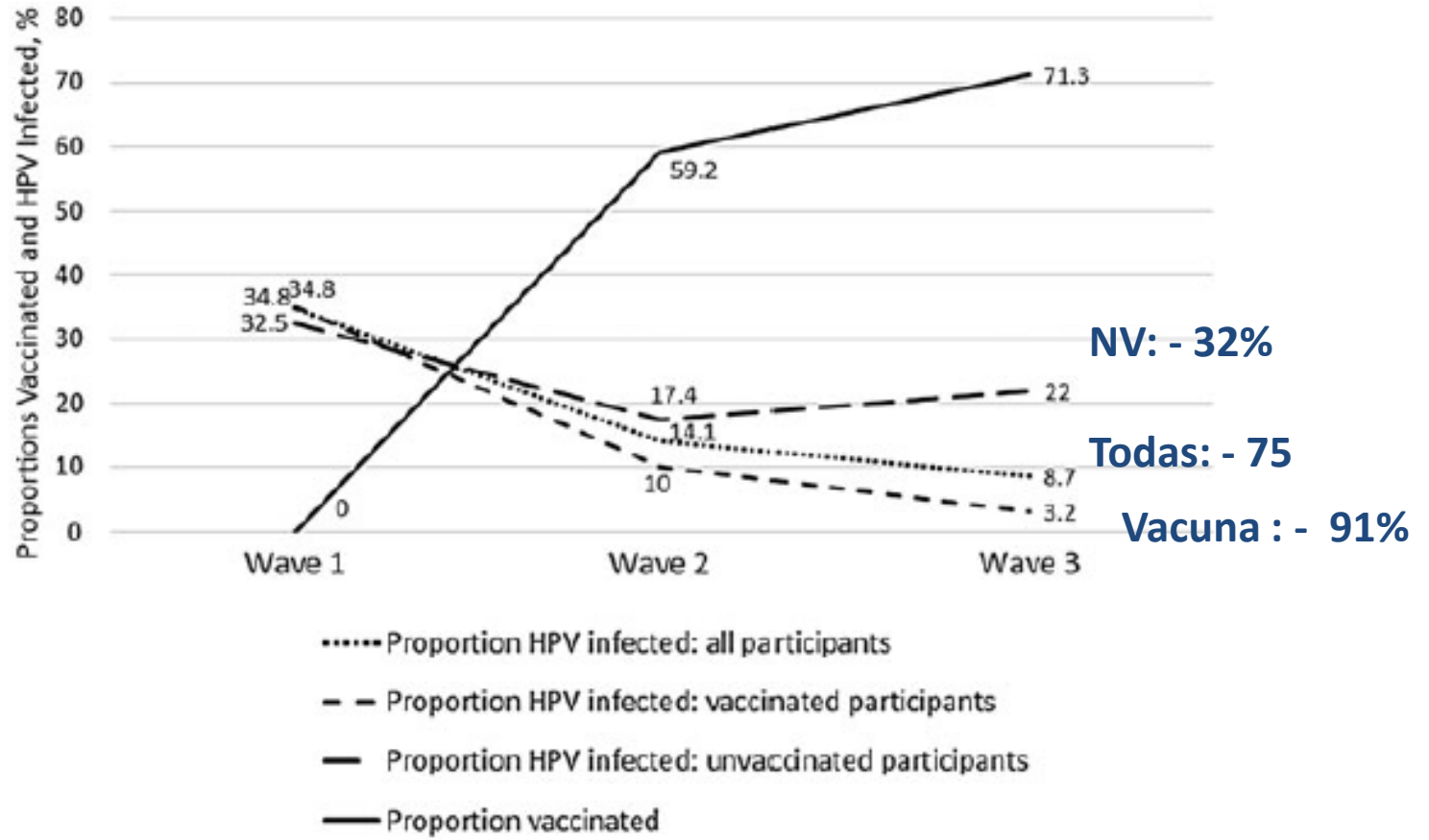


Tabla 3. Vacunación selectiva frente a VPH. Recomendaciones en España según Comunidad Autónoma (2016)

Comunidad Autónoma	Indicaciones vacunales
Asturias	Mujeres inmunocomprometidas hasta los 26 años
Cataluña	Mujeres infectadas por VIH hasta los 26 años
Islas Baleares	Mujeres sometidas a conización por CIN2+ o por adenocarcinoma <i>in situ</i>
Islas Canarias	Mujeres sometidas a conización de 25 a 45 años Mujeres con enfermedad inflamatoria intestinal de 18 a 65 años
La Rioja	Mujeres sometidas a conización hasta los 50 años por CIN2+ o por adenocarcinoma <i>in situ</i> en los últimos 6 meses o que estén programadas para la misma, y con resultado positivo de infección por tipos oncogénicos de VPH mediante PCR
Madrid	Mujeres sometidas a conización por CIN2+ en los últimos 3 años, hasta los 45 años; la vacuna se administrará lo antes posible una vez realizado el diagnóstico. Se puede vacunar antes, durante o después del tratamiento.
Murcia	Mujeres sometidas a conización con los siguientes criterios: <ul style="list-style-type: none"> • Proceso escisional por CIN 2+ o por adenocarcinoma <i>in situ</i>; • Intervalo máximo de un mes entre tratamiento y solicitud de la vacunación; • Edad comprendida entre los 20 y 45 años; • Determinación previa de infección por oncotipos VPH y seguimiento posterior mediante citología y determinación VPH
Navarra	Mujeres mayores de 26 años no inmunizadas previamente, sexualmente activas, y con indicación médica por: <ul style="list-style-type: none"> • Haber sido sometidas a conización; • Inmunodeficiencias congénitas o adquiridas, incluida la infección por VIH; • Enfermedades que requieran o puedan requerir tratamiento con fármacos inmunosupresores • Trasplante de órgano sólido o de precursores hematopoyéticos.

Eficacia de VPH-4 : ESTUDIO SPERANZA

Mujeres tratadas con escisión electroquirúrgica
para prevenir recaída por CIN

- ✓ **398** pacientes incluidas
- ✓ Mediana de seguimiento: 27 meses

Grupo control: 11/162 (**6%**) desarrolló recurrencia

Grupo vacunado: 2/162 (**1%**) desarrolló recurrencia

$p=0,0199$

- ✓ Estos resultados preliminares indican que 4vVPH después de LEEP podría ser útil para prevenir la recurrencia por la enfermedad
- ✓ La vacunación frente al VPH podría prevenir nuevas infecciones subsecuentes o recurrencias del mismo tipo
- ✓ Las implicaciones clínicas de esto podrían ser muy grandes, para modificar el manejo de las enfermedades VPH post tratamiento

Vacunación VPH

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Todas las autoridades sanitarias confirman una y otra vez la seguridad de las vacunas VPH

PRESS RELEASE EMA statement on the safety of Gardasil

The European Medicines Agency (EMA) has received reports of deaths in women who had previously received Gardasil, including two reports concerning the sudden and unexpected deaths of two young women in the European Union (EU). Gardasil is a vaccine approved in the EU for the prevention of cervical cancer and other diseases caused by human papillomavirus (HPV) types 6, 11, 16 and 18. It is estimated that about 1.5 million patients have been vaccinated with this HPV vaccine in Europe.

The two European cases were reported as part of the continuous monitoring of the vaccine. One of the cases occurred in Austria and the other in Germany. In both cases, the cause of death was not identified. No causal relationship has been established between the deaths and the administration of Gardasil.

On the basis of the currently available evidence, the Committee for Human Use (CHMP) is of the opinion that the benefits of the vaccine continue to outweigh the risks and that no changes to its product information are necessary.

The EMA will continue to monitor the safety of the vaccine and will update its position if new information emerges.

London, 24 January 2008
Doc. Ref. EMEA/37479/2008

2009, 84, 37-40



World Health Organization

Weekly Epidemiol record

hebdomadaire

No. 5

>200 millones de dosis

Comité consultatif mondial de la Sécurité vaccinale, 17-18 décembre 2008

Le Comité consultatif mondial de la Sécurité vaccinale (GACVS), composé de spécialistes des questions scientifiques et techniques, a été créé par l'OMS pour traiter, en toute indépendance et avec la rigueur scientifique voulue, des problèmes de sécurité vaccinale pouvant avoir une importance mondiale. Le GACVS a tenu sa première réunion à Genève, Suisse, le 17

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CDC Department of Health and Human Services
Centers for Disease Control and Prevention

Vaccine Safety

Vaccine Safety Basics

- Information for Parents
- Why It's Important to Monitor Vaccine Safety
- How Vaccines Are Tested and Monitored
- Common Questions
- Vaccine Safety Concerns
- History of Vaccine Safety

Public Health Activities

- Vaccine Adverse Event Reporting System (VAERS)
- Publications
- Gardasil Vaccine

Reports of Health Concerns Following HPV Vaccination

HPV Vaccine Safety

The safety of the HPV vaccine was studied in 5 clinical trials before it was licensed. There were over 21,000 girls and women ages 9 through 26 in these clinical trials.

Since it was licensed, CDC and FDA have been closely monitoring the safety of the HPV vaccine. There are 3 systems used to monitor the safety of the HPV vaccine. They are licensed and used to monitor the safety of the vaccine to be caused by the vaccine's clinical trials.

Quick Links

- HPV and HPV Disease Information
- HPV Vaccine Information
- Vaccine Safety Information
- HPV Questions and Answers
- FDA Center for Biologics Evaluation and Research
- To Report an Adverse Event in VAERS
- Related Information on Guillain-Barre Syndrome
- Information from FDA and CDC on Gardasil and its Safety

MINISTERIO DE SANIDAD Y POLÍTICA SOCIAL

GABINETE DE PRENSA

Press Release

Conclusions of the AEMPS Expert Panel on the safety of the human papilloma virus vaccine

23 April 2009

Regarding the administration of the human papilloma virus vaccine, and the two suspect cases of an adverse reaction in the Region of Valencia, the Expert Panel gathered by the Spanish Medicines and Health Products Agency (AEMPS) has issued its conclusions:

The Committee has examined the data of the cases communicated to the Spanish Pharmacovigilance System, and to the European database, where the safety of the human papilloma virus vaccine was monitored in depth the cases of the adverse reaction, including the different

SIN NINGUNA
SEÑAL DE ALERTA

SEGURIDAD VACUNA VPH-4

VACCINE REPORTS

An Overview of Quadrivalent Human Papillomavirus Vaccine Safety

2006 to 2015

Michelle Vichnin, MD, Paolo Bonanni, MD,† Nicola P. Klein, MD, PhD,‡ Suzanne M. Garland, MD,§
Stan L. Block, MD,¶ Susanne K. Kjaer, MD,|| ** Heather L. Sings, PhD,* Gonzalo Perez, MD,*††
Richard M. Haupt, MD, MPH,* Alfred J. Saah, MD,* Fabio Lievano, MD,* Christine Velicer, PhD,*
Rosybel Drury, PhD,‡‡ and Barbara J. Kuter, PhD, MPH**

Conclusions: These results, along with the safety data from the prelicen-
sure clinical trials, confirm that the HPV4 vaccine has a favorable safety
profile. Key policy, medical and regulatory organizations around the world
have independently reviewed these data and continue to recommend routine
HPV vaccination.

Original Investigation

Quadrivalent HPV Vaccination and Risk of Multiple Sclerosis and Other Demyelinating Diseases of the Central Nervous System

Nikolai Madrid Scheller, MB; Henrik Svanström, MSc; Björn Pasternak, MD, PhD; Lisen Arnheim-Dahlström, PhD; Karin Sundström, MD, PhD; Katharina Fink, MD, DrMed; Anders Hviid, DrMedSci

Dinamarca – Suecia

Evaluación de niñas y mujeres de 10 a 44 años
2006 al 2013

Población estudiada: 3.983.824

Vacunadas: 780.082

Con 3 dosis: 467.812

SEGURIDAD VACUNAS VPH


**NO asociación a esclerosis múltiple
u otras enfermedades desmielinizantes**

Outcome	Unvaccinated			Vaccinated		
	No. of Cases	Person-Years	Crude Incidence Rate (95% CI), Events/100 000 Person-Years	No. of Cases	Person-Years	Crude Incidence Rate (95% CI), Events/100 000 Person-Years
Other Demyelinating Diseases						
Main analysis	3154	19 546 190	16.14 (15.58-16.71) ^b	17	419 496	4.05 (2.52-6.52)
Analysis by age, y						
10-29	1175	10 000 000	11.75 (10.58-12.92)	1	10 000 000	0.01 (0.00-0.02)
30-44	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)
45-59	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)
60-74	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)
≥75	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)
Analysis by sex						
Male	1577	19 546 190 ^b	15.77 (15.18-16.36) ^b	17	419 496	4.05 (2.52-6.52)
Female	1577	19 546 190 ^b	15.77 (15.18-16.36) ^b	17	419 496	4.05 (2.52-6.52)
Analysis by country						
Sweden	1175	10 000 000	11.75 (10.58-12.92)	1	10 000 000	0.01 (0.00-0.02)
Denmark	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)
Norway	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)
Analysis by vaccination status						
Unvaccinated	3154	19 546 190 ^b	16.14 (15.58-16.71) ^b	17	419 496	4.05 (2.52-6.52)
Vaccinated	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)
Analysis by duration of follow-up						
0-10 y	1175	10 000 000	11.75 (10.58-12.92)	1	10 000 000	0.01 (0.00-0.02)
11-20 y	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)
21-30 y	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)
31-40 y	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)
41-50 y	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)
51-60 y	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)
61-70 y	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)
71-80 y	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)
>80 y	1000	10 000 000	10.00 (8.83-11.17)	1	10 000 000	0.01 (0.00-0.02)


CONCLUSIONS AND RELEVANCE In this study with nationwide coverage of 2 Scandinavian countries, qHPV vaccination was not associated with the development of multiple sclerosis or other demyelinating diseases. These findings do not support concerns about a causal relationship between qHPV vaccination and demyelinating diseases.

SEGURIDAD VACUNAS VPH


An agency of the European Union



EUROPEAN MEDICINES AGENCY
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Review concludes evidence does not support that HPV vaccines cause CRPS or POTS

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Press release

05/11/2015

Review concludes evidence does not support that HPV vaccines cause CRPS or POTS

Reports of CRPS and POTS after HPV vaccination are consistent with what would be expected in this age group

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) has completed a detailed scientific review of the evidence surrounding reports of two syndromes, complex regional pain syndrome (CRPS) and postural orthostatic tachycardia syndrome (POTS) in young women given human papillomavirus (HPV) vaccines. These vaccines are given to protect them from cervical cancer and other HPV-related cancers and pre-cancerous conditions. This review concluded that the evidence does not support a causal link between the vaccines (Cervarix, Gardasil/Silgard and Gardasil-9) and development of CRPS or POTS. Therefore, there is no reason to change

Related information

- Human papillomavirus vaccines: Article 20 procedures

Related content

- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 3-5 November 2015 (06/11/2015)
- [YouTube](#) Virtual press briefing: Human papillomavirus (HPV) vaccines – recommendation from the Pharmacovigilance Risk Assessment Committee (PRAC) (05/11/2015)

Disponible en:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/11/news_detail_002420.jsp&mid=WC0b01ac058004d5c1

Box 2

Recommendations and key strategies for health care providers to improve HPV vaccination rates

- Recommend the HPV vaccine with the same strength and conviction used to recommend other adolescent vaccines. A recommendation by an HCP is the most important reason that adolescents get the HPV vaccine.
- Health care providers should recommend the vaccine with a presumptive, rather than participatory style to improve parental acceptance of the vaccine
- Emphasize that the HPV vaccine prevents cancer
- Health care providers should educate themselves on HPV and HPV vaccines
- Address potential barriers through key elements of HPV education including: (1) provide sufficient information to parents on the disease and cancer prevention, (2) outline the rationale for vaccinating ages 11 to 12, (3) discuss safety and efficacy of the vaccine, (4) remind parents/patients of the 3-shot series, (5) address system barriers (eg, cost), and (6) highlight the benefit of male vaccination.
- Inform colleagues and staff to ensure that everyone delivers the same messages on HPV
- Communicate vaccination benefits to parents and adolescents at every opportunity
- Make vaccination procedures routine and focus on ways to reduce missed opportunities

Adapted from National Foundation for Infectious Diseases. Call to action: HPV vaccination as a public health priority. 2014. Available at: <http://www.adolescentvaccination.org/hpv-cta>. Accessed July 27, 2015.

Gardasil 9 : autorizada

The image displays two overlapping web pages. The top page is the FDA website, and the bottom page is the European Medicines Agency (EMA) website.

FDA Website (Top):

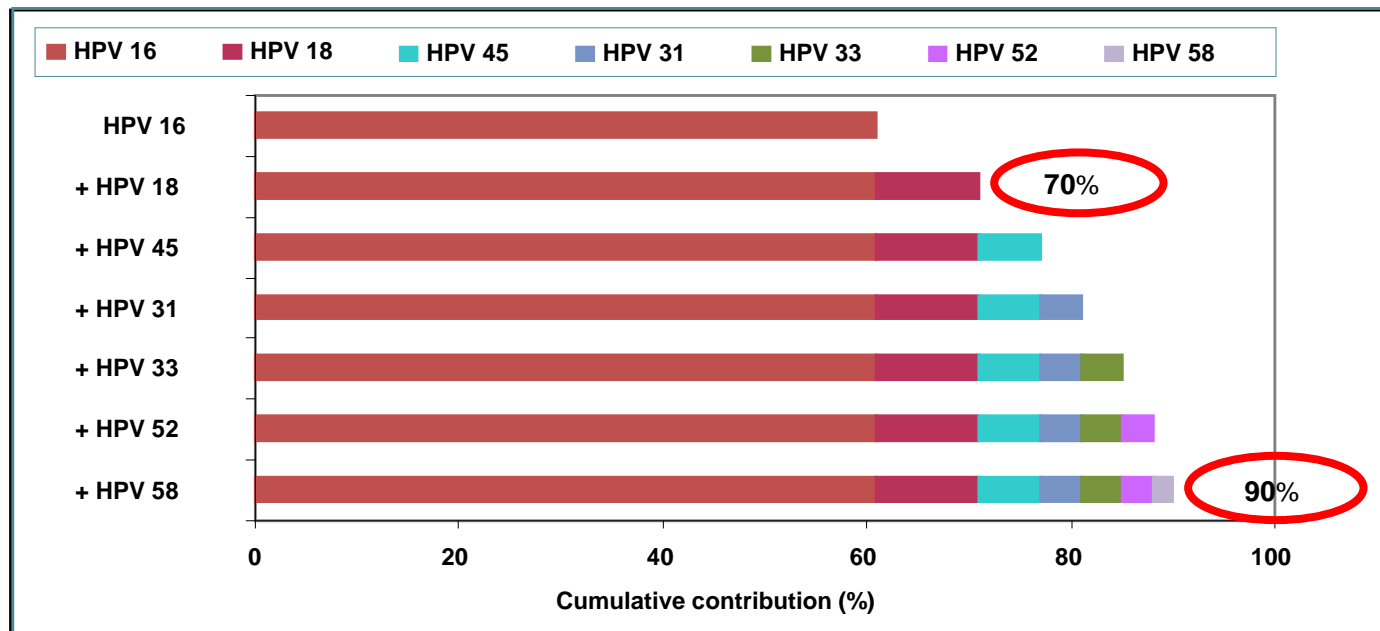
- Header: U.S. FOOD & DRUG ADMINISTRATION. Search bar: Search FDA.
- Navigation: Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Tobacco Products.
- Section: Vaccines, Blood & Biologics.
- Breadcrumb: Home > Vaccines, Blood & Biologics > Vaccines > Approved Products.
- Section: Approved Products.
- Section: Resources for You
 - Human Papillomavirus Vaccine
 - Licensed Biological Products with Supporting Documents
 - Vaccines Licensed for Use in the United States
- Section: Gardasil 9
 - STN: 125508
 - Proper Name: Human Papillomavirus 9-valent Vaccine, Recombinant
 - Tradename: Gardasil 9
 - Manufacturer: Merck & Co., Inc.
 - Indications: Indicated in girls
 - Cervical, vulvar and anal intraepithelial neoplasia and 58. (1.1)
 - Genital warts (condylomata acuminata)
 - And the following

EMA Website (Bottom):

- Header: AN AGENCY OF THE EUROPEAN UNION. Text size: A A A. Site-wide search: GO. Search document library. Follow us: Twitter, RSS, YouTube.
- Navigation: Home, Find medicine, Human regulatory, Veterinary regulatory, Committees, News & events, Partners & networks, About us.
- Breadcrumb: Home > Find medicine > Human medicines.
- Section: Gardasil 9
 - human papillomavirus 9-valent vaccine (recombinant, adsorbed)
 - Email, Print, Help, Share
 - Buttons: About, Authorisation details, Product information, Assessment history.
 - Text: This is a summary of the European public assessment report (EPAR) for Gardasil 9. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Gardasil 9.
- Section: AUTHORISED
 - This medicine is approved for use in the European Union.
 - Gardasil 9 RSS feed

VPH 9: aumento protección

Contribución de los genotipos VPH 6,11,16,18,31,33,45,52,58 en cánceres anogenitales femeninos (estudio realizado en el ICO)



La adición de los tipos VPH 31-33-45-52-58 a las vacunas actuales podría prevenir al menos el 90% de los cánceres anogenitales femeninos positivos a VPH

VPH 9-valente en previamente vacunados

Table 1
Scenarios and proposed approaches, for girls 9–14 years of age.

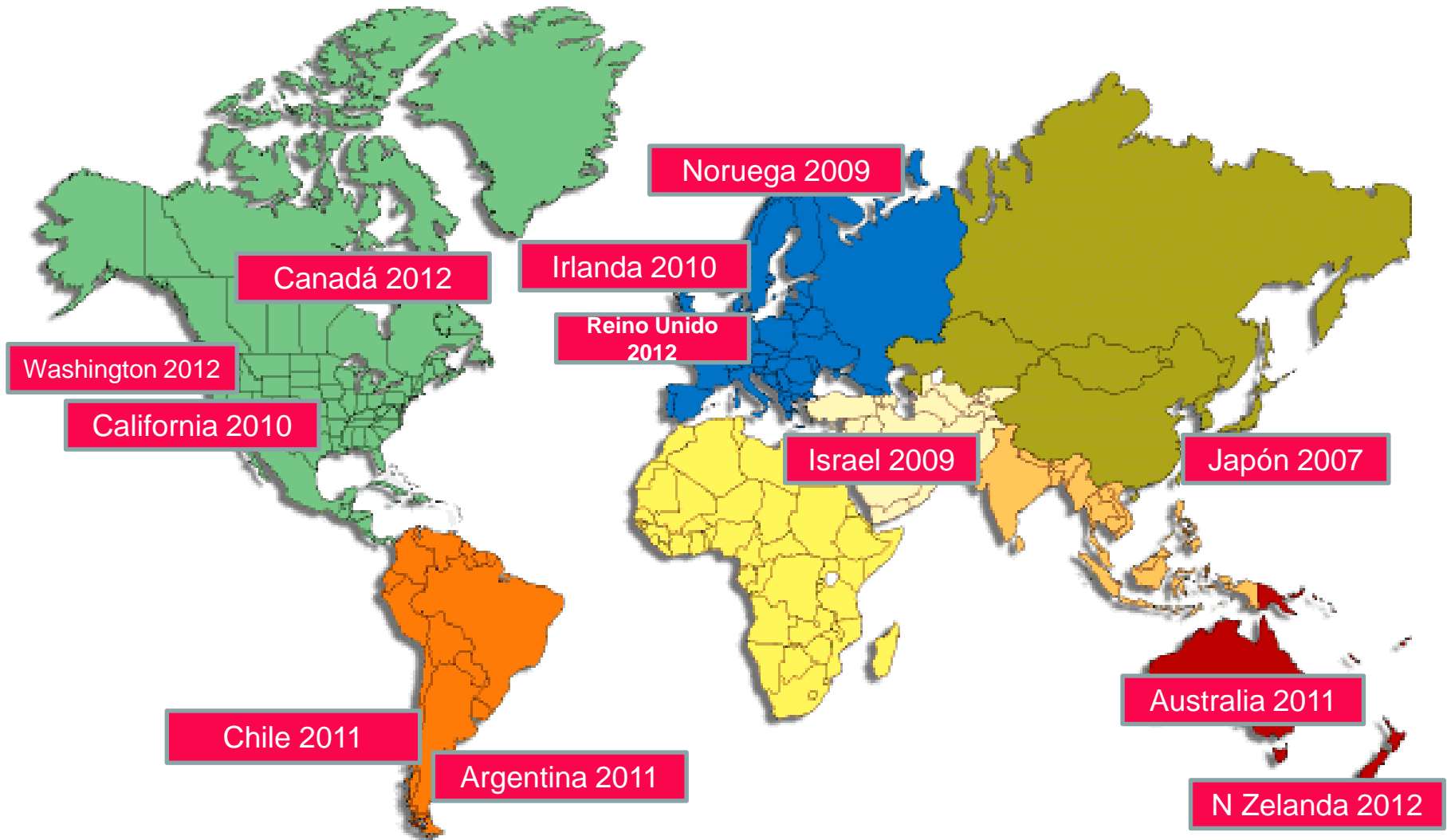
Scenario	Month 0	Month 2	Month 6	Month 12	Month 18	Expected protection*
Sequential doses administration						
A	2vHPV		2vHPV			2 types
	2vHPV		2vHPV	9vHPV	9vHPV	2 types and likely protection for the 7 extra types
	4vHPV		4vHPV			4 types
	4vHPV		4vHPV	9vHPV	9vHPV	4 types and likely protection for the 5 extra types
B	2vHPV	2vHPV				No evidence
	2vHPV	2vHPV	9vHPV			2 types
	2vHPV	2vHPV	9vHPV	9vHPV		2 types and likely protection for the 7 extra types
	4vHPV	4vHPV				Incomplete
	4vHPV	4vHPV	9vHPV			4 types
	4vHPV	4vHPV	9vHPV	9vHPV		4 types and likely protection for the 5 extra types
C	2vHPV					No evidence
	2vHPV		9vHPV			2 types
	2vHPV		9vHPV	9vHPV		2 types and likely protection for the 7 extra types
	4vHPV					No evidence
	4vHPV		9vHPV			4 types
	4vHPV		9vHPV	9vHPV		4 types and likely protection for the 5 extra types
Revaccination						
D	2vHPV	2vHPV	2vHPV			2 types
	2vHPV	2vHPV	2vHPV	9vHPV	9vHPV	2 types and likely protection for the 7 extra types
	4vHPV	4vHPV	4vHPV			4 types
	4vHPV	4vHPV	4vHPV	9vHPV	9vHPV	4 types and likely protection for the 5 extra types

: already received
 : additional

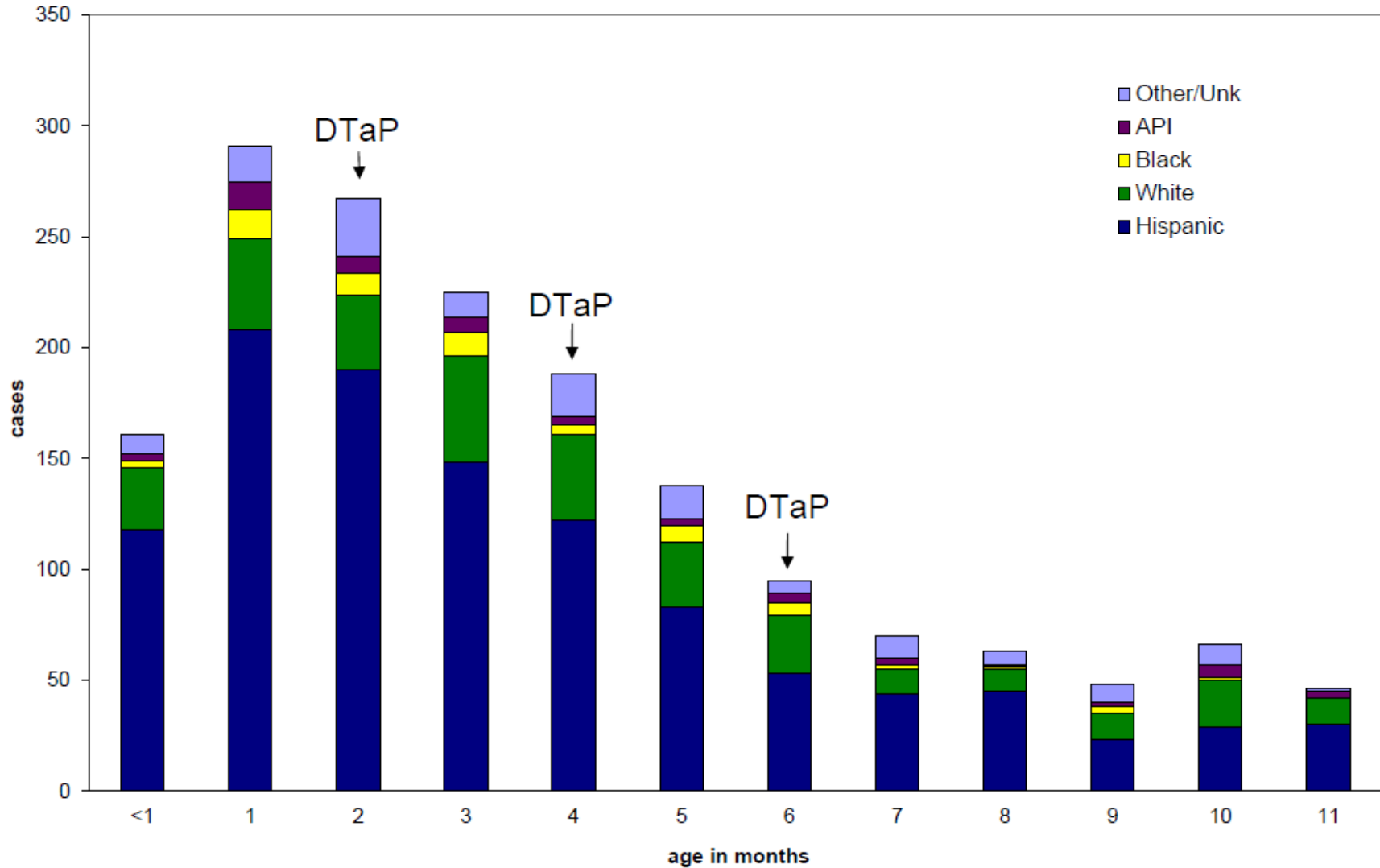
AÑADIR
 2 DOSIS
 VPH-9V

Vacunación frente a tosferina en embarazadas

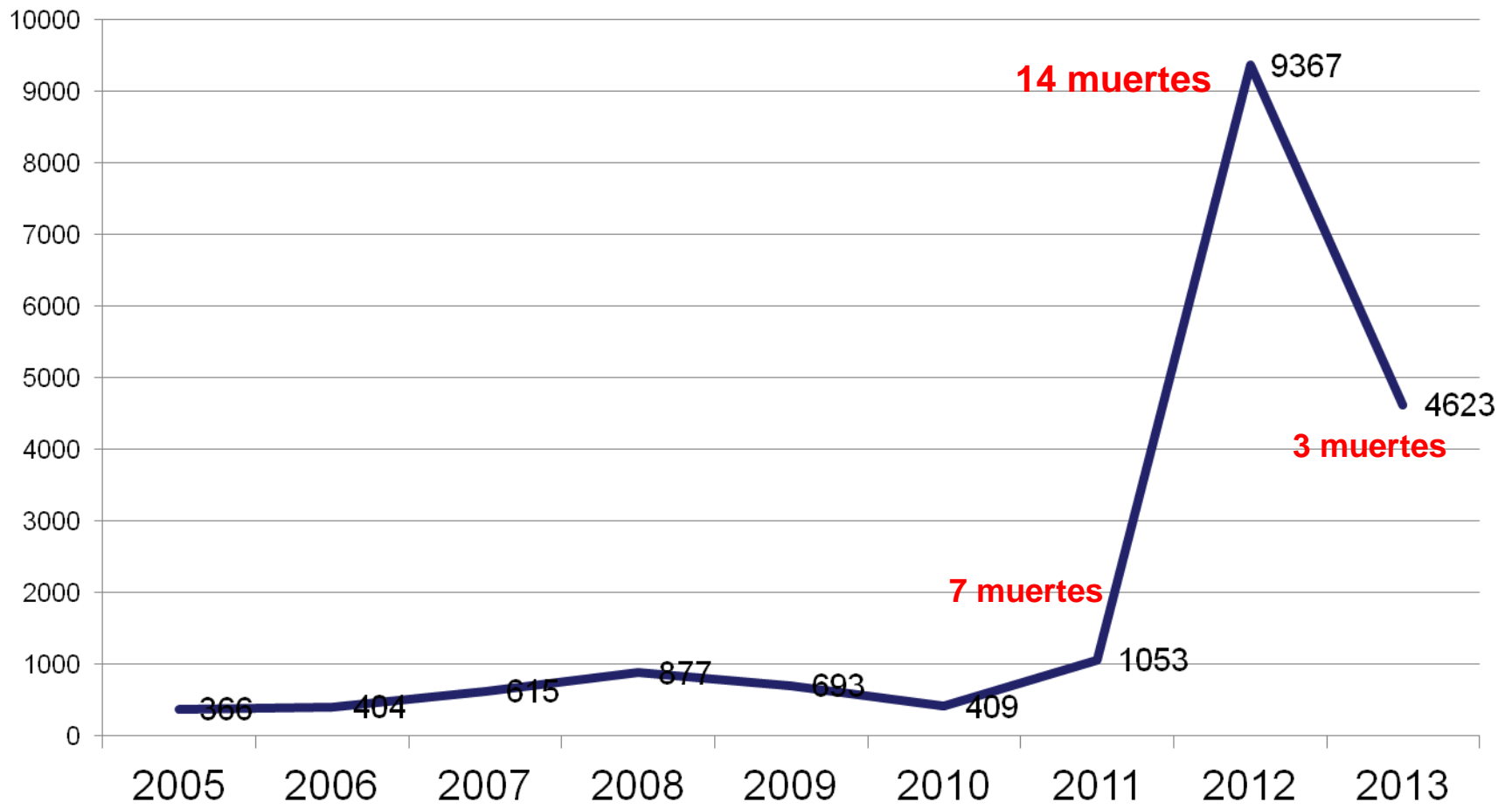
Brotos de tosferina en el mundo



Casos de tosferina por edad (California 2010)



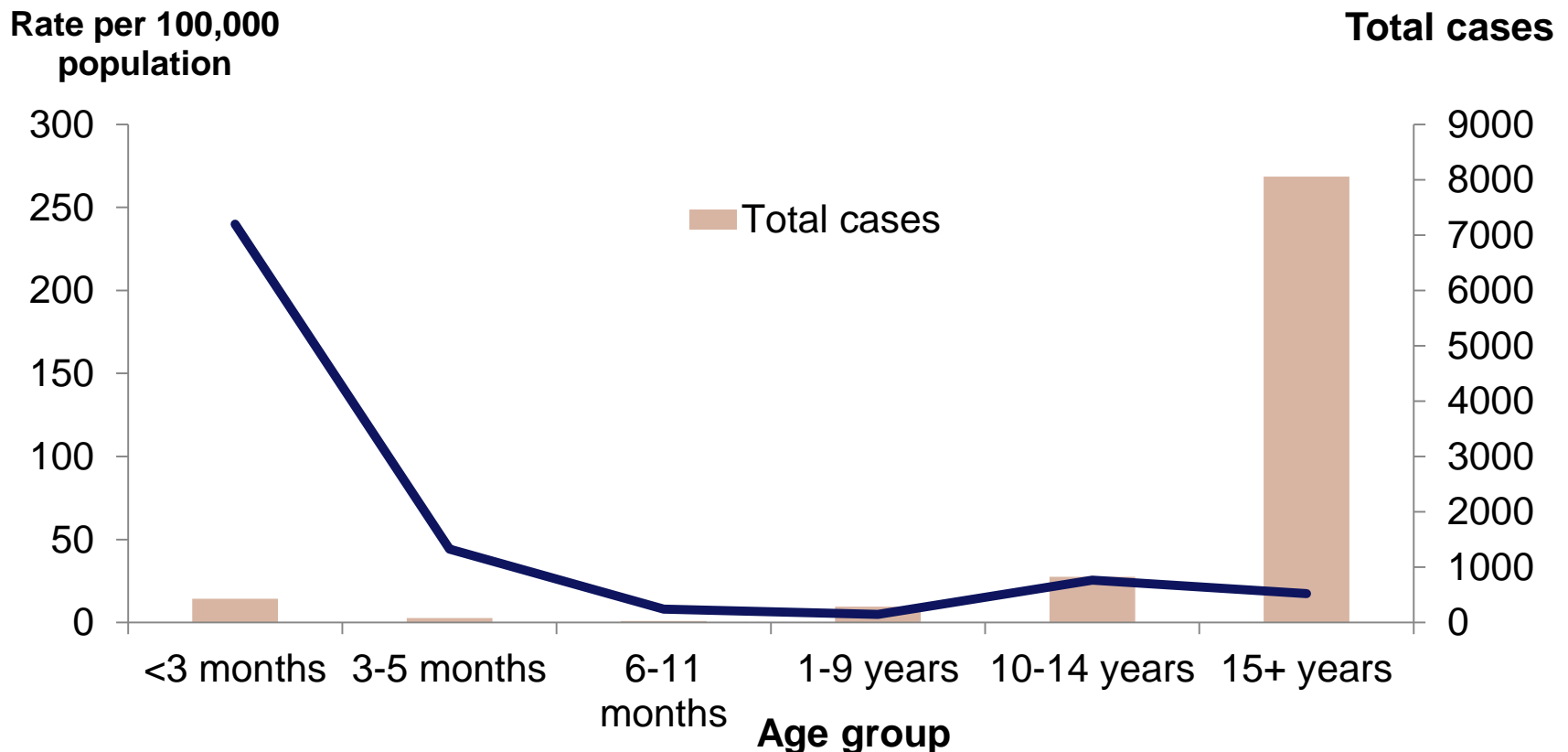
Casos de tosferina demostrada por laboratorio en Inglaterra y Gales



Health Protection Agency

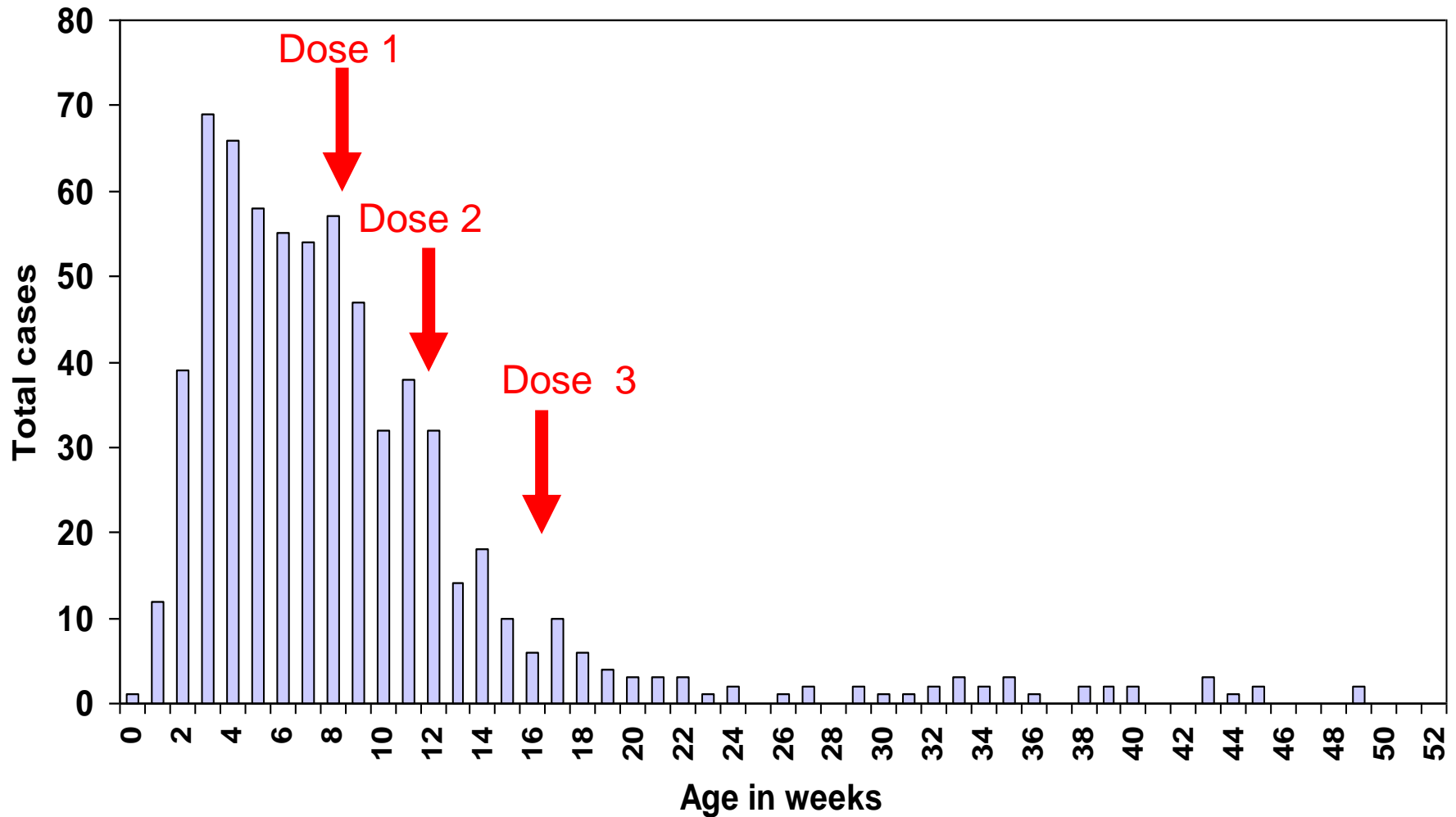


Age distribution of laboratory confirmed pertussis cases and rate per 100,000 England and Wales 2012

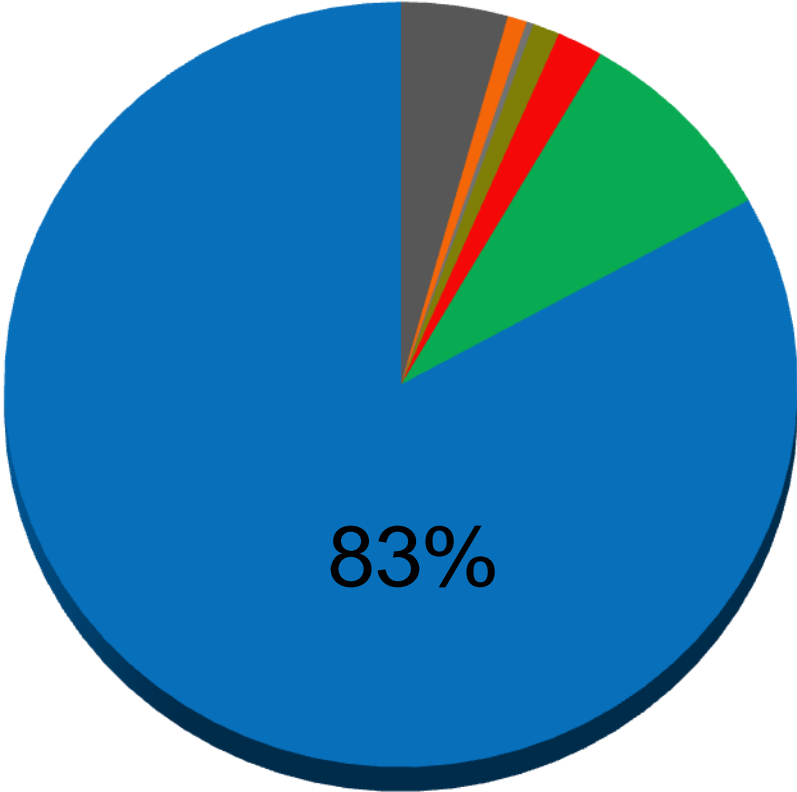




Confirmed cases in infants under 1 year, by week of age at onset* (2011-end August 2012) England and Wales

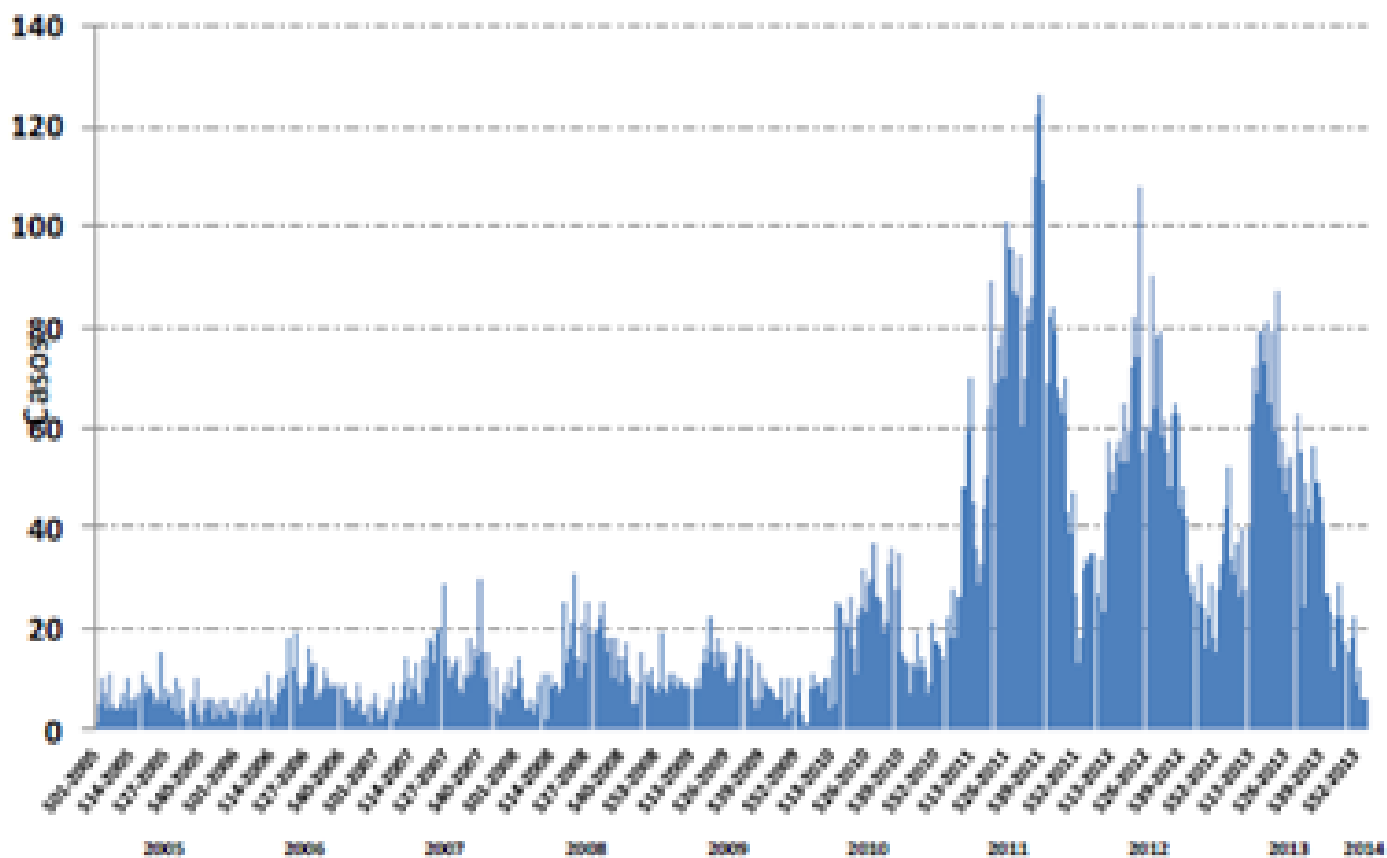


Casos de tosferina por edad en Inglaterra y Gales



■ < 3 m ■ 3-5 m ■ 6-11 m ■ 1-4 a ■ 5-9 a ■ 10-14 a ■ Más 15 a

Casos de Tos Ferina. Declaración numérica semanal. España, 2005-2014



Boletín Epidemiológico Semanal. 4 febrero 2014

*La tosferina ha resurgido y
afecta a todas las edades*

*Las hospitalizaciones y muertes
afectan a los lactantes < 6 meses
(3 meses)*

¿Por qué el resurgir de la
tosferina?

¿Quién contagia a los
lactantes?

Fuentes de infección en 164 niños hospitalizados con tos ferina

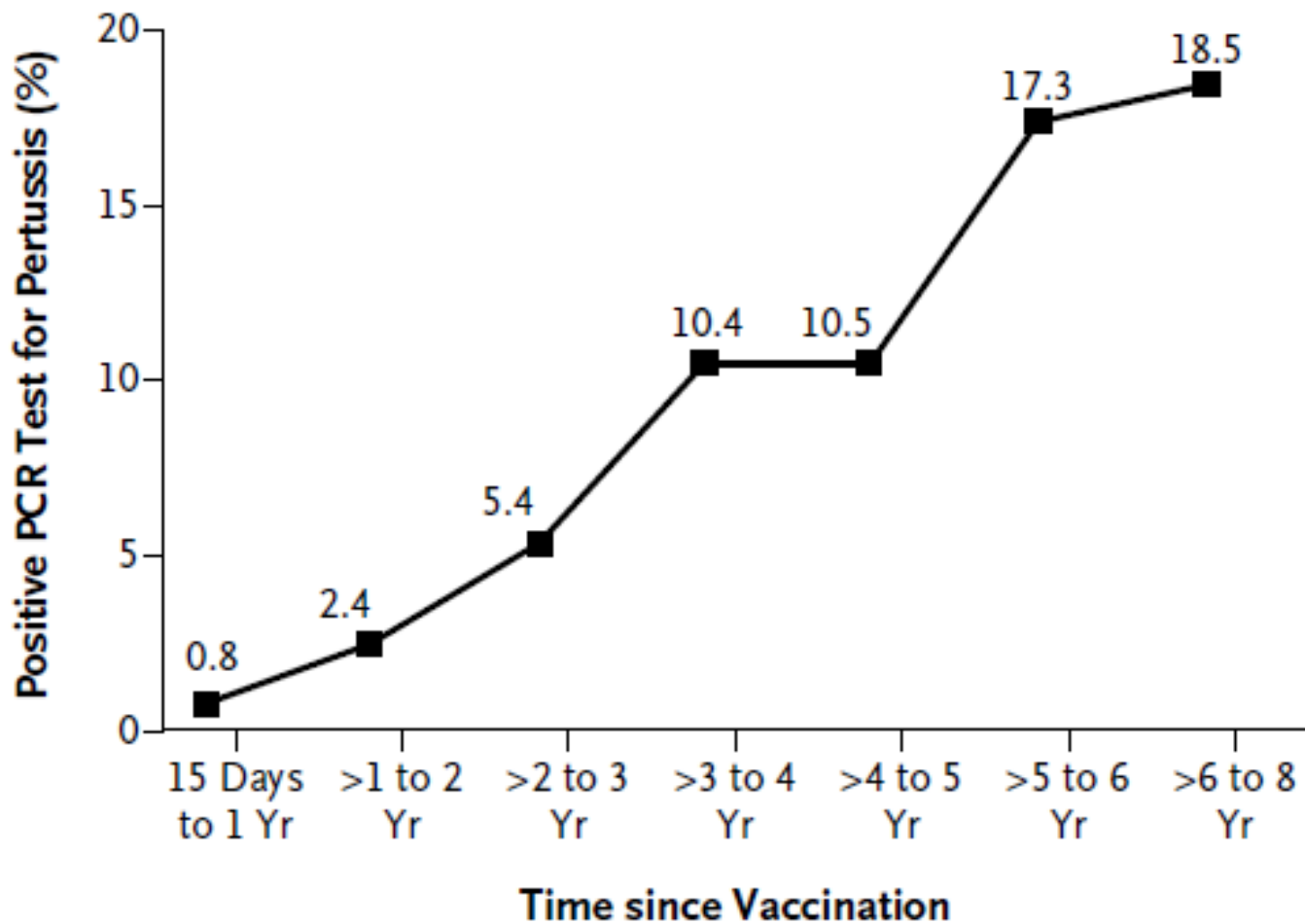
	Nº total	Nº personas fuente infección	% (IC 95%)
Madre	164	52	38 (30-46)
Padre	155	23	17 (11-24)
Otro adulto	28	6	4 (2-9)
14-19 años	12	0	0 (0-2)
9-13 años	27	11	8 (4-13)
5-8 años	85	20	15 (9-21)
1-4 años	92	25	18 (12-25)
0 años (gem.)	1	0	0 (0-2)

Pérdida de inmunidad a lo largo del tiempo (casos y controles)

Tiempo desde la 5 ^a dosis de DTPa (meses)	Casos	Controles	OR (IC 95%)
< 12	19	354	0,02 (0,01-0,004)
12-23	51	391	0,05 (0,02-0,09)
24-35	79	366	0,08 (0,04-0,13)
36-47	108	304	0,13 (0,07-0,24)
48-59	141	294	0,17 (0,09-0,31)
≥ 60	231	288	0,29 (0,15-0,54)

Misegades LK, et al. JAMA 2012; 308: 2126-2132

Waning Protection after Fifth Dose of Acellular Pertussis Vaccine in Children



Nlein Np, et al. N Engl J Med 2012, 367: 1012-9



How can we protect children too young to be vaccinated against pertussis?

- In October 2012, the Department of Health recommended that pregnant women receive one dose of pertussis containing vaccine from 28-38 weeks
- **This recommendation was updated and from April 2016, the vaccine should now be offered from week 16 of pregnancy (ideally around the time of the foetal anomaly scan at 20 weeks)**
- The aim is to **boost** antibodies in vaccinated women during pregnancy so that pertussis antibodies are passed from mother to baby
- This is considered the **best** way to provide passive protection to infants in the first weeks of life and offers women a **safe way to protect their baby** against this serious disease



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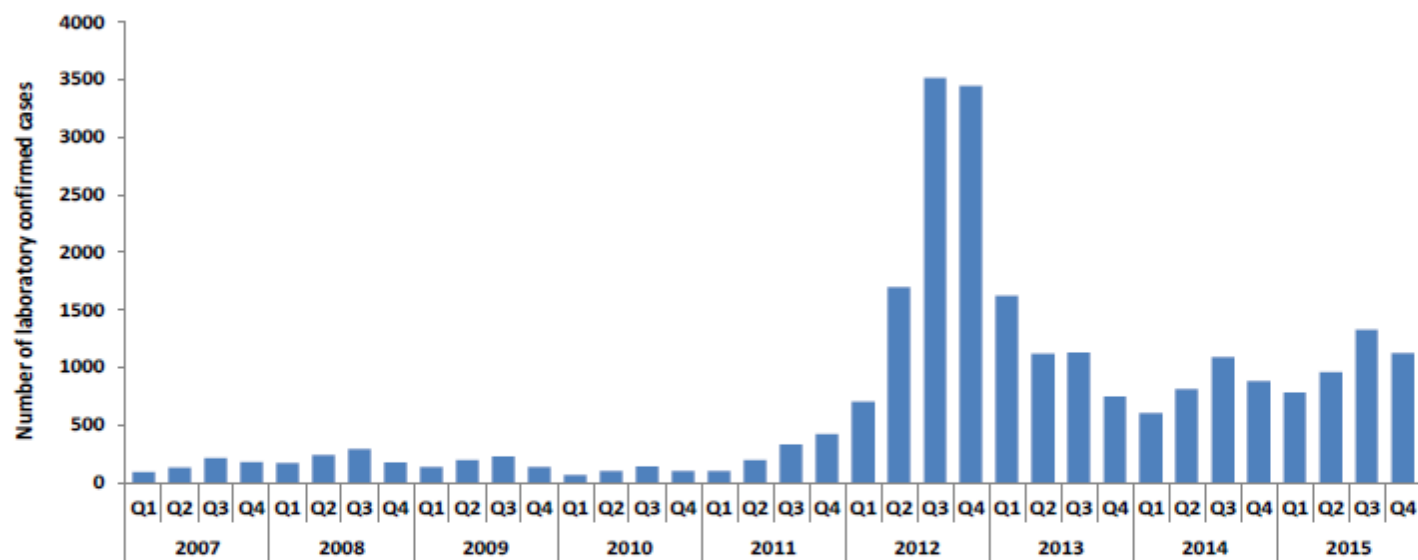
Adenda Actualización en «Revisión del programa de vacunación frente a tos ferina en España»

Junio de 2015

Durante la elaboración de esta agenda se han realizado recomendaciones de adaptación del calendario como consecuencia de problemas de suministro de vacunas con componentes de tos ferina, incluida dTpa. Este hecho ha cambiado el contexto y la perspectiva para establecer recomendaciones.

Se recomienda la puesta en marcha de esta estrategia de vacunación para el control de la enfermedad grave y la mortalidad en los niños menores de 3 meses de edad mediante la administración de vacuna dTpa entre las semanas 27-28 y 36 de gestación, e idealmente entre las 28 y 32 semanas de gestación. La vacuna se administrará en cada embarazo independientemente de su estado previo de vacunación.

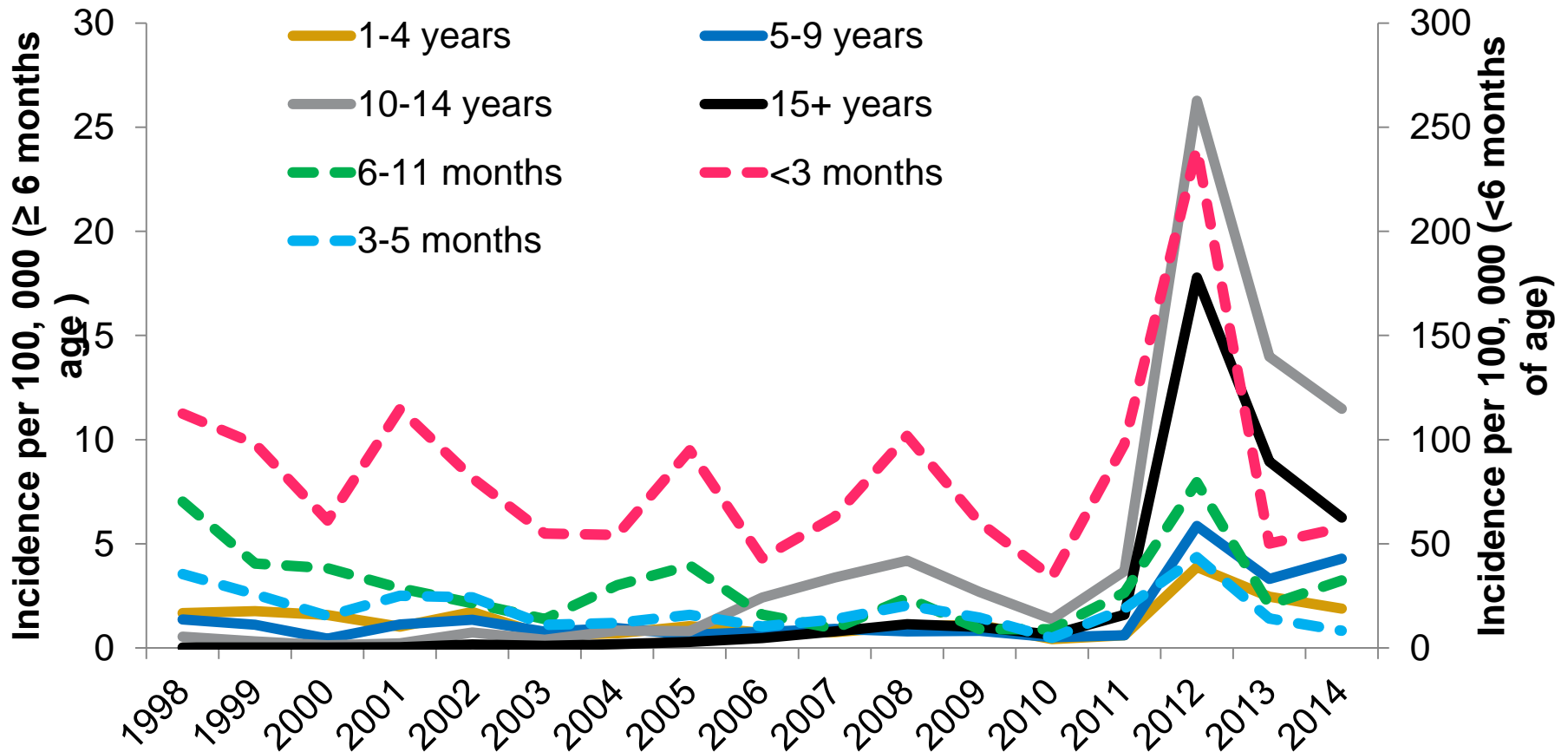
Figure 1: Laboratory confirmed cases of Pertussis infection by year and quarter, England: 2007 to 2015*



*2015 are provisional data



Annual pertussis incidence in England



Effectiveness of maternal pertussis vaccination in England: an observational study

Gayatri Amirthalingam, Nick Andrews, Helen Campbell, Sonia Ribeiro, Edna Kara, Katherine Donegan, Norman K Fry, Elizabeth Miller, Mary Ramsay

91% (84%-95%) en niños menores de 3 meses

Effectiveness of Prenatal Versus Postpartum Tetanus, Diphtheria, and Acellular Pertussis Vaccination in Preventing Infant Pertussis

Kathleen Winter,^{1,2} Steve Nickell,¹ Michael Powell,¹ and Kathleen Harriman¹

California: 85% (33%-98%)

Effectiveness of Prenatal Tetanus, Diphtheria, and Acellular Pertussis Vaccination on Pertussis Severity in Infants

Kathleen Winter,^{1,3} James D. Cherry,² and Kathleen Harriman¹

Riesgo hospitalización: 0,47 (0.35-0.63)

Amirthalingam G, et al. Lancet 2014; 384: 1521-28

Winter K, et al. CID 2017; 64: 3-8

Winter K, et al. CID 2017; 3-8

Conclusiones

- Perseguir la vacunación de todas las niñas (recomendar con firmeza)
- Vacunación de inmunodeprimidas ¿y varones?
- Vacunación frente a tosferina en embarazadas: muy efectiva
- Carga global en niños

Evaluation of the Association of Maternal Pertussis Vaccination With Obstetric Events and Birth Outcomes

Table 2. Rates of Adverse Gestational and Birth Outcomes and Relative Risks Associated With Receipt of Pertussis Vaccine (Tdap) During Pregnancy

Outcome	No. (%)		Risk Ratios (95% CI)		P Value
	Tdap Exposed	Unexposed	Unadjusted	Adjusted ^a	
Full cohort	26 229	97 265			
Chorioamnionitis	1596 (6.1)	5329 (5.5)	1.11 (1.05-1.17)	1.19 (1.13-1.26)	<.001
Preterm delivery, ≥37 wk	1527 (6.3)	7544 (7.8)	1.01 (0.95-1.06)	1.03 (0.97-1.09)	.33
Small for gestational age, <10th percentile	2214 (8.4)	8086 (8.3)	1.02 (0.97-1.06)	1.00 (0.96-1.06)	.68
Vaccinated at <20 wk gestation	6083	97 265			
Hypertensive disorders	497 (8.2)	7736 (8.0)	1.03 (0.94-1.12)	1.09 (0.99-1.20)	.05
Vaccinated at 27-≤36 wk gestation	11 351	97 265			
Chorioamnionitis	637 (5.6)	5329 (5.5)	1.02 (0.95-1.11)	1.11 (1.03-1.21)	.009
Preterm delivery, <37 wk	602 (5.3)	7544 (7.8)	0.88 (0.81-0.96)	0.88 (0.80-0.95)	.002
Small for gestational age, <10th percentile	978 (8.6)	8086 (8.3)	1.04 (0.97-1.10)	1.03 (0.96-1.10)	.40