Enfermedad meningocócica invasora, ¿dónde estamos y, sobre todo, a dónde vamos?

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Comité Asesor de Vacunas de la AEP

Córdoba
02/03/2019

Declaración de intereses

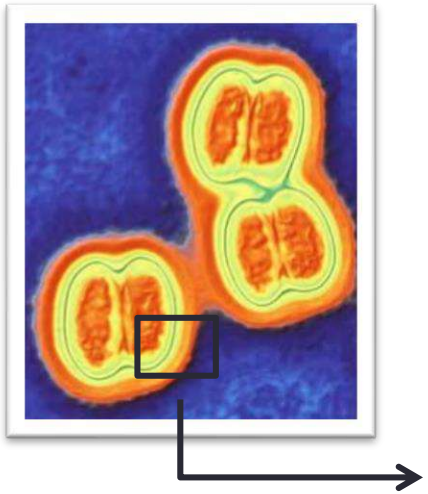
- Colaboradora en actividades formativas patrocinadas por GlaxoSmithKline, Sanofi Pasteur, Pfizer and Novartis
- Participación en congresos y reuniones: GlaxoSmithKline, Pfizer
- Investigadora en ensayos clínicos de GlaxoSmithKline y Wyeth

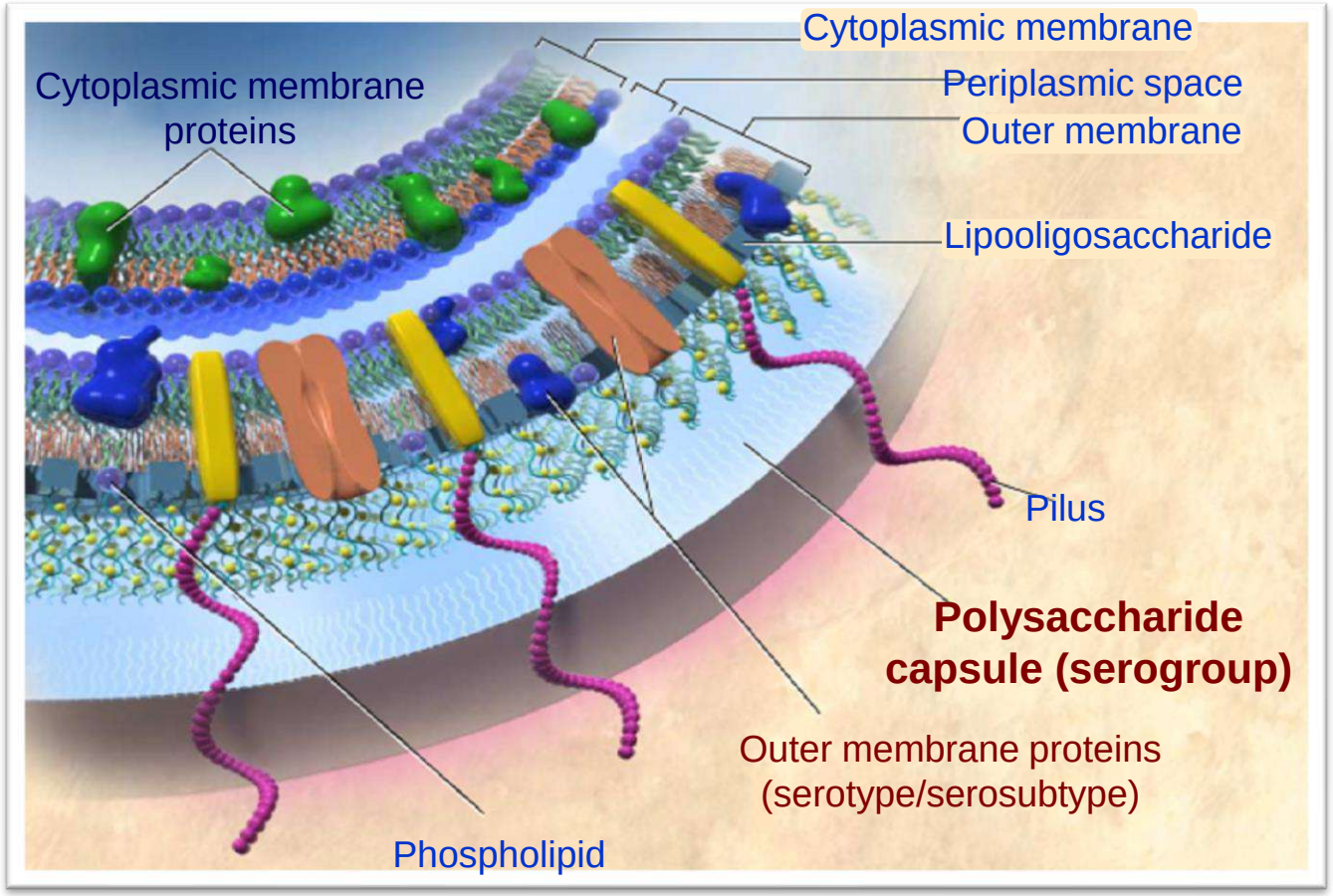
Contenido

1. **Introducción. Enfermedad meningocócica invasora**
    1. Meningitis
    2. Sepsis
2. **¿Dónde estamos?**
    1. **Epidemiología**
        1. Mundo
        2. Europa
        3. España
    2. **Vacunas antimeningocócicas**
        1. Vacunas MenC
        2. Vacunas MenACWY
        3. Vacunas MenB
3. **¿Dónde vamos?**
4. **Mensajes finales**

Introducción
EMI

Neisseria meningitidis





***Diplococcus* Gram (-)**

13 serogrupos:

basado en la estructura del polisacarárido capsular

Análisis del genoma completo

6 serogrupos: A, B, C, X, W, Y

Serotipos y serosubtipos: basado en las proteínas de la membrana externa

Colonización nasofaríngea por *N. meningitidis* según edad

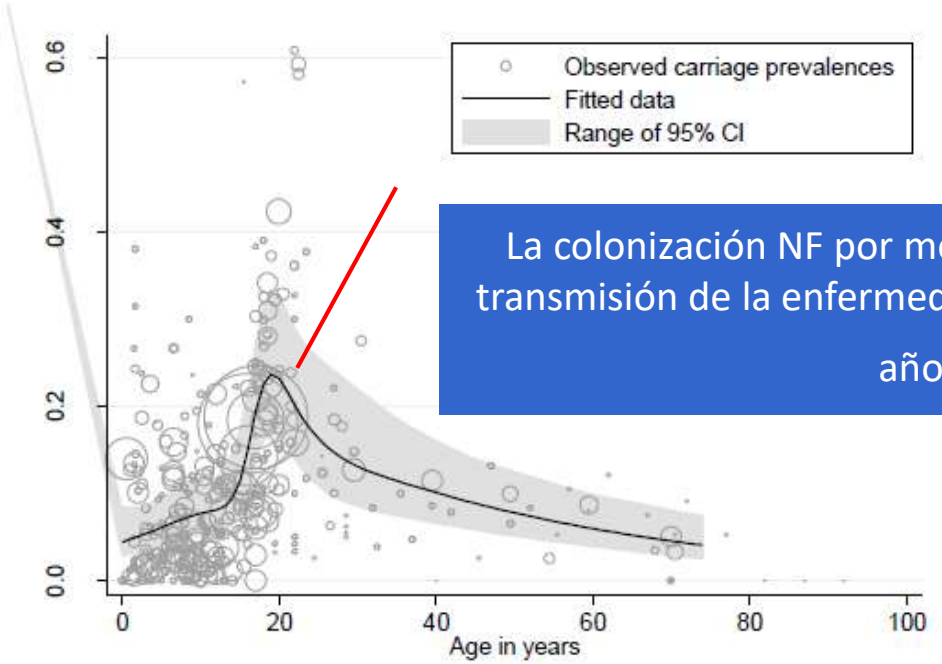
Prevalencia de colonización NF:

-Lactantes: 4-5%

-Adolescentes: aumento hasta 23,7% a los 19 años

-Adultos: descenso progresivo hasta 7-8% (50 años)

Reservorio exclusivamente humano
(enfermos y portadores)

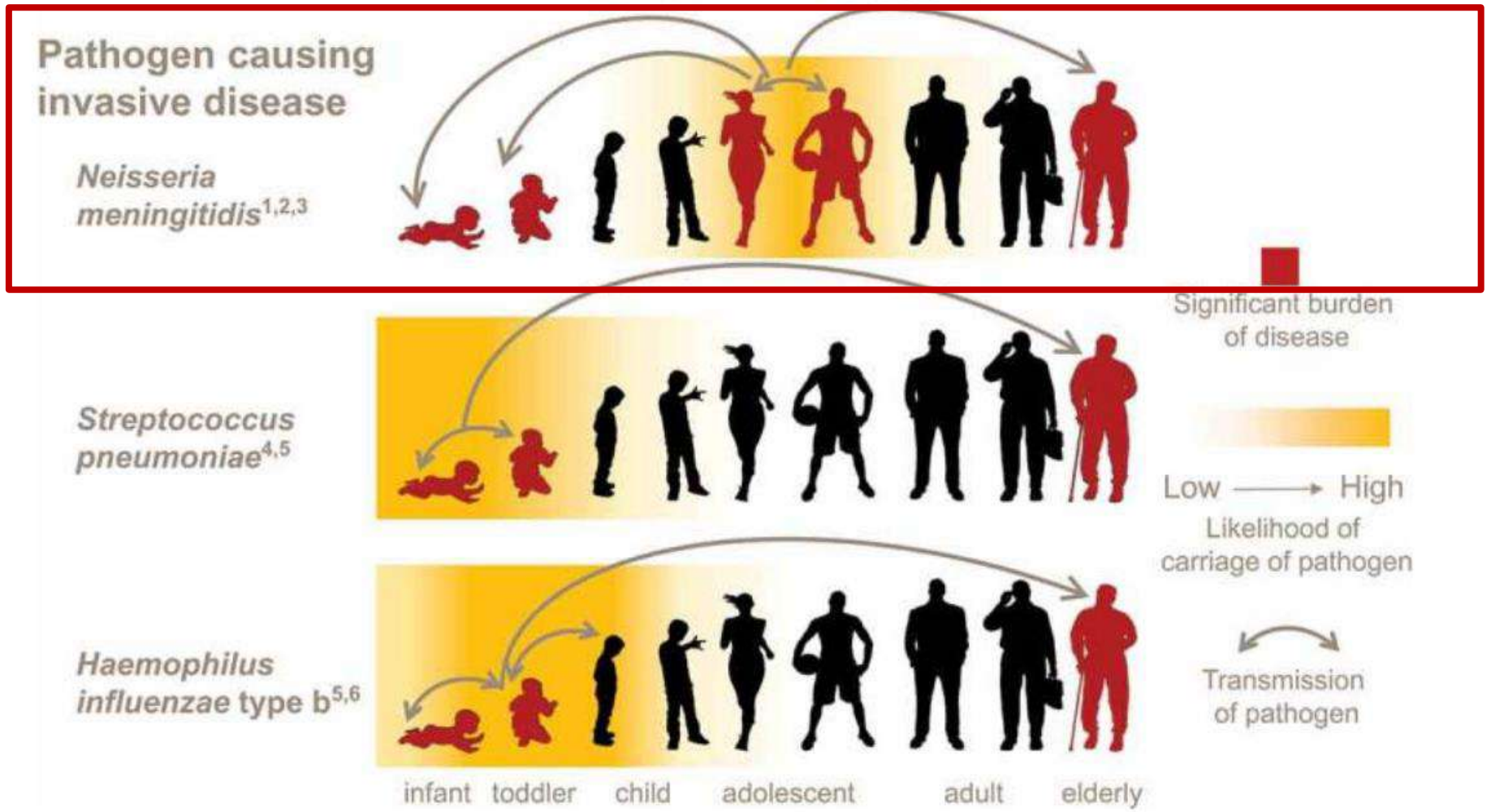


La colonización NF por meningococo, el primer paso en la transmisión de la enfermedad, tiene un pico máximo a los 19 años de edad.

N studies = 89
N individuals >140,000

Christensen *et al*. Lancet Infectious Diseases 2010

Christensen H et al. Meningococcal carriage by age: Systematic review and meta-analysis .Lancet Infectious Diseases 2010:10:853-61.



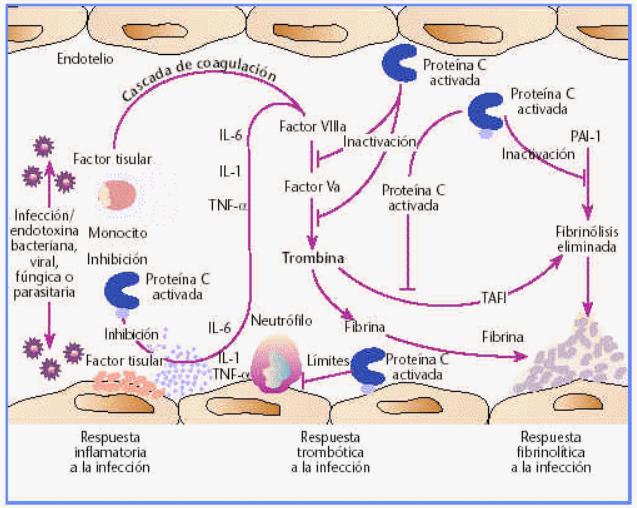
En las campañas de vacunación antimeningocócica es esencial incluir a los adolescentes para reducir la colonización y conseguir un efecto de inmunidad de grupo.

Vetter et al. EXPERT REVIEW OF VACCINES, 2016
http://dx.doi.org/10.1586/14760584.2016.1130628

Presentación clínica

Clínica inespecífica "flu-like":
Fiebre
Cefalea
Mialgias

Meningitis
Sepsis



- Desarrollo progresivo de síntomas en 1-3 días
- Evolución aguda y fulminante en pocas horas

Triada clásica:
fiebre + rigidez de nuca + alteración nivel conciencia < 30%

Mortalidad 10%
Secuelas 30%
Neurológicas graves 10%

Urgencias Pediátricas 23:45 hs

Varón 14 meses.

Fiebre (Tª máxima 39ºC) 6 hs

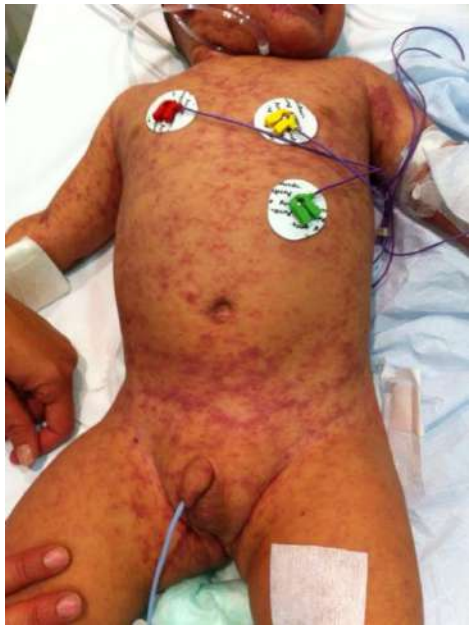
02:10 hs

Exantema petequial generalizado

Hipotensión arterial

Expansión de volumen

Inotrópicos



04:40 hs

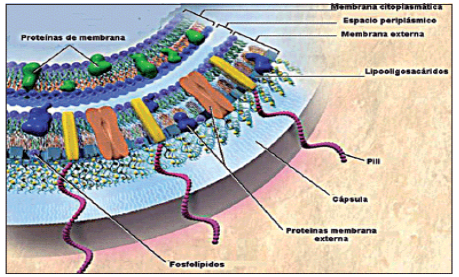
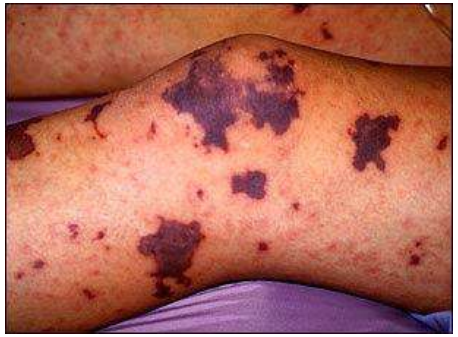
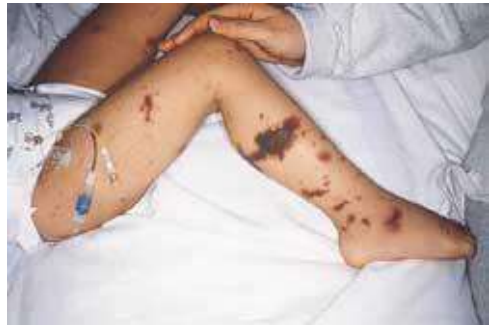


Figura 1. Estructura de la envoltura de *Neisseria meningitidis*. Reproducida de la publicación original D. S. Stephens, B. Greenwood, and P. Brandtzaeg. Epidemic meningitis, meningococcaemia, and *Neisseria meningitidis*. Lancet 369 (9580): 2196-2210, 2007.

En resumen
Enfermedad meningocócica invasora

- **El ser humano es el único reservorio**
- **El 10-25%** de la población es **portadora en nasofaringe**
  - Baja prevalencia en lactantes
  - Elevada prevalencia en adolescentes
- **Cuadro clínico inicial inespecífico**
- **Difícil diagnóstico precoz**
- **Rápida evolución:** sepsis/meningitis y shock
- **Mortalidad 10%**
- **Secuelas 10-20%**
  - Neurológicas
  - Amputaciones





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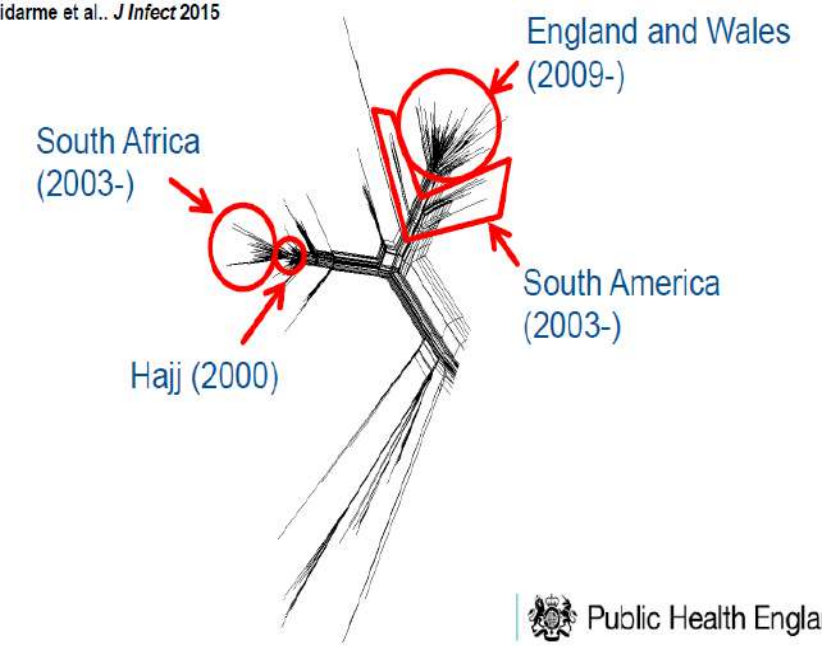
Epidemiología de la EMI

Harrison et al. Vaccine 2009;27S:B51-B63

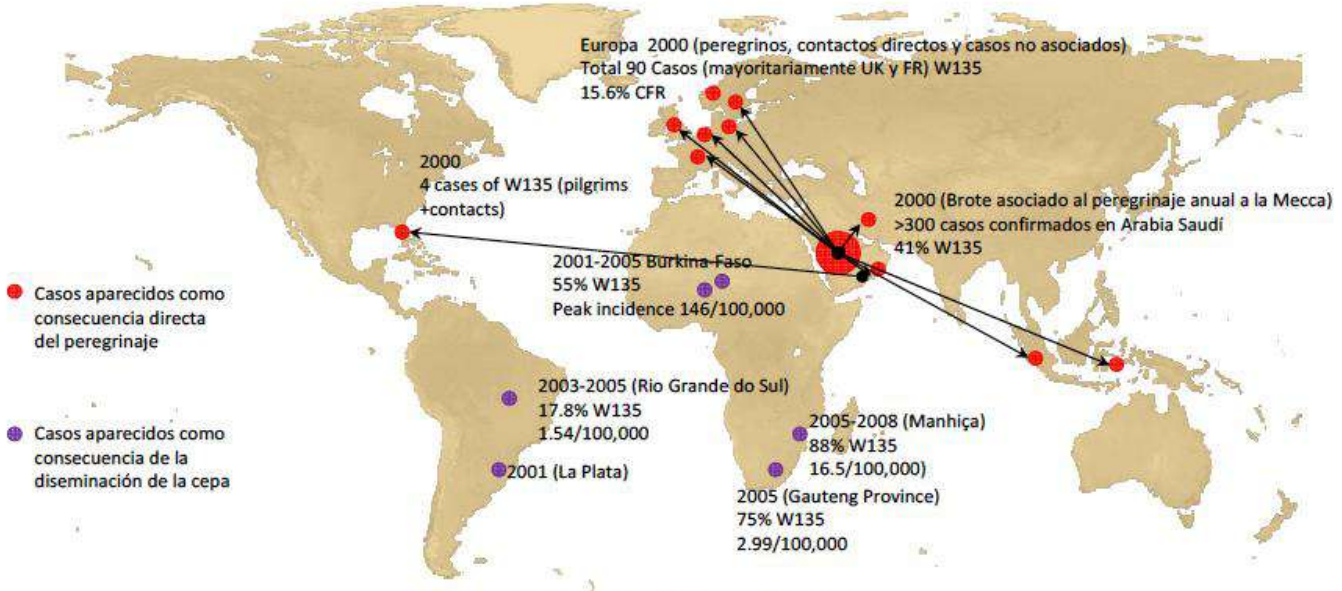
ST-11 complex (cc11): MenW

Lucidarme et al.. *J Infect* 2015



Public Health Engla

Expansión de la cepa W135 (Peregrinaje a la Mecca, 2000)

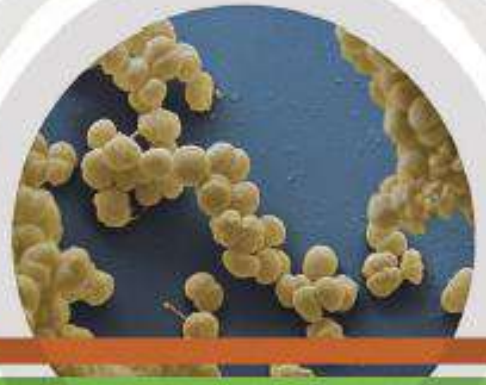


W135:2a:P1.5,2:ST-11

W135:2a:P1.5:ST-11
W135:2a:P1.2:ST-11
W135:2a:NST:ST-11
W135:NT:P1.5, 2:ST-11
W135:NT:P1.2:ST-11

Weidlich L, et al. (2008) J Infect 57: 324-331., Von Gottberg A, et al. (2008). Clin Infect Dis 46: 377-386; Ibarz-Pavon AB, et al. (2011). PLoS One 6: e19717; Mayer LW,et al. (2002). J Infect Dis 185: 1596-1605.; Aguilera JF, 2002). Emerg Infect Dis 8: 761-767; Traore Y et al. (2006). Clin Infect Dis 43: 817-822; Efron AM et al. (2009) J Clin Microbiol 47: 1979-1980.; Popovic T, et al. (2000) Emerg Infect Dis 6: 428-429.

Epidemiología en Europa



SURVEILLANCE REPORT

Annual Epidemiological Report for 2016

Invasive meningococcal disease

Key facts

- In 2016, 3 280 confirmed cases of invasive meningococcal disease (IMD), including 304 deaths, were reported in 30 EU/EEA Member States.
- France, Germany, Spain and the United Kingdom accounted for 60% of all confirmed cases in 2016.
- The notification rate was 0.6 cases per 100 000 population, the same as in 2015.
- Age-specific rates were highest in infants, followed by 1-4-year-olds.
- Serogroup B caused 54% of cases overall and the majority of cases in all age groups below 65 years.
- From 2012 to 2016, the notification rates of serogroups B and C decreased and increased for W and Y.
- The notification rate of serogroup C was low in all countries regardless of whether meningococcal C conjugate (MCC) vaccine was included in national routine immunisation schedules.
- Continued strengthening of disease surveillance for IMD is essential to evaluate the impact of ongoing immunisation programmes and support decision makers in view of the availability of new vaccines.

Suggested citation: European Centre for Disease Prevention and Control. Invasive meningococcal disease. In: ECDC. Annual epidemiological report for 2016. Stockholm: ECDC; 2018.

Stockholm, August 2018

Surveillance Atlas of Infectious Diseases

Invasive meningococcal disease | Confirmed cases | Reported cases | 2016

Region	Reported cases (N)
Netherlands	
Norway	
Poland	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	262
Sweden	62
United Kingdom	859

3280 cases

0.61/100.000

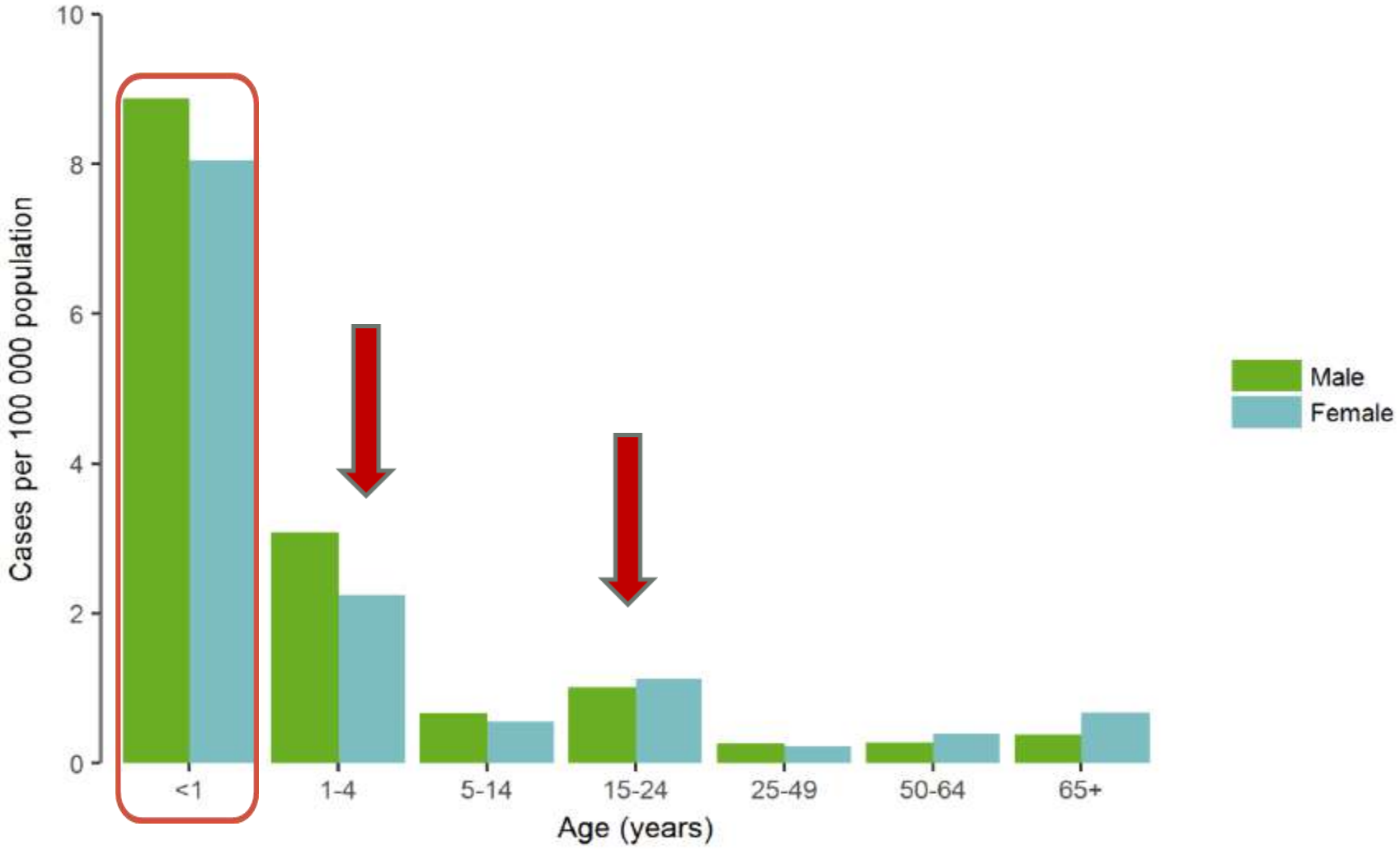
Annual epidemiological report for 2016 — SURVEILLANCE REPORT

Table 2. Serogroup distribution of confirmed cases of invasive meningococcal disease, EU/EEA, 2016

Serogroup	Cases	%
B	1 647	54
C	485	16
W	464	15
Y	344	11
Other	91	3
Total	3 031	100

'Other' refers to all cases reported as serogroup A, X, 29E, non-groupable or 'other'.

Figure 2. Rate per 100 000 population of confirmed cases of invasive meningococcal disease by age and gender, EU/EEA, 2016



Source: Country reports from Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.

Incidence of IMD in England and Wales 2008-2018

Public Health England

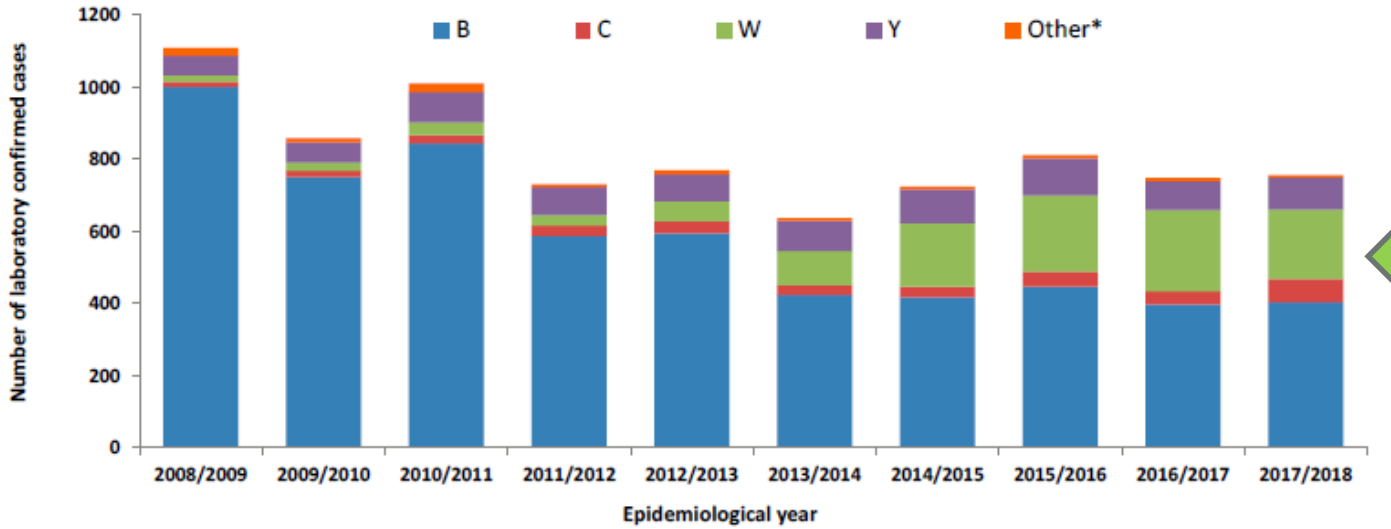
Protecting and improving the nation's health

Invasive meningococcal disease in England: annual laboratory confirmed reports for epidemiological year 2017 to 2018

Health Protection Report
Volume 12 Number 38
26 October 2018

Invasive meningococcal disease in England: annual laboratory confirmed reports for epidemiological year 2017/2018.
Health Protection Report Volume 12 Number 38

Figure 1. Invasive meningococcal disease in England by capsular group: 2008/2009 to 2017/2018

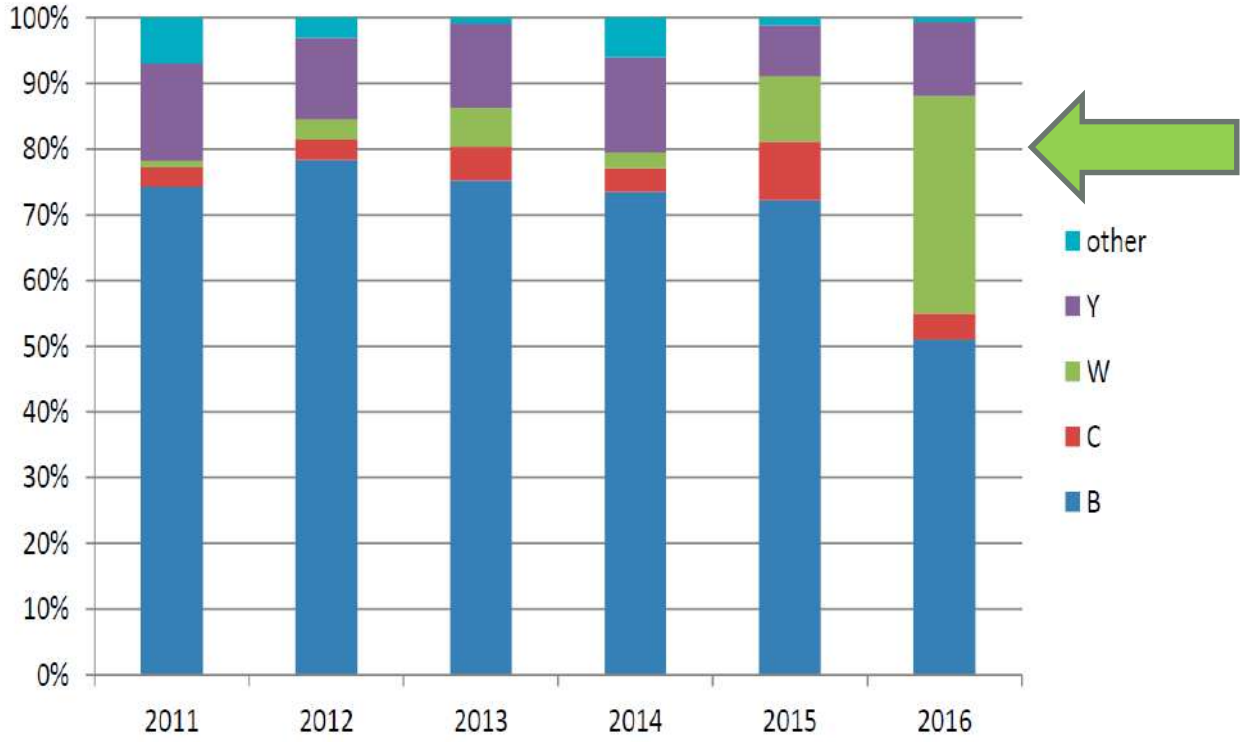


*Other includes capsular groups: A, X, Z/E, ungrouped and ungroupable. Ungroupable refers to invasive clinical meningococcal isolates that were non-groupable, while ungrouped cases refers to culture-negative but PCR screen (ctrA) positive and negative for the four genogroups [B, C, W and Y] routinely tested for.

Aumento de la incidencia de EMI durante los últimos años, principalmente por incremento del serogrupo W

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/751821/hpr3818_IMD.pdf

Incidencia de EMI en Holanda 2011-2016



Incremento preocupante de la incidencia de EMI por SG W durante los últimos 2 años de vigilancia epidemiológica

M.J.Knol et al. **Meningococcal disease in the Netherlands.** RIVM Report 2017-0031

Epidemiología en España

MINISTERIO
DE CIENCIA, INNOVACIÓN
Y UNIVERSIDADES

Red
Nacional de
Vigilancia
Epidemiológica

Enfermedad meningocócica

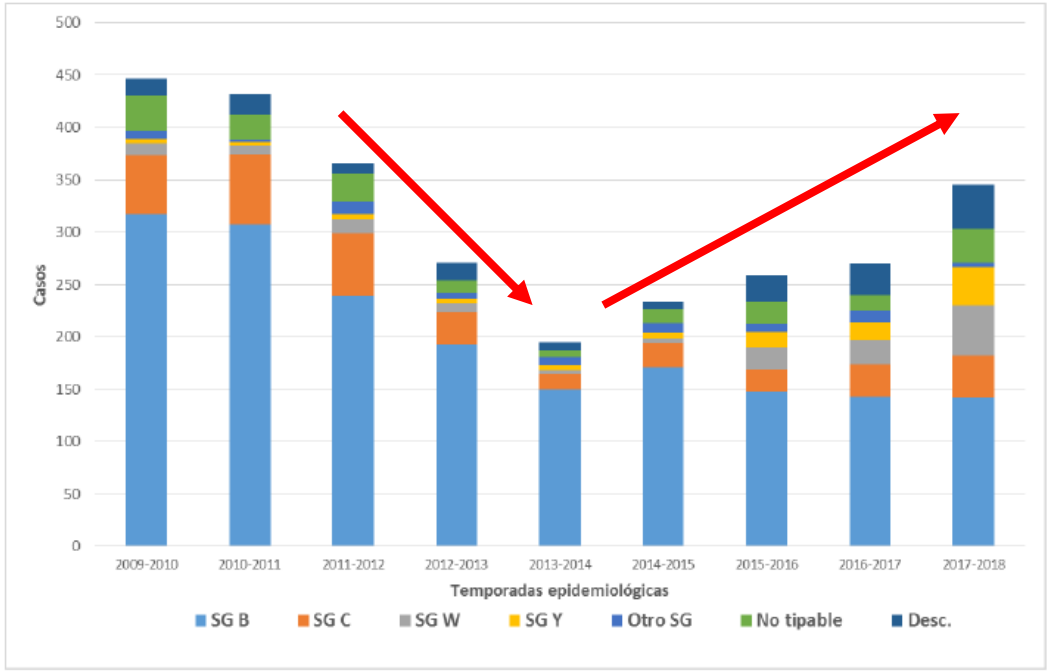
Vigilancia de la temporada 2017-2018

Resultados de la Red Nacional de Vigilancia Epidemiológica

La incidencia de enfermedad meningocócica en España presentó una tendencia decreciente desde la temporada 1999-2000. En los últimos 18 años se ha producido un descenso del 90,6% en la tasa de casos confirmados, desde una tasa de 4,04 y 1.625 casos confirmados notificados en 1999-2000 a una tasa de 0,74 y 346 casos confirmados en la temporada 2017-2018.

Sin embargo, en la temporada 2017-2018 se produjo un incremento en el número de casos y tasas notificados con respecto a las temporadas anteriores (figura 1). En esa temporada se notificaron un total de 372 casos, de los que se confirmaron 346 (93%). La tasa de incidencia para los casos confirmados fue de 0,74 por 100.000 habitantes. Esta tasa de incidencia se incrementó en un 27,6% con respecto a la registrada en la temporada previa y un 76,2% con respecto a la temporada 2013-2014 (tabla 1) por lo que se interrumpió la tendencia descendente que se venía observando, aunque la incidencia sigue siendo baja.

Figura 1. Enfermedad meningocócica. Tendencia temporal de los casos declarados según el serogrupo. Temporadas 2009-2010 a 2017-2018.



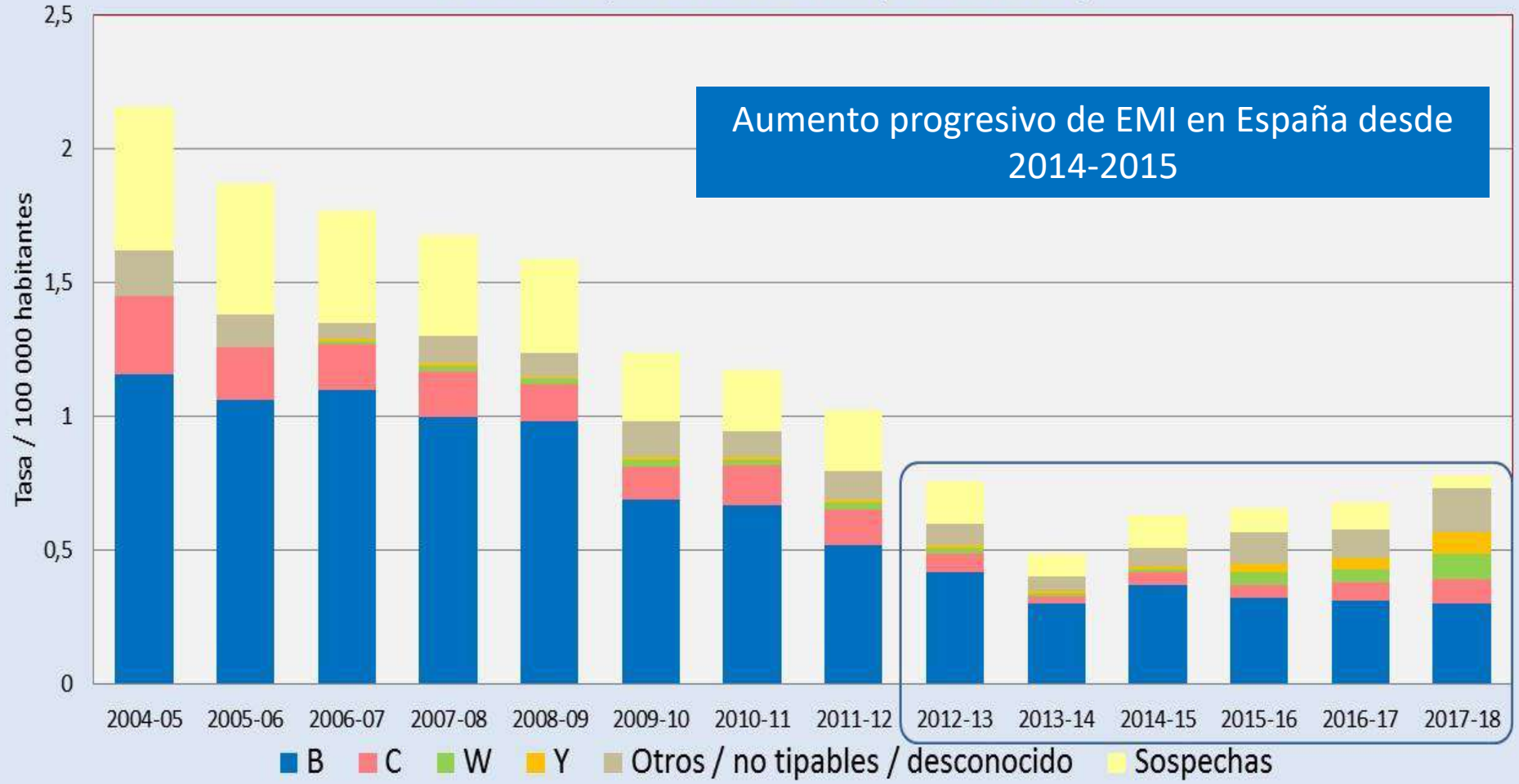
Fuente: Red Nacional de Vigilancia Epidemiológica.

@CAV_AEP

Enfermedad meningocócica, España

Evolución de las tasas, 2004-05 a 2017-18

Fuente: adaptado de CNE, ISCIII (enero de 2019)



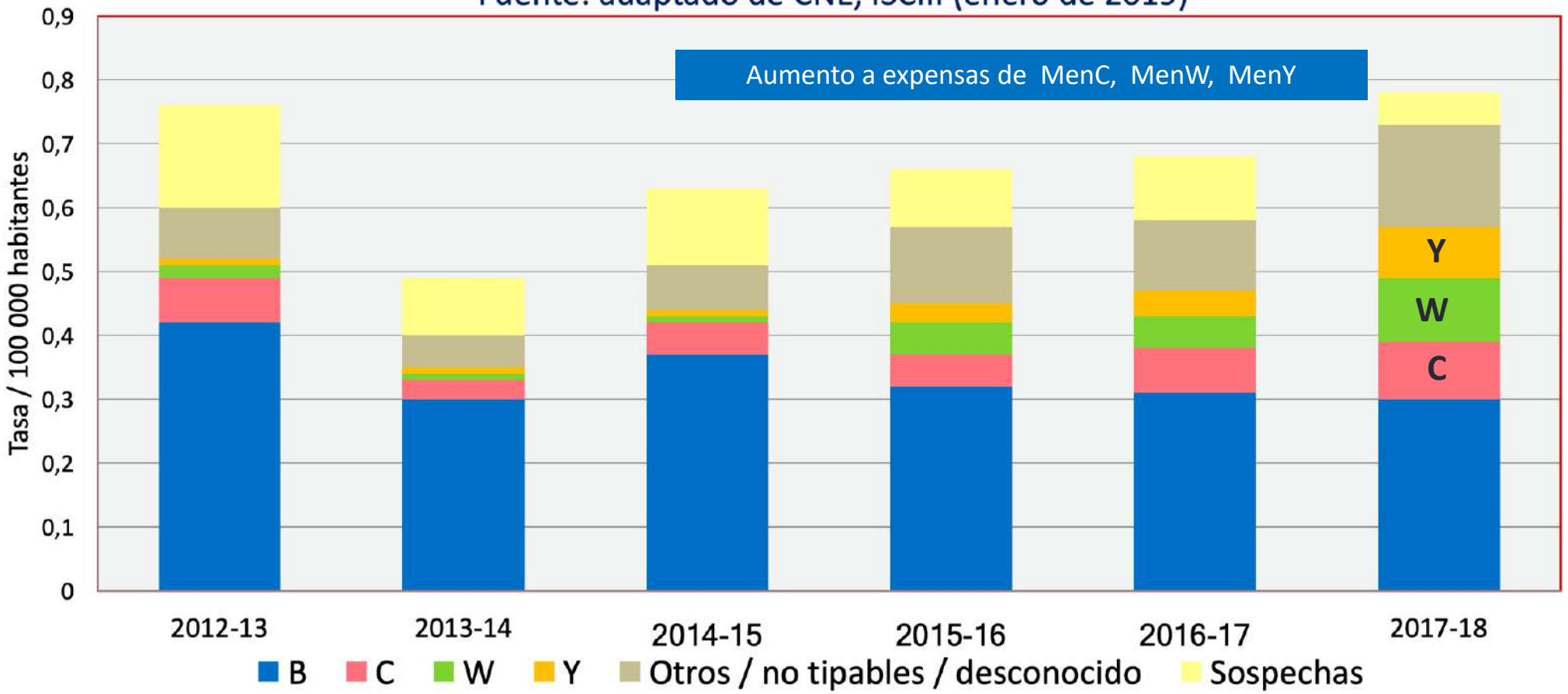
Disponible en: https://vacunasaep.org/profesionales/noticias/enfermedad-meningococica-2017-2018

@CAV_AEP

Enfermedad meningocócica, España

Evolución de las tasas, 2012-13 a 2017-18

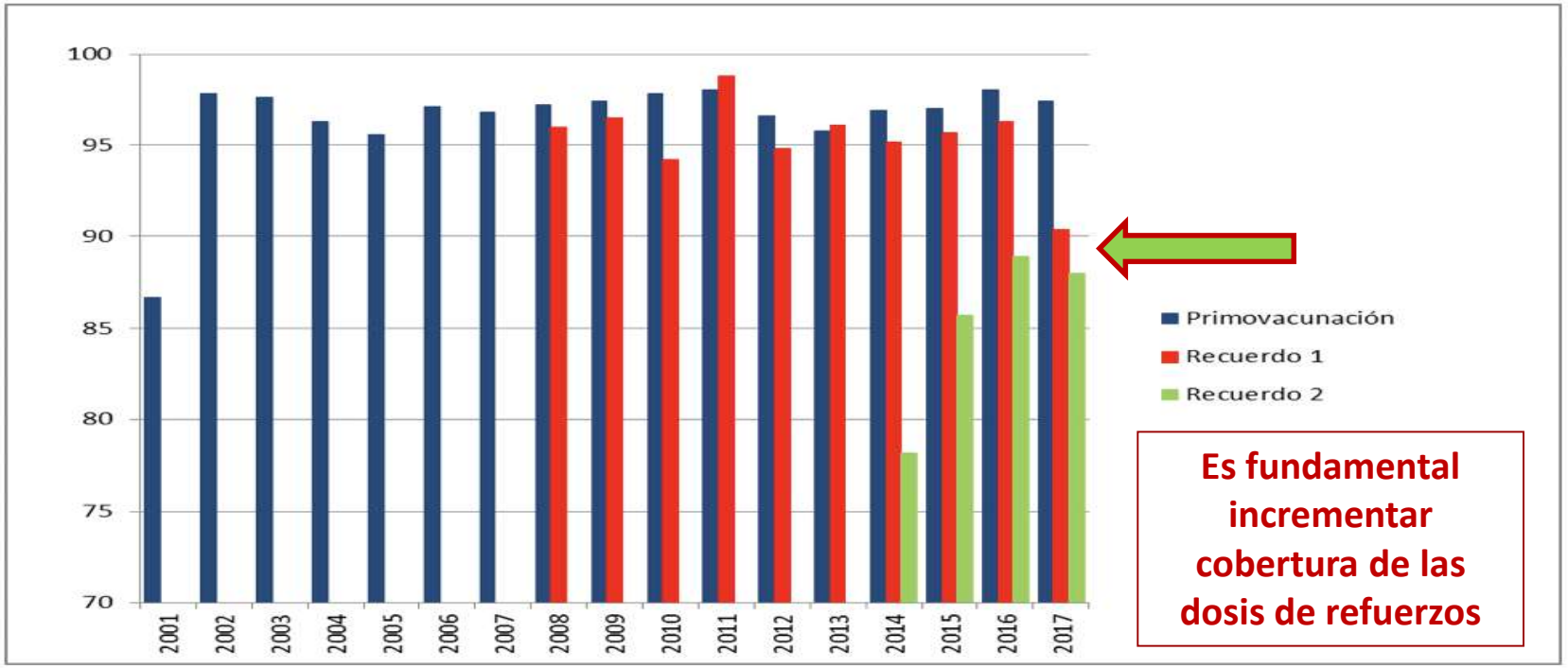
Fuente: adaptado de CNE, ISCIII (enero de 2019)



Disponible en: https://vacunasaep.org/profesionales/noticias/enfermedad-meningococica-2017-2018

Coberturas vacunales MenC

Figura 12. Evolución de las coberturas de vacunación frente a MenC.

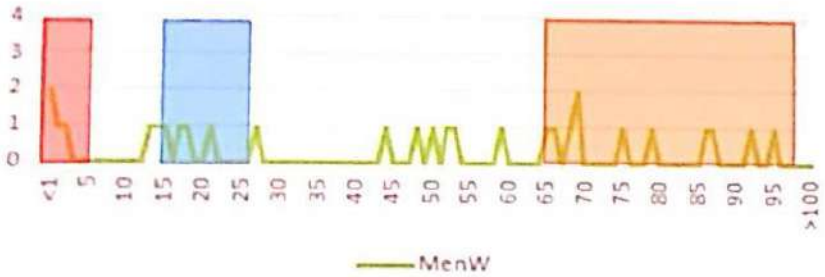


https://www.mscbs.gob.es/profesionales/saludPublica/prevPromocion/vacunaciones/coberturas.htm

Distribución por edades y año de los casos de MenW

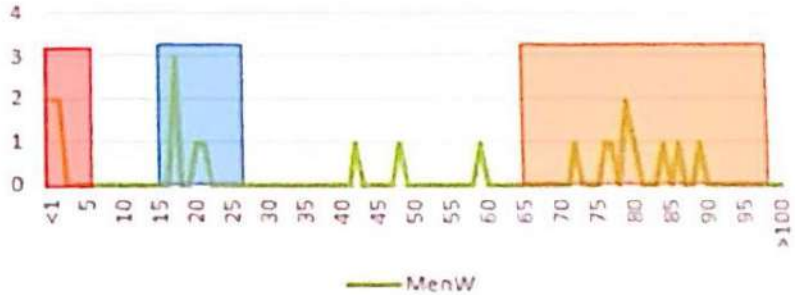
2015

MenW



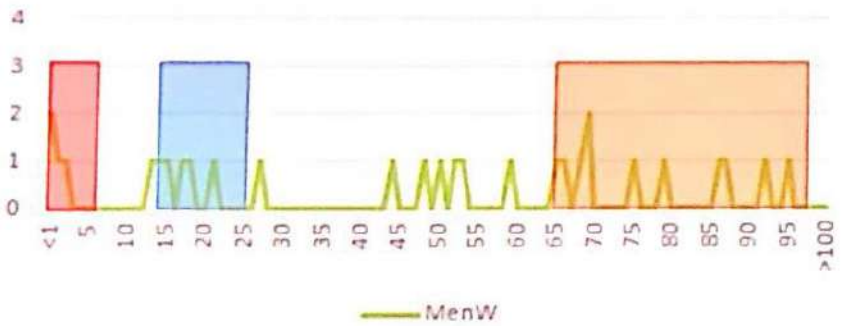
2016

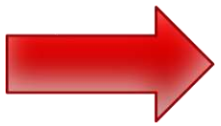
MenW



2017

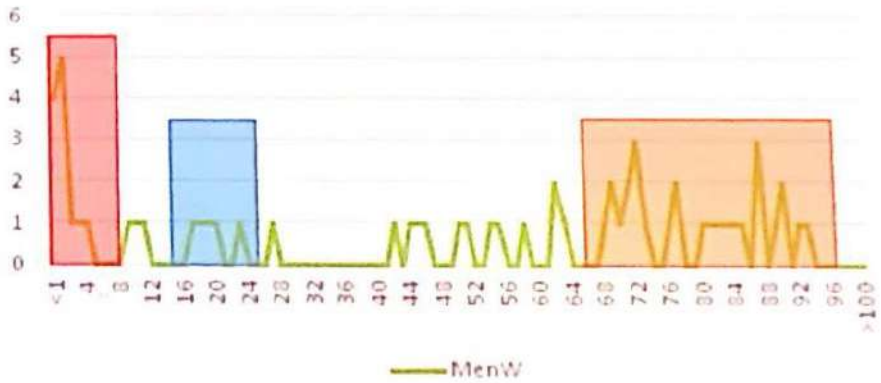
MenW



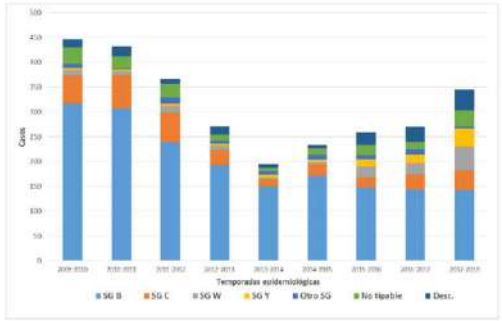


2018

MenW



Diapositiva "robada" del Dr. Julio Vázquez



Fuente: Red Nacional de Vigilancia Epidemiológica.

En resumen
Epidemiología de la EMI

- **Desde el año 2000 descenso de la incidencia** de la enfermedad a nivel mundial
- En los últimos años se mantiene **incidencia baja pero en lento ascenso**
- **En España descenso hasta temporada 2013-14**
- **Desde 2013-14 incremento progresivo:**
  - **Temporada 2017-18 incremento del 27% respecto a la previa**
  - **Temporada 2017-18 incremento del 76% respecto a 2013-14**
- **Aumento de casos de SG C (coberturas vacunales!!!)**
- **Aumento de casos de SG W e Y desde 2016. Aumento en lactantes!**

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¡BUENAS
NOTICIAS!


Meningitec®
Suspension injectable en seringue préremplie
Vaccin méningococcique du sérogroupe C
oligosidique conjugué (adsorbé)


NeisVac-C 0,5 ml
Suspensión inyectable en jeringa precargada
Vacuna Conjugada de Polisacárido
frente a Meningococo del Grupo C (adsorbida)


Noticias


BEXSERO®
NOVARTIS


Meningococcal
Group B Vaccine
Trumenba


MENJUGATE®


MenAfriVac™
Meningococcal A
Conjugate Vaccine
(Lyophilized)
MenAfriVac


Menactra®
Meningococcal (Groups A, C, Y and W-135)
Polysaccharide Diphtheria Toxoid
Conjugate Vaccine
Rx only
sanofi pasteur
www.medicinapreventiva.com.ve


MENVEO®
powder and solution
for solution for injection
Meningococcal Group A, C, W135 and Y
conjugate vaccine
Intramuscular injection.
Not for intravascular, subcutaneous or intradermal injection.
One dose (2 vials) per package.
One dose consists of 1 vial of MenA Lyophilised Conjugate Component
to be reconstituted with 1 vial of MenCWY Liquid Conjugate Component.


Nimenrix®
Powder and solvent for solution
for injection in pre-filled syringe
Meningococcal group A, C,
W-135 and Y conjugate vaccine
1 dose (0.5 ml)
1 pre-filled syringe: solvent
1 vial: powder
2 needles
After reconstitution, use immediately
Shake well before use
Intramuscular use

Vacunas antimeningocócicas

Vacunas monovalentes MenC
Vacunas tetravalentes MenACWY
Vacunas monovalentes MenB

Table 2. Available meningococcal vaccines.

Serogroup	Vaccine Formulation	Vaccine Type	Vaccine Name	Manufacturer
A	MenA-TT	Conjugate	MenAfri Vac[83]	Serum Institute of India
B	MenB-FHbp	Recombinant (FHbp subfamily A and B)	Trumenba[70]	Pfizer
	MenB-4C	Recombinant (FHbp subfamily B, NadA, NHBA, OMV)	Bexsero[72]	GlaxoSmithKline
C	MCC-TT	Conjugate	NeisVac-C[53]	Pfizer
	MCC-TT	Conjugate	Menitorix[120]	GlaxoSmithKline
	MCC-CRM	Conjugate	Menjugate[52]	GlaxoSmithKline
	MCC-CRM	Conjugate	Meningitec[51]	Pfizer
C + Y	Hib-MenCY-TT	Conjugate	MenHibrix[121]	GlaxoSmithKline
ACWY	MenACWY-DT	Conjugate	Menactra[122]	Sanofi Pasteur
	MenACWY-CRM	Conjugate	Menveo[63]	GlaxoSmithKline
	MenACWY-TT	Conjugate	Nimenrix[123]	Pfizer

Vacunas monovalentes MenC

Vaccine 35 (2017) 2034–2041

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

The epidemiology of invasive meningococcal disease in EU/EEA countries, 2004–2014

Robert Whittaker [a,*], Joana Gomes Dias [a], Miriam Ramliden [a,b], Csaba Ködmön [a], Assimoula Economopoulou [a,c], Netta Beer [a], Lucia Pastore Celentano [a], the ECDC network members for invasive meningococcal disease [1,2]

[a] European Centre for Disease Prevention and Control (ECDC), Solna, Sweden
[b] Tufts University, Boston, MA, USA
[c] Hellenic Centre for Disease Control and Prevention, Athens, Greece

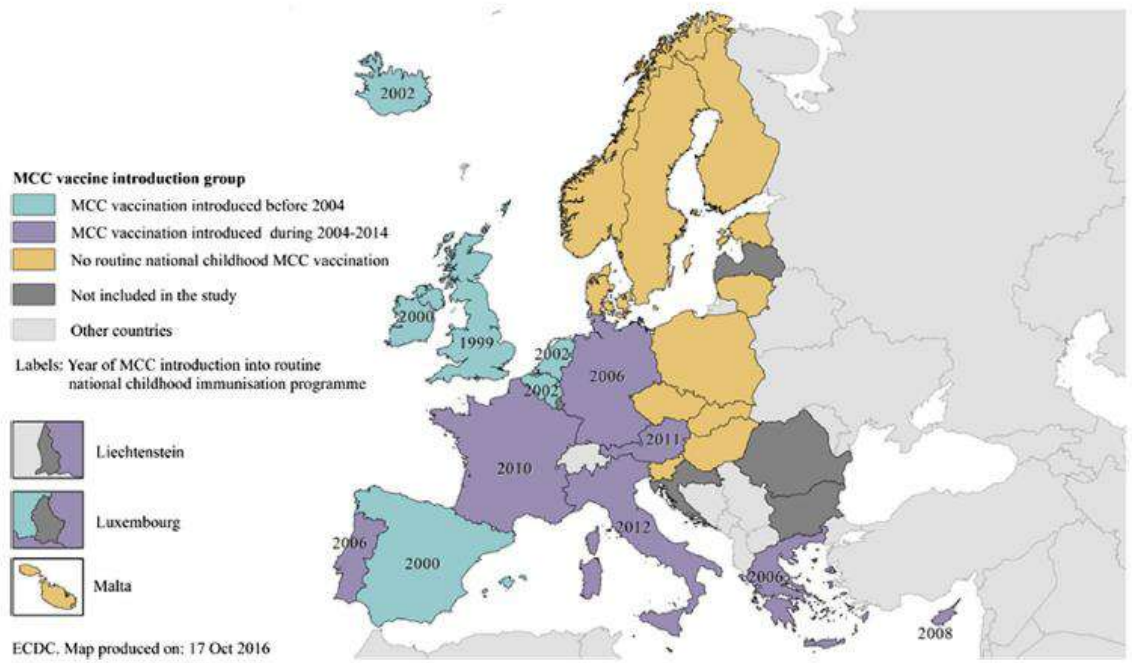


Fig. 1. Year of introduction of routine childhood MCC vaccination among the 25 European countries included in the study, and the respective MCC vaccine introduction group into which they were classified.

Vacunas MenC

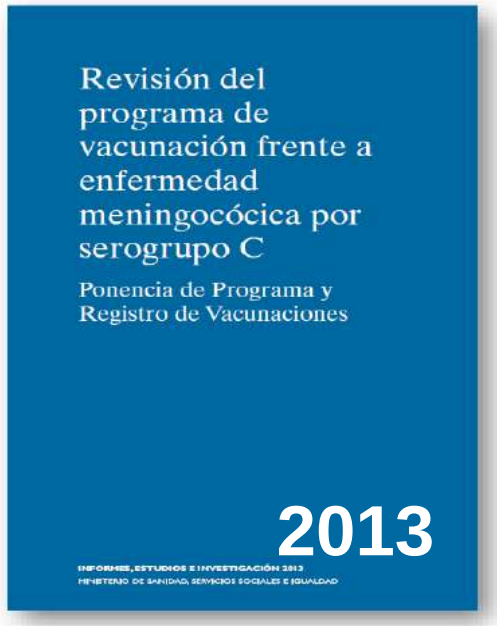
Tabla 30.1. Vacunas antimeningocócicas disponibles en España.

Nombre comercial (Laboratorio)	Serogrupos frente a los que actúa	Principio activo	Proteína transportadora	Adyuvante
Menjugate (GSK)	C	10 µg oligosacárido capsular del grupo C	12,5-25 µg CRM_{197}	0,3 a 0,4 mg de hidróxido de aluminio
Meningitec (Nuron Biotech)	C	10 µg oligosacárido capsular del grupo C	15 µg CRM_{197}	0,125 mg de fosfato de aluminio
NeisVac-C (Pfizer)	C	10 µg polisacárido capsular (de- O-acetilado) del grupo C	10-20 µg toxoide tetánico	0,5 mg de hidróxido de aluminio hidratado

CAV-AEP. Manual Vacunas en línea. Meningococo. https://vacunasaep.org/documentos/manual/cap-30#12

Vacunas antimeningocócicas C

Documento de la Ponencia de Vacunas sobre enfermedad meningocócica por serogrupo C



6.2. Persistencia de anticuerpos

En cuanto a la persistencia de anticuerpos tras la vacunación, diversos estudios publicados ponen de manifiesto que los resultados varían según la vacuna utilizada obteniéndose **títulos ABS mayores en vacunas que tienen como transportador toxoide tetánico** (MenCC-TT) [13,14]

13 Diez-Domingo JJ et al. *Pediatr Infect Dis J* 2010.
14 Southern J et al. *Clinical and Vaccine immunonology*, 2009.

La vacuna **MenC-TT** es la única que en su FT presenta resultados de **inmunogenicidad** tras la administración de **una única dosis** como primovacunación en menores de 1 año

https://www.msssi.gob.es/profesionales/saludPublica/prevPromocion/vacunaciones/docs/MenC.pdf

Vacunas tetravalentes MenACWY

Vacunas tetravalentes ACWY

Vacunas frente a los meningococos de los serogrupos ACWY		
	Nimenrix®	**Menveo®**
Meningococos	A, C, W e Y	A, C, W e Y
Proteína conjugación	Toxoide tetánico	CRM197
Edad mínima	6 semanas	2 años
Posología	• 6 sem a 11 meses: 2 dosis, intervalo mínimo de 2 meses. Refuerzo >12 ms de vida • ≥12 meses: 1 dosis	• 1 dosis

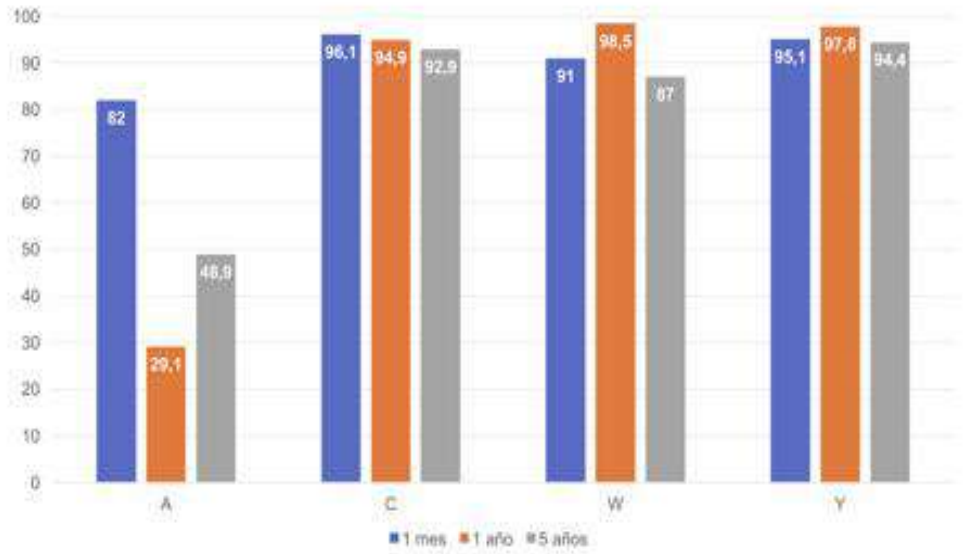
CAV-AEP. Fichas técnicas de vacunas.
http://vacunasaep.org/profesionales/fichas-tecnicas-vacunas/resultados?diseases=12542

Vacunas tetravalentes ACWY

Persistencia de anticuerpos en adolescentes/adultos jóvenes tras 5 años

VACUNA MENINGOCOCO ACWY-TT (Nimenrix®)

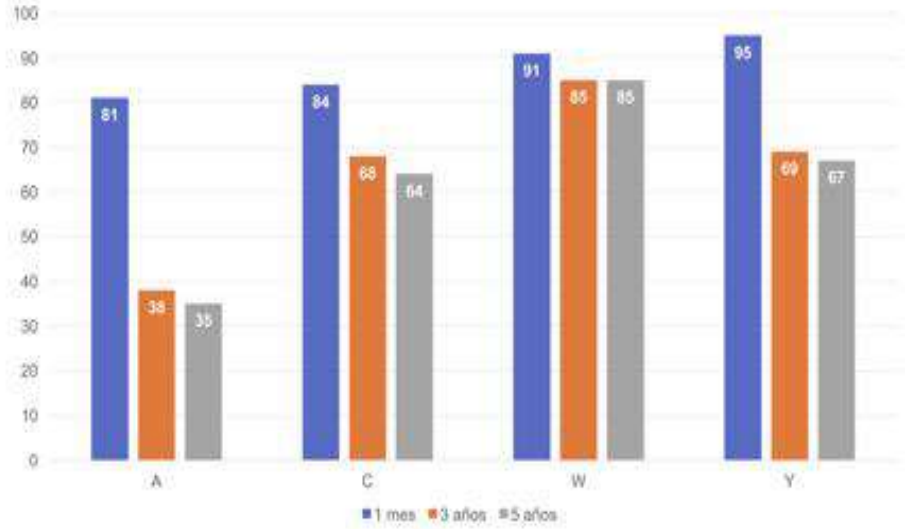
MenACYW-TT: Inmunogenicidad (11 - 25 años)



FICHA TECNICA DE NIMENRIX 2017

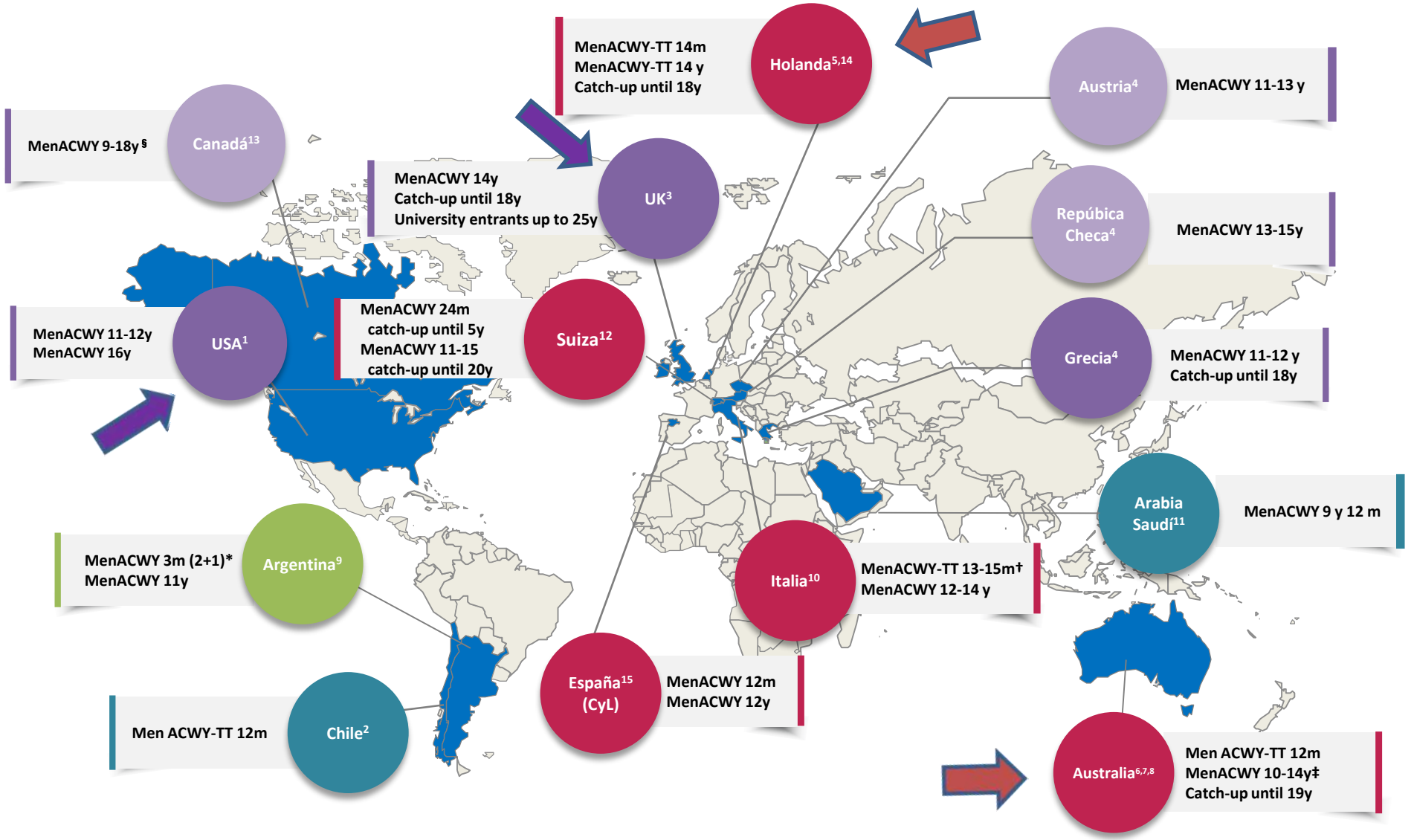
VACUNA MENINGOCOCO ACWY-CRM197 (Menveo®)

MenACYW-CRM197: Inmunogenicidad (11 - 18 años)



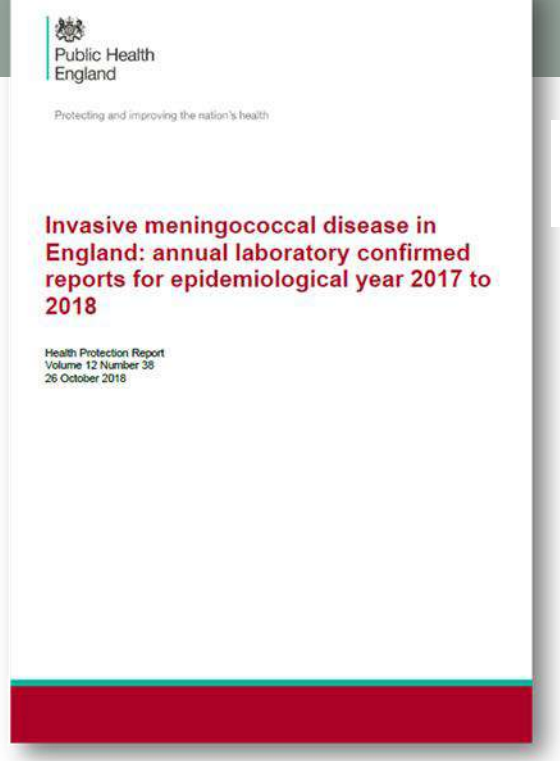
FICHA TECNICA DE MENVEO 2017

Abordaje de la EMI por serogrupo W e Y en el mundo



*Los niños y niñas que comiencen su vacunación a los 3 meses de vida, deben recibir un esquema "2+1" (3, 5 y 15 meses)
†8 regiones (Veneto, Emilia Romagna, Marche, Lazio, Molise, Campania, Puglia y Sicilia) han introducido MenACWY-TT en sustitución MenC
‡6 regiones (Nueva Gales del Sur, Victoria, Queensland, Tasmania, Australia Occidental y el Territorio de la Capital Australiana) para algunos adolescentes
§Used for the adolescent booster in all provinces and territories, except Manitoba, Quebec and Nunavut (as of 2017)

Referencias bibliográficas en las notas a pie de diapositiva



- average Year 10 coverage for the MenACWY vaccine up to the end of August 2018 was 84.6% compared to 82.5% in 2016/17 and 77.2% in 2015/16

- **Es la primera temporada en la que objetivan descenso de casos de SG W**

- **El número de casos de SG C sigue siendo bajo, pero con incremento del 73%**

Public Health England

Protecting and improving the nation's health

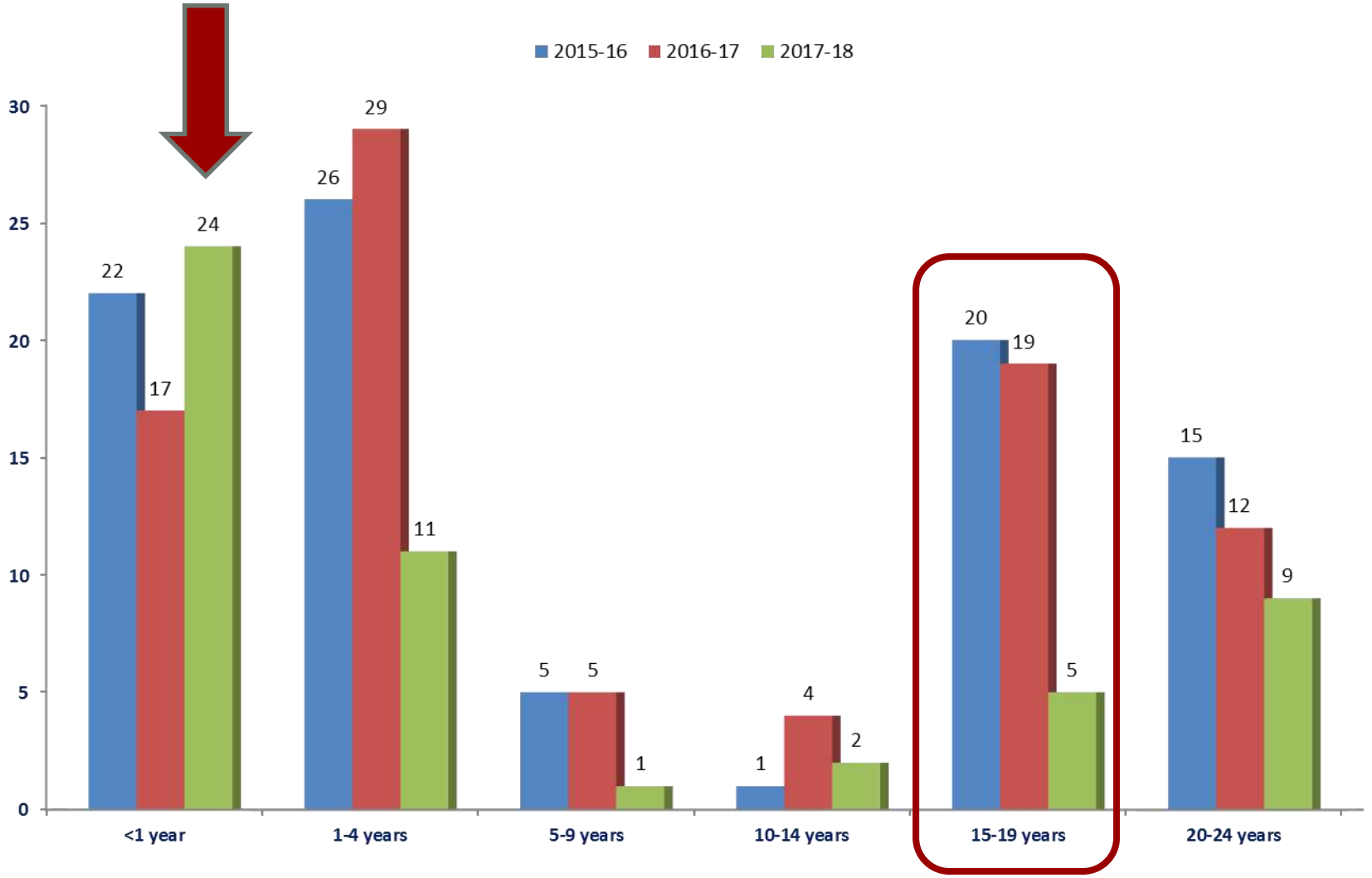
Vaccine coverage estimates for the school based meningococcal ACWY (MenACWY) adolescent vaccination programme in England, to 31 August 2018

Health Protection Report
Volume 13 Number 3
25 January 2019

Table 1. Invasive meningococcal disease in England by capsular group and laboratory testing method: 2016/2017 and 2017/2018

Capsular groups*	CULTURE AND PCR		CULTURE ONLY		PCR ONLY		Annual total	
	2016/2017	2017/2018	2016/2017	2017/2018	2016/2017	2017/2018	2016/2017	2017/2018
B	100	101	82	88	215	215	397	404
C	10	15	14	22	13	27	37	64
W	43	34	146	129	36	30	225	193
X	0	0	0	1	0	0	0	1
Y	11	12	56	55	13	21	80	88
Z/E	1	0	0	0	0	0	1	0
Ungrouped	0	0	0	0	7	2	7	2
Ungroupable**	0	0	1	3	0	0	1	3
Total	165	162	299	298	284	295	748	755

Reino Unido. Casos de EMI por serogrupo W



https://www.gov.uk/government/publications/meningococcal-disease-laboratory-confirmed-cases-in-england-and-wales

Vacunas monovalentes MenB

El polisacárido capsular del serogrupo B es poco inmunogénico y puede generar fenómenos autoinmunes

Las vacunas se han desarrollado utilizando proteínas subcapsulares

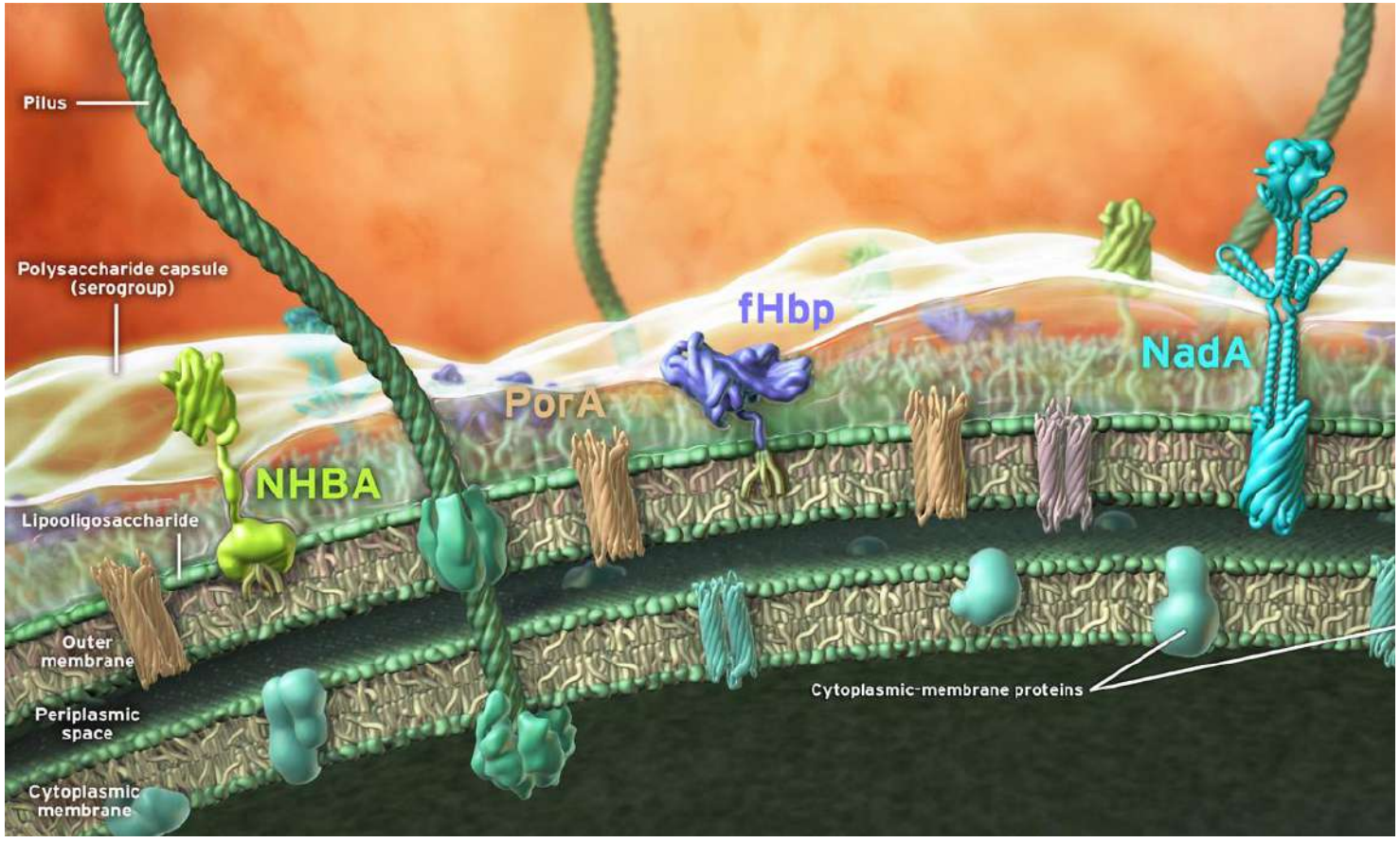
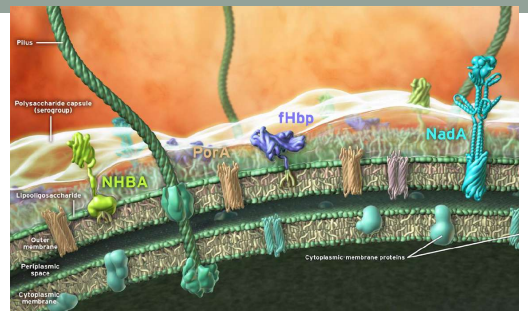


Tabla 30.1. Vacunas antimeningocócicas disponibles en España.

Nombre comercial (Laboratorio)	Serogrupos frente a los que actúa	Principio activo	Proteína transportadora	Adyuvante
Bexsero (GSK) Ver apartado 12	B	50 µg proteína recombinante de fusión NHBA (antígeno de *Neisseria* de unión a heparina) 50 µg proteína recombinante NadA (adhesina A de *Neisseria*) 50 µg proteína recombinante de fusión fHbp (proteína de unión al factor H), subfamilia B 25 µg vesículas de la membrana externa (OMV) de *Neisseria meningitidis* grupo B cepa NZ98/254 (PorA P1.4)	-	0,5 mg de hidróxido de aluminio
Trumenba (Pfizer) Ver apartado 12	B	60 µg fHbp lipidada de la subfamilia A (A05) de *Neisseria meningitidis* del serogrupo B 60 µg fHbp lipidada de la subfamilia B (B01) de *Neisseria meningitidis* del serogrupo B	-	0,25 mg de fosfato de aluminio

CAV-AEP. Manual Vacunas en línea. Meningococo. https://vacunasaep.org/documentos/manual/cap-30#12



Vacuna bivalente: vacuna fHbp

- **La vacuna está constituida por la proteína subcapsular fHbp**
  - fHbp se expresa en >96% de las cepas invasoras de MenB
  - Existen dos subfamilias de fHbp genética e inmunológicamente distintas: A y B
- **La vacuna contiene 2 variantes lipidades de fHbp (A05 and B01), una de cada subfamilia**

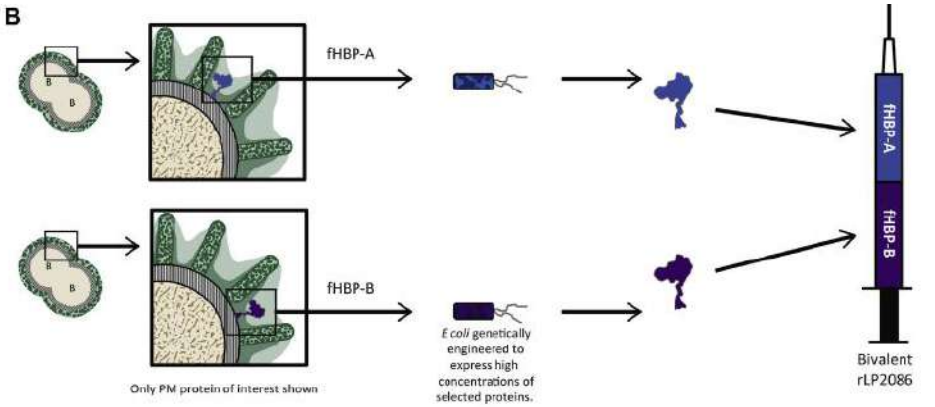
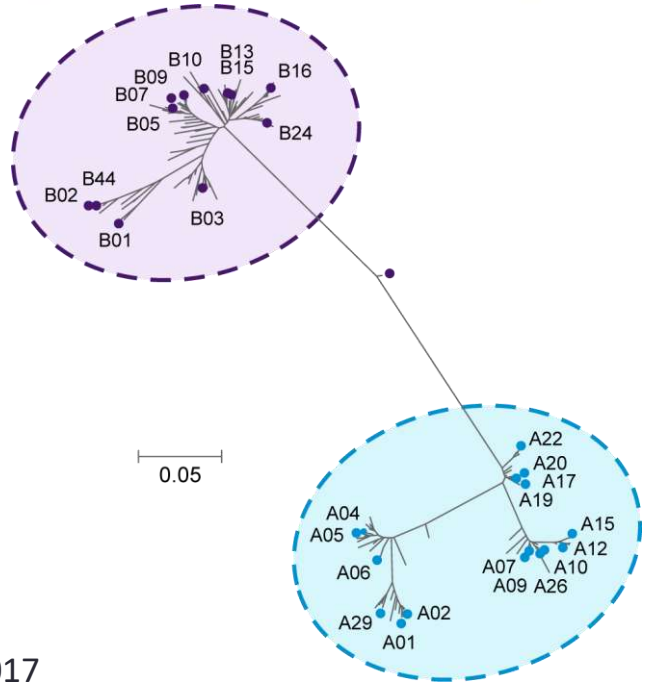
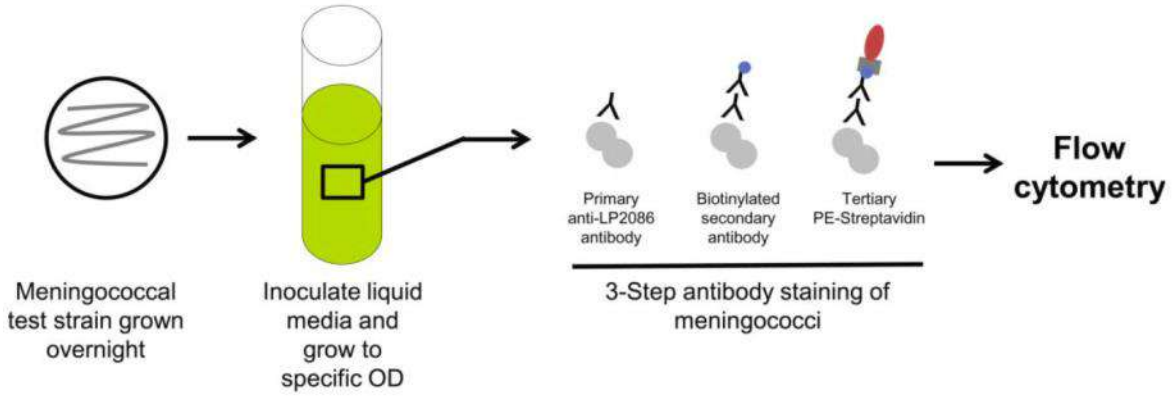


Figure 2. Development of serogroup B recombinant protein vaccines (A), 4CMenB (B). *E.coli* – *Escherichia coli*; NadA – neisserial adhesin A; NHBA – neisserial heparin-binding antigen.



European Medicines Agency; March 23, 2017. EMA/CHMP/232746/2017

MEASURE: The Meningococcal Antigen Surface Expression Assay[3,4]



Measure **usa una citometría de flujo para identificar y cuantificar la expresión de fHbp en la superficie celular**

Un estudio de >2150 cepas invasivas de MenB* demostró que >91% de todos los aislados de MenB expresaban niveles suficientes de fHbp para ser susceptibles a la actividad bactericida por los anticuerpos inducidos por la vacuna[1]

1. Committee for Medicinal Products for Human Use. *Assessment Report: Trumenba*. London, United Kingdom: European Medicines Agency; March 23, 2017. EMA/CHMP/232746/2017

2. TRUMENBA Ficha técnica. http://www.ema.europa.eu/docs/es_ES/document_library/EPAR_Product_Information/human/004051/WC500228995.pdf

3. Donald RGK, et al. *Hum Vaccin Immunother*. 2017;13:255-265. **4**. McNeil LK et al. MBio. 2018 Mar 13;9(2). pii: e00036-18.

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Trumenba

meningococcal group b vaccine (recombinant, adsorbed)

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This is a summary of the European public assessment report (EPAR) for Trumenba. 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 Trumenba.

AUTHORISED
This medicine is approved for use in the European Union

Trumenba RSS feed

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 March 2017
EMA/152667/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Trumenba

Meningococcal group B vaccine (recombinant, adsorbed)

On 23 March 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Trumenba, intended for prophylaxis against invasive meningococcal disease caused by meningococcal serogroup B bacteria. The applicant for this medicinal product is Pfizer Limited.

Vacuna bivalente: vacuna fHbp

Trumenba® está indicada para la inmunización active de individuos de 10 años de edad y mayores, para prevenir la enfermedad meningocócica invasora causada por *Neisseria meningitidis* serogrupo B.

4.2 Posología y forma de administración

Posología

Serie primaria
Dos dosis (0,5 ml cada una) administradas a intervalos de 6 meses (ver sección 5.1).

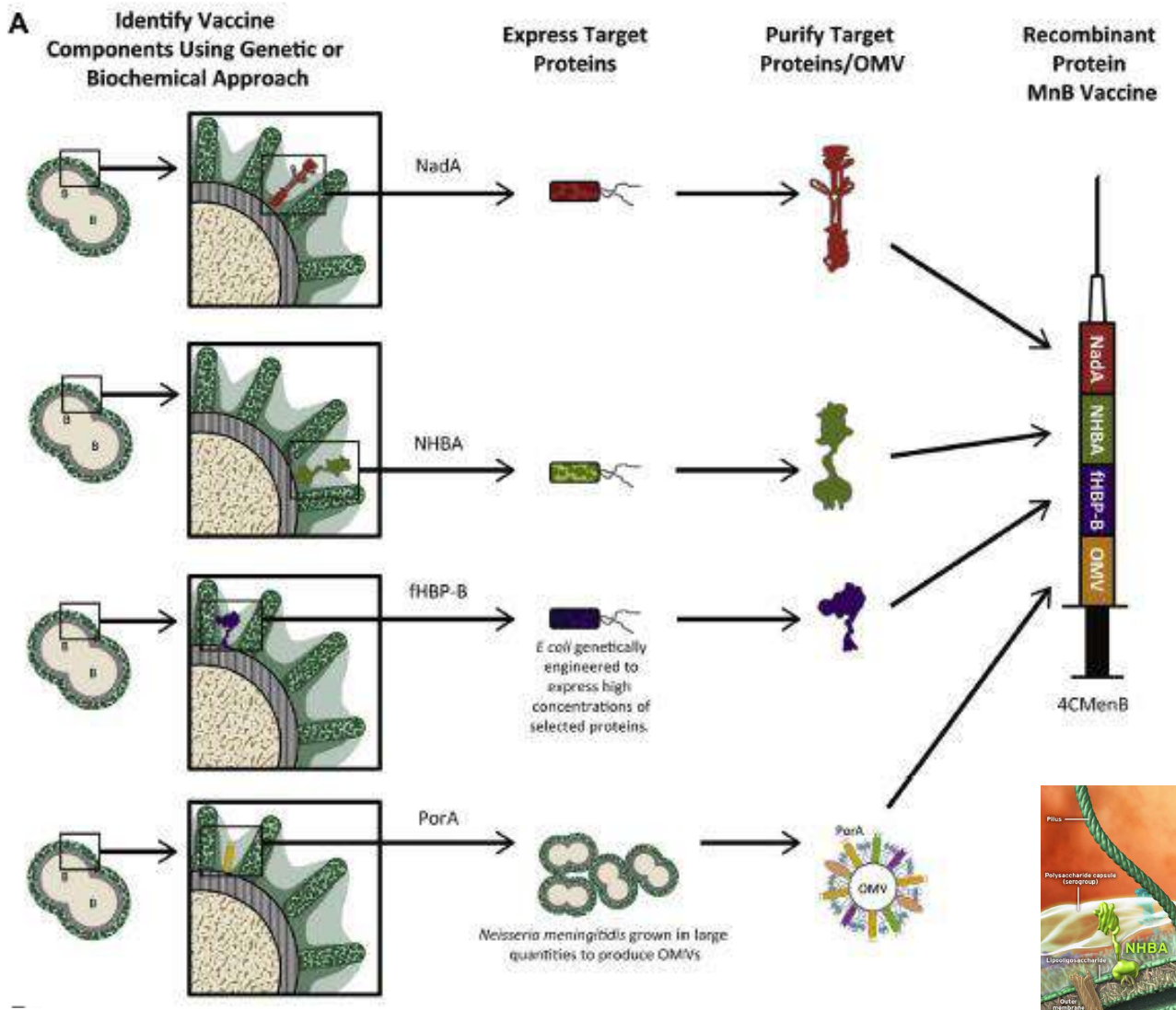
Tres dosis: 2 dosis (0,5 ml cada una) administradas con al menos 1 mes de intervalo, seguidas de una tercera dosis al menos 4 meses después de la segunda dosis (ver sección 5.1).

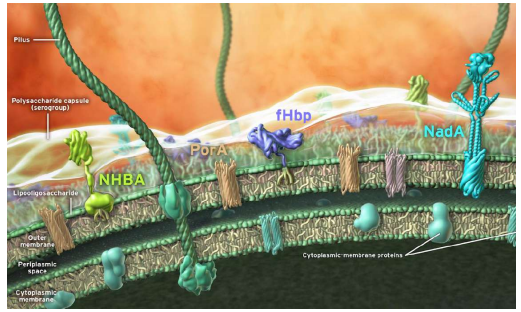
Dosis de recuerdo
Se debe valorar administrar una dosis de recuerdo siguiendo cualquiera de los dos pautas posológicas en individuos con riesgo continuado de enfermedad meningocócica invasiva (ver sección 5.1).

Otras poblaciones pediátricas
No se ha establecido la seguridad y eficacia de Trumenba en niños menores de 10 años. No se dispone de datos.

Trumenba SmPc. http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004051/WC500228995.pdf

Vacuna tetravalente: 4CMenB





MATS
Meningococcal Antigen Typing System

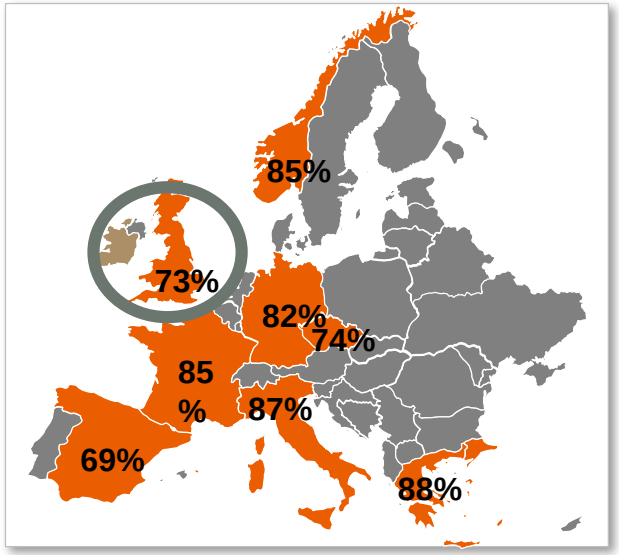
Lancet Infect Dis 2017;
17: 754–62

Discussion

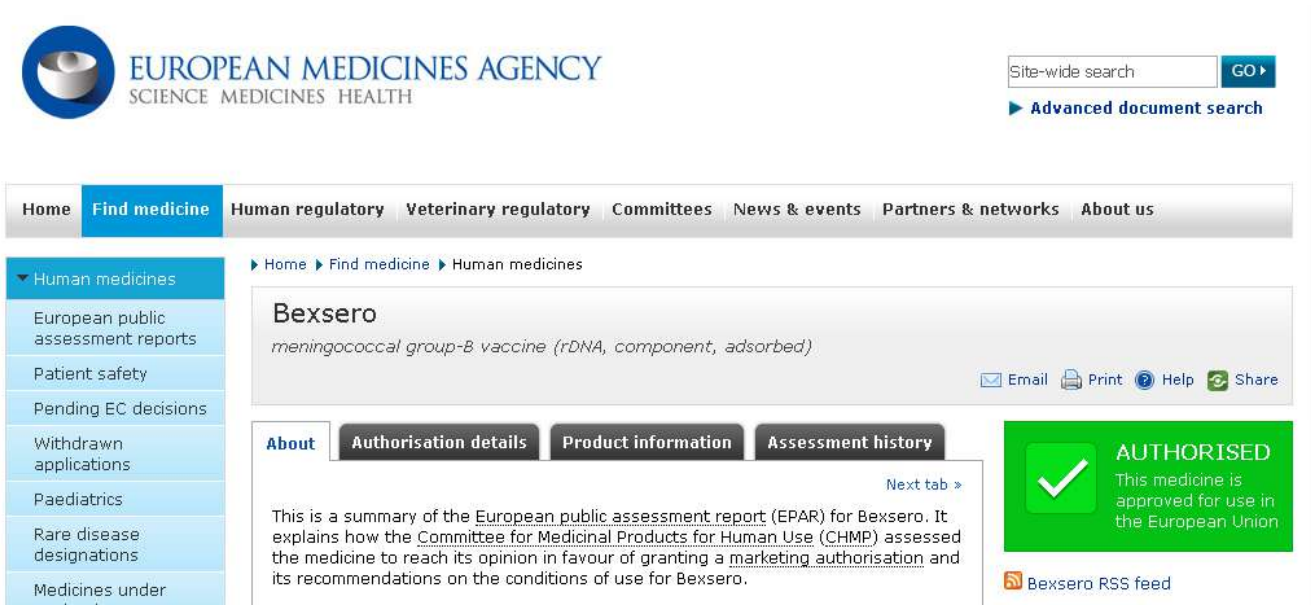
This study provides baseline data for MATS coverage of serogroup B meningococcal disease in England, Wales, and Northern Ireland before introduction of the 4CMenB (Bexsero) vaccine. Cases of serogroup B meningococcal disease more than halved between 2007–08 and 2014–15, from 1123 cases to 440 cases (61% decrease), MATS coverage declined from 73% to 66%, and the proportion of isolates covered by more than one antigen fell from 50% to 35%. In infants younger than 1 year, the age group targeted for vaccination, a third of isolates were MATS-negative and more than a third (37%) were only covered by one vaccine antigen. We found some evidence of more severe disease, in terms of lower comorbidity prevalence and increased risk of intensive-care admissions and death, associated with MATS-positive isolates.

Meningococcal serogroup B strain coverage of the multicomponent 4CMenB vaccine with corresponding regional distribution and clinical characteristics in England, Wales, and Northern Ireland, 2007–08 and 2014–15: a qualitative and quantitative assessment

Sydel R Parikh, Lynne Newbold, Stephanie Slater, Maria Stella, Monica Moschioni, Jay Lucidarme, Rosita De Paola, Maria Giuliani, Laura Serino, Stephen J Gray, Stephen A Clark, Jamie Findlow, Mariagrazia Pizza, Mary E Ramsay, Shamez N Ladhani, Ray Borrow



MATS-positive strains were also associated with more severe disease, a finding that is, perhaps, not surprising since the selected vaccine antigens are important virulence factors. Immunised infants could, therefore, potentially develop milder disease; this possibility is being monitored after 4CMenB introduction.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Bexsero
meningococcal group-B vaccine (rDNA, component, adsorbed)
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This is a summary of the European public assessment report (EPAR) for Bexsero. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Bexsero.
AUTHORISED
This medicine is approved for use in the European Union
Bexsero RSS feed


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
The European Commission granted a marketing authorisation valid throughout the European Union for Bexsero on 14 January 2013.
EPAR summary for the public
Bexsero
meningococcal group B vaccine (rDNA, component, adsorbed)
This is a summary of the European public assessment report (EPAR) for Bexsero. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Bexsero.

Vacuna tetravalente 4CMenB

Bexsero® está indicada para la inmunización active de individuos a partir de 2 meses de edad frente a la enfermedad meningocócica invasora causada por *Neisseria meningitidis* grupo B

Tabla 30.7. Esquema de vacunación de la vacuna frente al meningococo B (Bexsero) según la edad.

Población	Inmunización primaria - Núm. de dosis	Intervalos mínimos entre dosis primarias	Dosis de refuerzo	Núm. TOTAL de dosis
Lactantes de 2 a 3 meses[a]	3	1 mes	Sí, entre los 12 y 15 meses de edad (al menos 6 meses después de la última dosis de la inmunización primaria)[b]	4
Lactantes de 3 a 5 meses	2	2 meses		3
Lactantes no vacunados de 6 a 11 meses	2	2 meses	Sí, 1 dosis en el 2.º año de vida (12 a 23 meses) con un intervalo de, al menos, 2 meses entre la dosis final de primovacunación y la dosis de refuerzo	3
Lactantes no vacunados de 12 a 23 meses	2	2 meses	Sí, 1 dosis con un intervalo de 12 a 23 meses entre la dosis final de primovacunación y la dosis de refuerzo	3
Niños de 2 a 10 años, adolescentes y adultos[c]	2	1 mes	No[d]	2

vacunasaep.org/documentos/manual/cap-30#12

Diferencias entre las vacunas MenB fHbp y 4CMenB

Ambas son vacunas proteicas, desarrolladas según estrategias distintas, con el objetivo de proporcionar amplia cobertura de protección

La composición de ambas vacunas es diferente. No hay estudios de eficacia comparativa

Los estudios de inmunogenicidad utilizan diferentes antígenos y diferentes criterios, por lo que no son comparables

Sólo 4CMenB está autorizada para su uso en menores de 10 años

Ambas tienen el potencial de proporcionar protección cruzada frente a serogrupos no B
El impacto sobre la colonización nasofaríngea parece ser muy limitado

La vacuna 4C MenB tiene datos de compatibilidad con las vacunas habituales del calendario infantil y fHbp con las usadas en adolescentes

Vacunas monovalentes MenB

Experiencia en Reino Unido

Public Health England

UK MenB programme

Negotiations to procure at cost-effective price were concluded in late March 2015

MenB vaccine given with routine immunisation appointments from 1st September 2015

Routine cohort: infants born on or after the **1 July 2015**

Schedule: 2, 4 and 12 months (2+1)

Catch-up cohort: infants born from **1 May to 30 June 2015**

Schedule: 3, 4 and 12 months (2+1)

Schedule: 4 and 12 months (1+1)

Vaccine 35 (2017) 3548–3557

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Reduced schedules of 4CMenB vaccine in infants and catch-up series in children: Immunogenicity and safety results from a randomised open-label phase 3b trial

Federico Martinón-Torres [a,*], Marco Aurelio P. Safadi [b], Alfonso Carmona Martinez [c], Pilar Infante Marquez [d], Juan Carlos Tejedor Torres [e], Lily Yin Weckx [f], Edson Duarte Moreira Junior [g], Ilhem Mensi [h], Marco Calabresi [i,1], Daniela Toneatto [i]

The current study was designed to investigate different immunisation schedules in infants in whom the 4CMenB vaccine could be administered alone either between or after routine vaccinations. Preliminary study results were already reviewed by the Joint Committee on Vaccination and Immunisation, and supported the recommendation to introduce a routine infant MenB immunisation programme according to a 2 + 1 dose schedule with concomitant routine vaccines [17,18]. The immunogenicity and safety of a 2-dose catch-up series of 4CMenB in healthy 2- to 10-year-old children were also evaluated.

Journal of Infection (2018) 76, 258-269

www.elsevierhealth.com/journals/jinf

Antibody persistence and booster responses 24–36 months after different 4CMenB vaccination schedules in infants and children: A randomised trial

Federico Martinón-Torres [a,b,*], Alfonso Carmona Martinez [c], Róbert Simkó [d], Pilar Infante Marquez [e], Josep-Lluis Arimany [f], Francisco Gimenez-Sanchez [g], José Antonio Couceiro Gianzo [h], Éva Kovács [i], Pablo Rojo [j,k], Huajun Wang [l], Chiranjiwi Bhusal [m], Daniela Toneatto [m]

Grupo 1	Grupo 2	Grupo 3
2+1	**2+1**	**3+1**
3,5 ms	6 ms	2,5 ms
5 ms	8 ms	3,5 ms
11 ms	11 ms	5 ms
		11 ms

Resultados tras 10 meses

Junio 2016

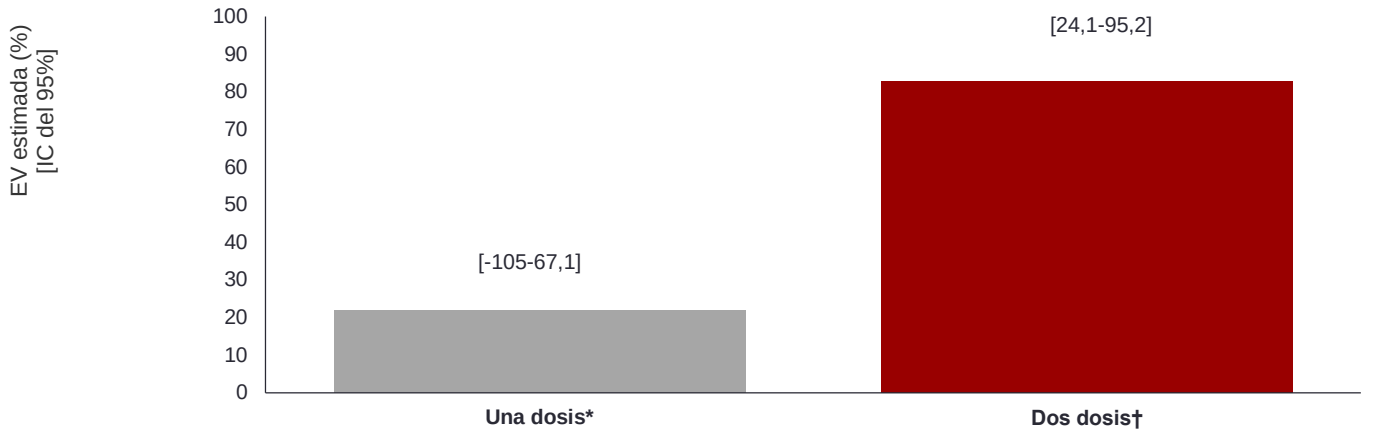
Programa nacional de vacunación

EFECTIVIDAD: 83% /94%

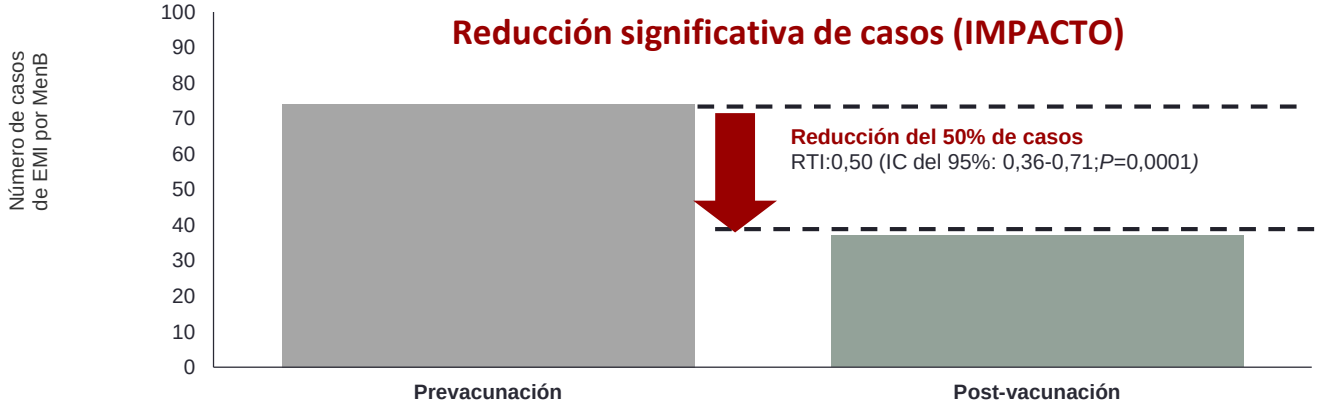
para cualquier cepa de MenB/ cepas vacunales

IMPACTO: 50%

EFECTIVIDAD estimada con dos dosis



Reducción significativa de casos (IMPACTO)



*Se incluyeron 28 casos de MenB en el análisis de la EV con una dosis: 20 vacunados y 8 no vacunados; †se incluyeron 13 casos de MenB en el análisis de la EV con dos dosis: 9 vacunados y 4 no vacunados; ǂ el período de prevacunación transcurrió entre septiembre y junio de los 4 años anteriores a la introducción de 4CMenB (2011/12 a 2014/15); § la vigilancia posterior a la vacunación se inició desde septiembre de 2015 hasta junio de 2016; los casos se incluyen con independencia del estado de vacunación del lactante o de la cobertura prevista de MenB; RTI: razón entre las tasas de incidencia; EV:efectividad vacunal. La gráfica/figura/tabla ha sido creada de forma independiente por GSK a partir de los datos originales publicados por Parikh SR, *et al.*

1. Parikh S, Andrews N, Beebeejaun K, Campbell H, Ribeiro S, Ward C, *et al*. Effectiveness and impact of a reduced infant Schedule of 4CMenB vaccine against group B meningococcal disease in England: a national observational cohort study. Lancet. 2016;388:2775–2782

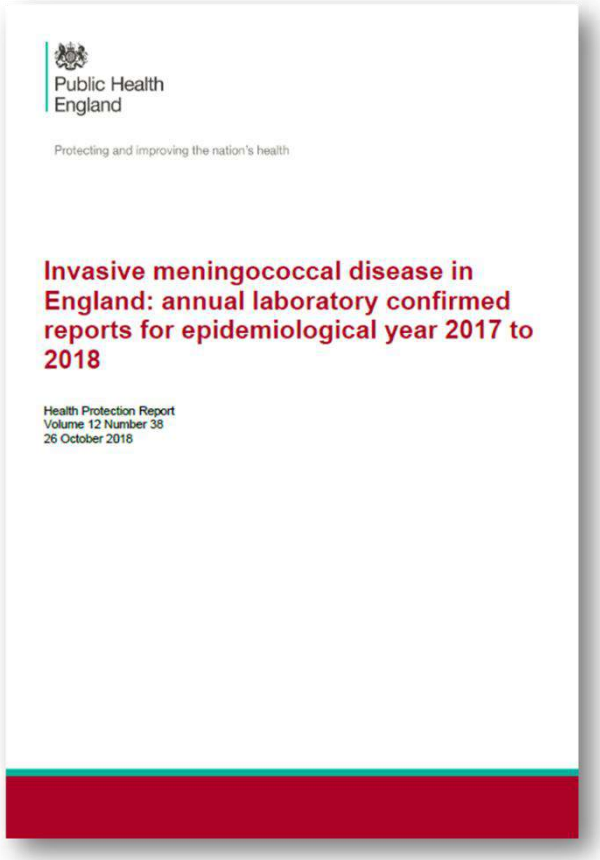
This minute will remain draft until ratified by JCVI at its next meeting

The advice of JCVI is made with reference to the UK immunisation programme and may n necessarily transfer to other epidemiological circumstances

JOINT COMMITTEE ON VACCINATION AND IMMUNISATION

Minute of the meeting on 03 October 2018

Skipton House, London Road, London


Public Health England

Protecting and improving the nation's health

Invasive meningococcal disease in England: annual laboratory confirmed reports for epidemiological year 2017 to 2018

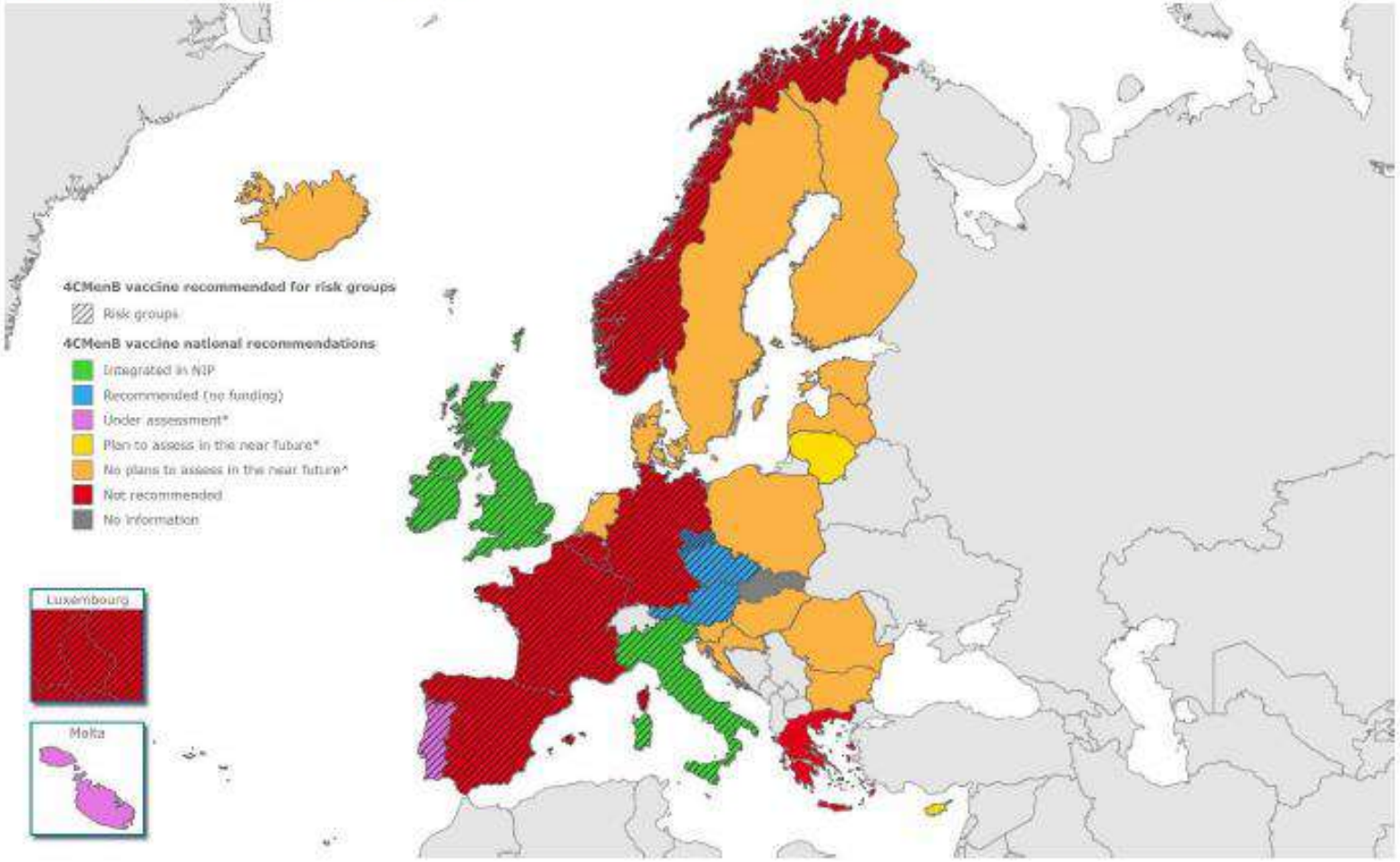
Health Protection Report
Volume 12 Number 38
26 October 2018

21. On the MenB vaccination programme, the Committee noted that:

- in the second year of the programme, there had been an estimated 72% reduction in the number of cases of MenB IMD in infants;
- in the third year of the programme there had been a 60% reduction in the estimated number of cases of MenB IMD in infants;
- the data indicated protection from the two dose infant schedule up until the 12 month booster dose;
- the data indicated that protection lasted at least until at least the end of the second year of life;
- vaccine effectiveness for the 2+1 was estimated at 70% against all MenB strains, and 88% against vaccine preventable strains(based on MATS, not taking into account any cross protection); and
- there were no safety concerns after ~3 million doses had been given.

23. Overall the Committee noted estimates that the MenB programme had prevented about 250 cases in the last three years, with the MenACWY programme preventing around 50 cases of MenW disease. There had, in contrast, been a small increase in MenC cases.

Figure 2. Decision-making status of 4CMenB vaccine introduction in the national immunisation programmes in EU/EEA countries



** Defined as 'assessment within the next six months from March 2015' (based on VENICE III survey, 2015)*

Note: Adapted from VENICE III survey (2015), presentations from country experts and ad hoc consultation with Member States

National Immunisation Program

South Australia Schedule#

AGE	† CAUTION brand name similarity	ADDITION Aboriginal people*
Birth	Engerix B® paediatric (IM) OR HB Vax II® paediatric (IM) Within 7 days of birth. No catch-up required	
6 weeks	Infanrix hexa® (IM) † Prevenar 13® (IM) Rotarix® (Oral) (Administration limitation 6-14 weeks of age) Bexsero® (IM) (L leg alone) (Administer prophylactic paracetamol)	
4 months	Infanrix hexa® (IM) † Prevenar 13® (IM) Rotarix® (Oral) (Administration limitation 10-24 weeks of age) Bexsero® (IM) (L leg alone) (Administer prophylactic paracetamol)	
6 months	Infanrix hexa® (IM) †	Prevenar 13® (IM)
12 months	Nimenrix® (IM) MMR II® (Subcut) OR Priorix® (Subcut/IM) Prevenar 13® (IM) Bexsero® (IM) (L arm alone) (Administer prophylactic paracetamol)	Vaqta® paediatric (IM)
	For 12 month schedule point, refer to *'Principles for Vaccine Administration at 12 M*	
18 months	Act-HIB® (IM) Tripacel® (IM) OR Infanrix® † (IM) Priorix Tetra® (Subcut/IM) OR ProQuad® (Subcut)	Vaqta® paediatric (IM)
4 years	Infanrix IPV® † (IM) OR Quadracel® (IM)	

MEDIA RELEASE

Government of South Australia

Hon Steven Marshall MP
Premier

Hon Stephen Wade MLC
Minister for Health and Wellbeing

Friday 1 February 2019

World-first Meningococcal B program for teens

In a world-first, adolescents and young adults in South Australia will be able to receive free vaccinations against the potentially deadly meningococcal B disease from today, as part of the Marshall Liberal Government's Meningococcal B Immunisation Program.

Premier Steven Marshall said that, after babies and young children, adolescents aged 15 to 20 were the next highest group at-risk from this insidious disease.

"This awful disease has cut short the lives of young South Australians and left others with lifelong disability," Premier Marshall said.

"That's why we introduced the Meningococcal B Immunisation Program to help protect those most at-risk, preventing an average of 12 cases of meningococcal B each year."

Minister for Health and Wellbeing Stephen Wade said, to coincide with the new school year, eligible teens in Year 10 and Year 11 will be able to receive free meningococcal B vaccinations through the School Immunisation Program.

En resumen
Vacunas antimeningocócicas

- **Vacunas conjugadas frente a Men C, Men A, Men ACWY**

- **Vacunas proteicas frente a Men B**

- **Vacunas Men C** incluidas en 16 países UE
- **Vacunas Men ACWY** incluidas en 14 países

- **Vacuna Men B (4CMenB)** incluida en Reino Unido, Andorra, Irlanda, Italia, Lituania, S Marino y Australia

Contenido

1. **Introducción. Enfermedad meningocócica invasora**
    1. Meningitis
    2. Sepsis
2. **¿Dónde estamos?**
    1. **Epidemiología**
        1. Mundo
        2. Europa
        3. España
    2. **Vacunas antimeningocócicas**
        1. Vacunas MenC
        2. Vacunas MenACWY
        3. Vacunas MenB
3. **¿Dónde vamos?**
4. **Mensajes finales**

A dónde vamos???

Predicting is very difficult, especially if it is about the future

N. Bohr

A dónde vamos???

1. Persistencia de anticuerpos bactericidas. Duración de la protección
2. Influencia de la vacunación en la colonización nasofaríngea
3. Vacunas pentavalentes
4. Efectividad real de las vacunas. Complejos clonales. Expresión antigénica
5. Posicionamiento del CAV-AEP. Cambios en las recomendaciones
6. Otros

Vaccine 37 (2019) 1209–1218

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Antibody persistence and booster response in adolescents and young adults 4 and 7.5 years after immunization with 4CMenB vaccine

Terry Nolan [a], Maria Elena Santolaya [b], Ferdinandus de Looze [c], Helen Marshall [d], Peter Richmond [e], Sam Henein [f], Paul Rheault [g], Ken Heaton [g], Kirsten P. Perrett [h], Hartley Garfield [i], Anil Gupta [i], Murdo Ferguson [j], Diego D'Agostino [k], Daniela Toneatto [l], Miguel O'Ryan [m,*]

A B S T R A C T

Background: Data on duration of protection against invasive meningococcal disease post-vaccination with the recombinant, 4-component, meningococcal serogroup B vaccine (4CMenB) are limited. We evaluated bactericidal activity persistence in adolescents/young adults up to 7.5 years post-primary vaccination with 4CMenB, and response to a booster dose compared with vaccine-naïve controls.
Methods: This open-label, multicenter study (NCT02446743) enrolled 15–24 year-old-previously vaccinated participants from Canada, Australia (group Primed_4y) 4 years post-priming with 4CMenB (2 doses; 0,1-month schedule), and Chile (Primed_7.5y) 7.5 years after priming with 4CMenB (2 doses; 0,1/0,2/0,6-month schedule) and vaccine-naïve participants of similar age (Naïve_4y and Naïve_7.5y groups). Primed participants received a booster dose; vaccine-naïve participants received 2 catch-up doses of 4CMenB, 1 month apart. We evaluated antibody persistence and immune responses using hSBA in terms of geometric mean titers and percentages of participants with hSBA titers ≥4, the kinetics of bactericidal activity post-booster (previously vaccinated) or post-2 doses (vaccine-naïve), and safety.
Results: Antibody levels declined at 4 (Primed_4y) and 7.5 (Primed_7.5y) years post-primary vaccination, but remained higher than in vaccine-naïve participants at baseline (≤44% vs ≤ 13% [fHbp]; ≤84% vs ≤ 24% [NadA]; ≤29% vs ≤ 14% [PorA]) for all vaccine antigens except NHBA (≤81% vs ≤ 79%). One month post-booster and post-second dose, 93–100% of primed and 79–100% of vaccine-naïve participants had hSBA titers ≥4 for all antigens. Kinetics of the antibody response were similar across groups with an early robust response observed 7 days post-booster/second dose. No vaccine-related serious adverse event was reported.

Conclusion: For all antigens except NHBA, a higher proportion of primed participants had hSBA titers ≥4, at 4 and 7.5 years post-vaccination, compared with vaccine-naïve participants. A more robust immune response after booster compared to a first dose in vaccine-naïve individuals, showed effective priming in an adolescent/young adult population. No safety or new reactogenicity issues were identified.

Vaccine. 2019 Feb 12. pii: S0264-410X(18)31636-0. doi: 10.1016/j.vaccine.2018.11.073. [Epub ahead of print]

Persistence and 4-year boosting of the bactericidal response elicited by two- and three-dose schedules of MenB-FHbp: A phase 3 extension study in adolescents.

Vesikari T[1], Østergaard L[2], Beeslaar J[3], Absalon J[4], Eiden JJ[4], Jansen KU[4], Jones TR[4], Harris SL[4], Maansson R[5], Munson S[5], O'Neill RE[4], York LJ[6], Perez JL[5].

Abstract

BACKGROUND: The pe
aimed to evaluate persi
Bivalent rLP2086) unde
European Union, and t

METHODS: This was an
includes data through 1
an interactive voice or
0-, 2-month; or 0-, 4-m
to their vaccine study g
the primary study were
Denmark, Germany, an
stage; 14 sites in Czech
bactericidal assays with
the United States and E
immunogenicity endpoi
quantitation (LLOQ; 1:8
and 1 and 48 months a
evaluations during the
immediate AEs, serious
missed days of school
evaluations in the persi
analyses were also per
blood draw, whereas fo
trial is registered at Clir

FINDINGS: A total of 465 subjects were enrolled in the persistence stage, and 271 subjects were enrolled in the booster stage. Sera for the extension phase of this interim analysis were collected from September 7, 2012 to December 7, 2015. One month after primary vaccination, 73.8-100.0% of subjects depending on study group responded with hSBA titers ≥LLOQ. Response rates declined during the 12 months after last primary vaccination and then remained stable through 48 months, with 18.0-61.3% of subjects depending on study group having hSBA titers ≥LLOQ at this time point. One month after receipt of the booster dose, 91.9-100.0% of subjects depending on study group had hSBA titers ≥LLOQ against the four primary strains individually and 91.8-98.2% had hSBA titers ≥LLOQ against all four strains combined (composite response). Geometric mean titers were higher after booster vaccination than at 1 month after primary vaccination. Immune responses were generally similar across study groups, regardless of whether a two- or three-dose primary series was received. None of the AEs (2.2-6.9% of subjects depending on study group) or NDCMCs (1.8-5.0%) that were reported during the persistence stage were considered related to the investigational product. Local reactions and systemic events were reported by 84.4-93.8% and 68.8-76.6% of subjects depending on study group, respectively, in the booster stage; these were generally similar across study groups, transient, and less frequent than after any primary vaccination. Additionally, there was no general progressive worsening in severity of reactogenicity events (ie, potentiation; ≤3 subjects per group), and reactogenicity events did not lead to any study withdrawals. No NDCMCs or immediate AEs were reported during the booster stage. AEs were reported by 3.7-12.5% of subjects depending on study group during the booster stage. The two possibly related AEs included a mild worsening of psoriasis and a severe influenza-like illness that resolved in 10 days.

INTERPRETATION: Immune responses declined after the primary vaccination series; however, a substantially greater number of subjects retained protective responses at 48 months after primary vaccination compared with subjects having protective responses before vaccination. Persistence trends were similar across all 5 study groups regardless of whether a two- or three-dose primary schedule was received. Furthermore, a booster dose given 48 months after primary vaccination was safe, well-tolerated, and elicited robust immune responses indicative of immunologic memory; these responses were similar between two- and three-dose primary schedule study groups. Use of a booster dose may help further extend protection against MenB disease in adolescents.

RESEARCH PAPER

Human Vaccines & Immunotherapeutics 12:1, 132–139; January 2016; Published with license by Taylor & Francis Group, LLC

Antibody persistence up to 5 years after vaccination of toddlers and children between 12 months and 10 years of age with a quadrivalent meningococcal ACWY-tetanus toxoid conjugate vaccine

Timo Vesikari[1,*], Aino Forsten[1], Veronique Bianco[2], Marie Van der Wielen[2], and Jacqueline M Miller[3]

We studied the persistence of serum bactericidal antibody using rabbit and human complement (rSBA/hSBA, cut-offs 1:8) 5 y after a single dose of meningococcal serogroups A, C, W, Y tetanus toxoid conjugate vaccine (MenACWY-TT) compared with age-appropriate control vaccines in toddlers and children (NCT00427908). Children were previously randomized (3:1) to receive either MenACWY-TT or control vaccine (MenC-CRM_{197} in 1-<2 y olds; MenACWY-polysaccharide vaccine [Men-PS] in 2-<11 y olds). Subjects with rSBA-MenC titers <1:8 at any time point were revaccinated with MenC conjugate vaccine and discontinued from the study. A repeated measurement statistical model assessed potential selection effects due to drop-outs. At year 5 in MenACWY-TT-vaccinated-toddlers for serogroups A, C, W, and Y respectively, percentages with rSBA titers ≥1:8 were 73.5%, 77.6%, 34.7%, and 42.9%, hSBA ≥1:8 were 35.6%, 91.7%, 82.6% and 80.0%. For MenC-CRM_{197} recipients, 63.6% had persisting rSBA-MenC titers ≥1:8 and 90.9% had hSBA-MenC ≥1:8 (not significantly different versus MenACWY-TT for either assay: exploratory analyses). In 2-<11 y olds rSBA titers ≥1:8 in MenACWY-TT-vaccinees were 90.8%, 90.8%, 78.6%, and 78.6% and 15.4%, 100%, 0.0%, 7.7% in Men-PS-vaccinees (significantly different for serogroups A, W and Y, exploratory analyses). Serogroups A, W and Y rSBA GMTs were ≥ 26-fold higher in MenACWY-TT-vaccinees. As expected, GMTs modeled at year 5 to assess the impact of subject drop out (mainly for revaccination), appeared lower for serogroup C. No vaccine-related SAEs were reported. Antibody persistence was observed for all serogroups up to 5 y after MenACWY-TT vaccination.

Vaccine 33 (2015) 2175–2182

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Antibody persistence 5 years after vaccination at 2 to 10 years of age with Quadrivalent MenACWY-CRM conjugate vaccine, and responses to a booster vaccination

Stan L. Block[a,*], Shane Christensen[b], Bikash Verma[c], Fang Xie[c], Pavitra Keshavan[d], Peter M. Dull[c], Igor Smolenov[d]

[a] Kentucky Pediatric and Adult Research, Bardstown, KY, USA
[b] J. Lewis Research Inc., Salt Lake City, UT, USA
[c] Novartis Vaccines and Diagnostics, Inc., Cambridge, MA, USA
[d] Novartis Pharma BV, Amsterdam, The Netherlands

ARTICLE INFO

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Available online 2 March 2015

NCT01823536
Keywords:
Meningococcal vaccine
Childhood vaccination
Antibody persistence
Booster vaccination

ABSTRACT

Background: In a multi-center extension study, children 2–10 years of age, initially vaccinated with one or two doses (2–5 year-olds) or one dose (6–10 year-olds) of quadrivalent meningococcal CRM_{197}-conjugate vaccine (MenACWY-CRM), were assessed five years later for antibody persistence and booster response using serum bactericidal assay with human complement (hSBA).
Methods: Children 7–10 and 11–15 years of age, who received MenACWY-CRM in the original study, and age-matched vaccine-naïve children, were enrolled in this extension study. After an initial blood draw, children received one dose of MenACWY-CRM as booster or primary dose, with a second blood draw 28 days later.
Results: hSBA titers decreased five years after primary vaccination, but were higher than in non-vaccinated controls against serogroups C, W and Y, with substantial proportions having titers ≥8: 7–22% for A, 32–57% for C, 74–83% for W, and 48–54% for Y. Previously-vaccinated children demonstrated booster responses to revaccination against all four serogroups. Responses to primary vaccination in vaccine-naïve controls were lower and similar to primary responses observed in the original study. All vaccinations were generally well tolerated, with no safety concern raised.
Conclusions: Approximately half the children vaccinated as 2–10 year-olds maintained protective antibodies against serogroups C, W and Y five years later, but fewer did against serogroup A. Declining titers five years after vaccination and robust booster responses suggest that five years may be an appropriate interval to revaccinate children, subject to epidemiology and delivery considerations.

A dónde vamos???

1. Persistencia de anticuerpos bactericidas. Duración de la protección
2. Influencia de la vacunación en la colonización nasofaríngea
3. Vacunas pentavalentes
4. Efectividad real de las vacunas. Complejos clonales. Expresión antigénica
5. Posicionamiento del CAV-AEP. Cambios en las recomendaciones
6. Otros

Trial record **9 of 17** for: vaccines | Recruiting, Not yet recruiting, Active, not recruiting Studies | Meningococcal Disease | Child

◂ Previous Study | Return to List | Next Study ▸

South Australian Meningococcal B Vaccine Herd Immunity Study (B Part of It)

Study Description

Go to

Brief Summary:

To estimate the effect on carriage, all year 10, 11, and 12 students will be offered 4CMenB vaccination in South Australia through schools over the study period with 50% of the students enrolled receiving the vaccine in 2017 and 50% in 2018. In year 10 and 11 students, posterior pharyngeal swabs will be obtained at baseline and 12 months post baseline to estimate the difference in carriage prevalence of all genogroups of N. meningitidis between vaccinated and unvaccinated participants.

Condition or disease	Intervention/treatment	Phase
Meningococcal Disease	Biological: Licensed 4CMenB vaccine	Phase 4

Show Detailed Description

Study Design

Go to

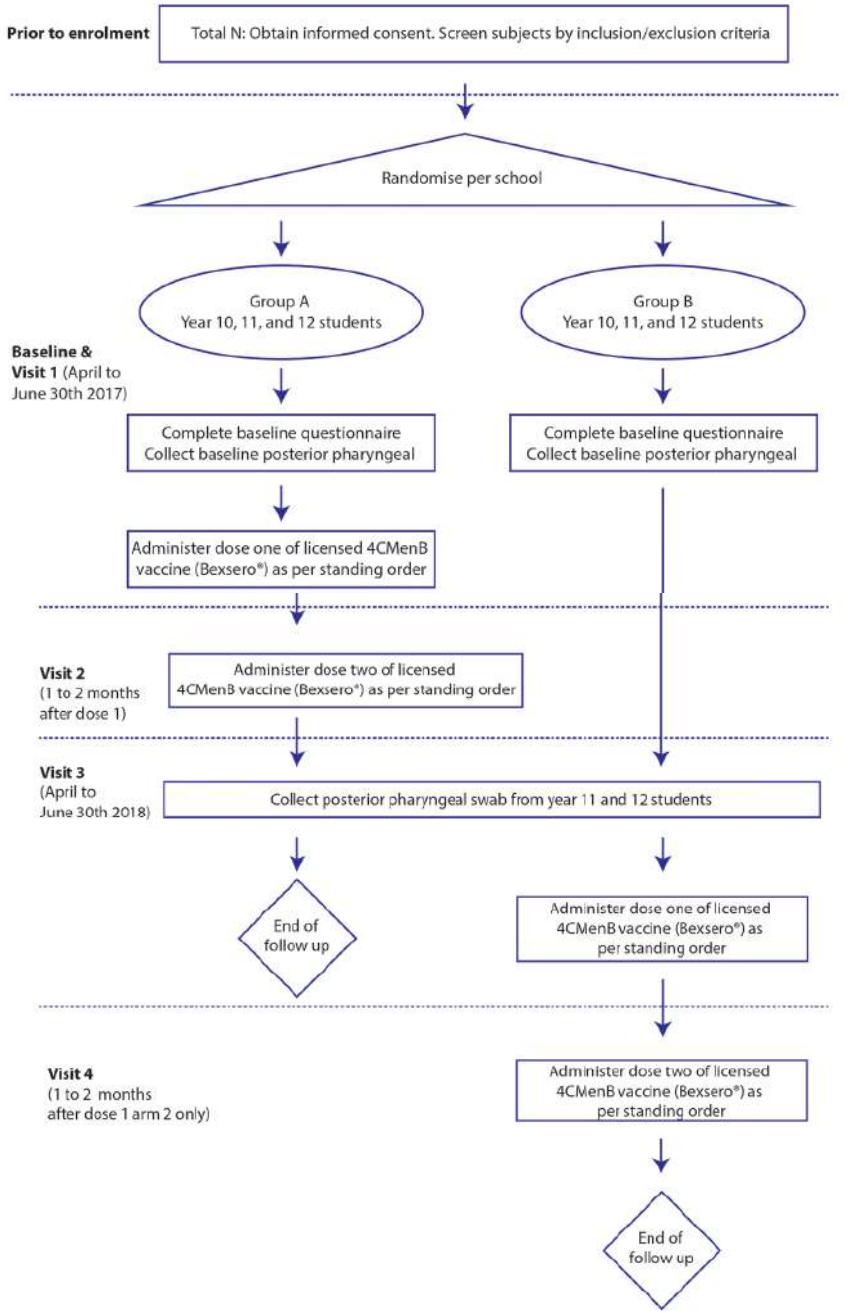
Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	24300 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	A cluster randomised controlled trial to assess the impact of meningococcal B vaccine 4CMenB on nasopharyngeal carriage of N. Meningitidis
Masking:	Double (Investigator, Outcomes Assessor)
Primary Purpose:	Prevention
Official Title:	South Australian Meningococcal B Vaccine Herd Immunity Study
Actual Study Start Date:	April 1, 2017
Actual Primary Completion Date:	July 13, 2018
Estimated Study Completion Date:	June 30, 2020

Open access Protocol

BMJ Open

B Part of It protocol: a cluster randomised controlled trial to assess the impact of 4CMenB vaccine on pharyngeal carriage of *Neisseria meningitidis* in adolescents

Helen S Marshall,[1,2] Mark McMillan,[1,2] Ann Koehler,[3] Andrew Lawrence,[4] Jenny M MacLennan,[5] Martin C J Maiden,[5] Mary Ramsay,[6] Shamez N Ladhani,[6] Caroline Trotter,[6,7] Ray Borrow,[8] Adam Finn,[9] Thomas Sullivan,[10] Peter Richmond,[11] Charlene M Kahler,[11] Jane Whelan,[12] Kumaran Vadivelu[13]



Go back to results

Be on the TEAM: Teenagers Against Meningitis

Medical Conditions

- Specialty: Infectious diseases and microbiology, Primary sub-specialty: Vaccines
- UKCRC code/ Disease: Infection/ Other bacterial diseases

Primary Contact Details

Mrs Emma Plested
See all trial contact details

Recruitment Status

Recruiting

This information is designed to help you decide whether this trial is of interest. In some cases it is provided as a link to more detailed patient information or it may still be awaited from the organisation running the trial. Please look again shortly if the information you need is not here or, if named, contact the researcher named above.

Summary

Background and study aims
Teenagers and young children are at increased risk of diseases such as meningitis and blood poisoning due to bacteria called meningococcus. Although these diseases can be serious, the meningococcus bacteria are carried in the back of the throat of 1 in 10 teenagers without causing any symptoms. Most meningococcal disease in teenagers is due to Meningitis B (also known as MenB). The aim of this study is to see whether immunising teenagers with vaccines against MenB can reduce the number of teenagers carrying these bacteria in their throat. This would be important because it could mean that teenage MenB immunisation would not only help protect teenagers against these potentially deadly diseases, but also that babies, children and older adults are less likely to be exposed to the bacteria. In short, immunising teenagers with a MenB vaccine might mean lower rates of meningococcal disease across all ages.

Who can participate?
Students aged 16-18 attending year 12 (or equivalent) at one of the participating 6th form colleges in England, Scotland and Wales

What does the study involve?
Participating schools are randomly allocated to deliver one of two types of MenB vaccine: 4CMenB (also known as Bexsero) and MenB-fHBP (also known as Trumenba). Participants either get two doses of 4CMenB or MenB-fHBP given 6 months apart at their first two study visits, or two doses of 4CMenB 1 to 6 months apart at their last two study visits. These vaccines are approved for use in the UK, but are not routinely given to teenagers in this country. Samples are collected from the participants' throats to compare rates of MenB carriage before and after getting the MenB vaccine. Teenagers have three study visits over 12 to 18 months and all visits take place within schools.

What are the possible benefits and risks of participating?
Not provided at time of registration

Key Dates

Recruitment Start Date
19 Mar 2018

Recruitment End Date
01 Oct 2019

Trial Start Date
01 Oct 2017

Trial End Date
31 May 2021

Date added to source
14 Mar 2018

Date updated in source
14 Mar 2018

BE ON THE TEAM
TEENAGERS AGAINST MENINGITIS

How many teenagers are taking part in this study? What is the study design?

Altogether 24 000 teenagers will take part in this study, who will be enrolled into one of three groups, as shown below.

Group	Study start	6 months	12 months	13-18 months Group 3 only
1 (8000 students)	Throat swab 1st dose 4CMenB	2nd dose 4CMenB	Throat swab *End of participation*	
2 **(Your group)** (8000 students)	Throat swab 1st dose MenB-fHBP	2nd dose MenB-fHBP	Throat swab *End of participation*	
3 (8000 students)	Throat swab		Throat swab 1st dose 4CMenB	2nd dose 4CMenB *End of participation*

1. https://beontheteam.web.ox.ac.uk/
2. Be on the TEAM: Teenagers against Meningitis Information booklet.
http://trials.ovg.ox.ac.uk/trials/sites/default/files/trials_attachments/BeontheTEAMParticipantInformationSheetMenBfHBPV3107Aug2018.pdf

A dónde vamos???

1. Persistencia de anticuerpos bactericidas. Duración de la protección
2. Influencia de la vacunación en la colonización nasofaríngea
3. Vacunas pentavalentes
4. Efectividad real de las vacunas. Complejos clonales. Expresión antigénica
5. Posicionamiento del CAV-AEP. Cambios en las recomendaciones
6. Otros

VACCINE REPORTS

Immune Responses to Booster Vaccination With Meningococcal ABCWY Vaccine After Primary Vaccination With Either Investigational or Licensed Vaccines

A Phase 2 Randomized Study

Leszek Szenborn, MD, Stan L. Block, MD,† Teresa Jackowska, MD,‡ Ryszard Konior, MD,§ Diego D'Agostino, MSc,¶ Igor Smolenov, MD,¶ Daniela Toneatto, PhD,‖ and Jo Anne Welsch, PhD***

Background: Current meningococcal prime-boost vaccination schedules include separate vaccines for serogroups ACWY and B. An investigational combined serogroups ABCWY vaccine (MenABCWY) was developed to protect against clinically important *Neisseria meningitidis* serogroups.

Methods: In this phase 2, randomized, observer-blind, extension study (NCT01272180), participants 10–25 years of age received 1 booster dose of MenABCWY vaccine at 24 months (M) postprimary series of MenABCWY (2 doses), 4CMenB (2 doses) or MenACWY-CRM vaccine (1 dose). Immune responses to booster dose (1M postbooster) and antibody persistence (24M, 36M postprimary series) were assessed using bactericidal assay with human complement (hSBA). Reactogenicity and safety were evaluated.

Results: One hundred ninety participants were vaccinated. At 1M after the MenABCWY booster dose, seroresponse rates against serogroups ACWY ranged between 85% and 96%, 73% and 100% and 83% and 95% for participants previously receiving MenABCWY, 4CMenB and MenACWY-CRM, respectively. At 12M postbooster dose, ≥67% of participants across all groups had hSBA titers ≥8 for serogroups ACWY, except in 4CMenB-primed individuals for serogroup Y (45%). Across MenABCWY and 4CMenB-primed groups, hSBA titers ≥5 across serogroup B test strains were observed in 82%–100% and 29%–100% of participants at 1M and 12M postbooster, respectively. Geometric mean titers against serogroups ACWY increased from pre- to 1M postboosting with MenABCWY and persisted at 12M. The reactogenicity and safety profile of MenABCWY was similar to that of 4CMenB.

Conclusions: MenABCWY may be suitable for prime-boost schedules against meningococcal disease, including regimens involving a primary series of either 4CMenB or MenACWY-CRM licensed vaccines.

Key Words: meningococcal, vaccine, booster, serogroups ABCWY

(*Pediatr Infect Dis J* 2018;37:475–482)

Invasive meningococcal disease (IMD) is caused by the bacterium *Neisseria meningitidis* and commonly presents as serious or life-threatening meningitis and septicemia in children and adolescents, with a fatality rate of up to 10% in affected individuals.[1] Virtually

Vaccine 36 (2018) 5309–5317

Contents lists available at ScienceDirect

Vaccine

http://www.sciencedirect.com/science/journal/0264410X

journal homepage: www.elsevier.com/locate/vaccine

Breadth of coverage against a panel of 110 invasive disease isolates, immunogenicity and safety for 2 and 3 doses of an investigational MenABCWY vaccine in US adolescents – Results from a randomized, controlled, observer-blind phase II study

Jo Anne Welsch [a,1,*], Shelly Senders [b], Brandon Essink [c], Thomas Klein [d], Igor Smolenov [e,2], Paola Pedotti [e], Silvia Barbi [e], Bikash Verma [f], Daniela Toneatto [g]

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MenABCWY
Meningococcal vaccine
Adolescents
Breadth of coverage
Endogenous complement human bactericidal assay

ABSTRACT

Background: *Neisseria meningitidis* serogroups A, B, C, W and Y cause most meningococcal disease worldwide. An investigational MenABCWY vaccine combining serogroup B antigens and a meningococcal ACWY CRM_{197}-glycoconjugate vaccine (MenACWY-CRM) could provide protection against all 5 serogroups. Complement mediated bactericidal activity induced by MenABCWY was tested against a panel of 110 randomly-selected serogroup B strains causing invasive disease in the US to evaluate the vaccine's breadth of coverage (BoC).

Methods: We conducted this observer-blind study (NCT02140762) and its extension (NCT02285777) in 8 centers in the US. Adolescents aged 10–18 years were randomized (1:1) to receive either 3 MenABCWY doses (MenABCWY group), on a 0, 2, 6-month (M) schedule or a single MenACWY-CRM dose at M2 and placebo at 0,6-M (Control group). MenABCWY BoC was calculated as (1 – relative risk) × 100 (relative risk = ratio between the percentage of samples seronegative at 1:4 dilution against the selected strains in the MenABCWY vs Control group). BoC was determined at 1 M and 4 M after 2 and 3 doses, using an endogenous complement serum bactericidal assay. Immunogenicity and safety were assessed.

Results: 301 and 189 adolescents were vaccinated in the parent and extension study, respectively. At 1 M post-vaccination, the BoC of MenABCWY across the 110 serogroup B strains was 67% (95%CI: 65–69) after 2 doses and 71% (95%CI: 69–73) after 3 doses. BoC decreased to 44% (95%CI: 41–47) and 51% (95%CI: 48–55) at 4 M after 2 and 3 MenABCWY doses, respectively. Robust immune responses to antigen-specific test strains for each serogroup were observed at all timepoints in the MenABCWY group. No reactogenicity or safety concerns arose during the study.

Conclusion: Two or 3 doses of MenABCWY showed similar BoC against the panel of invasive US serogroup B isolates and comparable immunogenicity against the antigen-specific test strains, with no safety concerns identified.

HUMAN VACCINES & IMMUNOTHERAPEUTICS
2018, VOL. 14, NO. 5, 1161–1174
https://doi.org/10.1080/21645515.2018.1457595

Taylor & Francis
Taylor & Francis Group

RESEARCH PAPER

OPEN ACCESS

Four-year antibody persistence and response to a booster dose of a pentavalent MenABCWY vaccine administered to healthy adolescents and young adults

Xavier Sáez-Llorens[a], Johnny Beltran-Rodriguez[b], Jose M. Novoa Pizarro[c], Ilhem Mensi[d], Pavitra Keshavan[d], and Daniela Toneatto[e]

[a]Hospital del Niño "Dr. José Renán Esquivel", Infectious Disease Department, Panama City, Panama and distinguished investigator of the SNI (Senacyt, Panama); [b]Centro de Atención e Investigación Médica Caimed. Bogotá, Colombia; [c]Faculty of Medicine University of Desarrollo/Clinica Alemana, Santiago, Chile; [d]GSK, Amsterdam, The Netherlands; [e]GSK, Siena, Italy

ABSTRACT

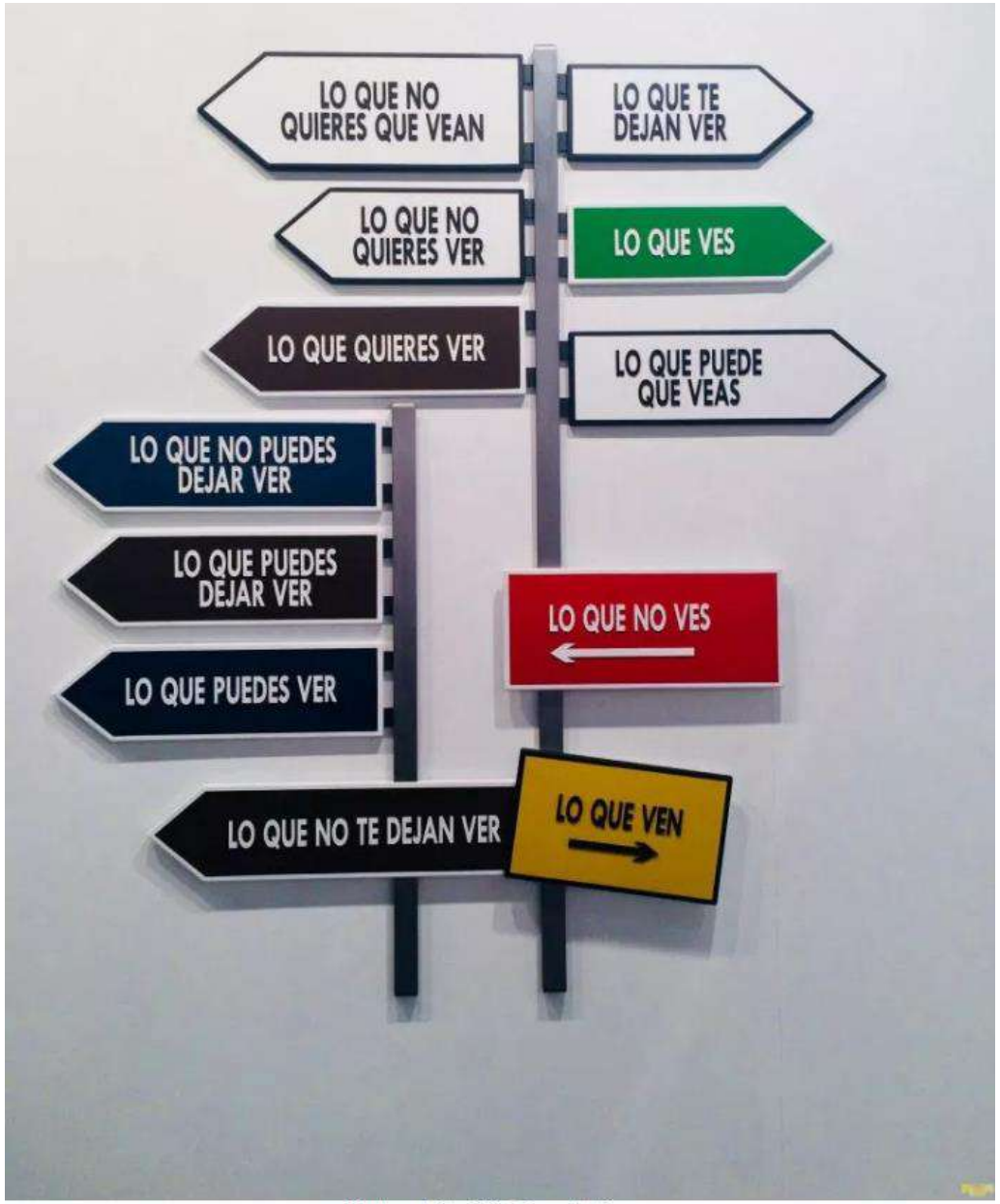
This open-label, multicenter extension study (NCT02451514) assessed persistence of *Neisseria meningitidis* serogroups ABCWY antibodies 4 years after primary vaccination. Adolescents and young adults who previously received 2 doses of MenABCWY+OMV (Group III), 1 dose of MenACWY-CRM (Group VI), or newly-recruited vaccine-naïve participants (Group VII) were administered 1 (Group III) or 2 doses (Groups VI and VII) of MenABCWY+OMV, 1 month apart. Immunogenicity was assessed by human serum bactericidal assay (hSBA). Safety and reactogenicity were also evaluated. Percentages of participants with hSBA titers ≥8 (serogroups ACWY), ≥5 (serogroup B) and hSBA geometric mean titers (GMTs) were evaluated in all 129 enrolled participants (Group III: 33; Group VI: 46; Group VII: 50). Anti-ACWY antibody concentrations waned over 4 years post-vaccination, but remained above pre-vaccination concentrations. Similarly, levels of antibodies against serogroup B test strains also waned over 4 years post-vaccination, but remained above pre-vaccination concentrations for some strains. MenABCWY+OMV booster induced a robust anamnestic anti-ACWY response in Group III and VI and a good response against serogroup B test strains (≥82%) in Group III. In serogroup B-naïve participants (Groups VI and VII), anti-B responses to 2 doses of MenABCWY+OMV were less homogenous and lower than in Group III. MenABCWY+OMV was reactogenic, but well-tolerated. No safety concerns were identified. These findings indicate that although antibodies against *N. meningitidis* serogroups ABCWY waned over 4 years post-vaccination, exposure to a MenABCWY+OMV booster dose elicits an anamnestic response in adolescents previously exposed to the same or another multivalent meningococcal vaccine.

ARTICLE HISTORY
Received 10 December 2017
Revised 15 March 2018
Accepted 22 March 2018

KEYWORDS
antibody persistence; booster dose; MenACWY; MenABCW; meningococcal vaccine

A dónde vamos???

1. Persistencia de anticuerpos bactericidas. Duración de la protección
2. Influencia de la vacunación en la colonización nasofaríngea
3. Vacunas pentavalentes
4. Efectividad real de las vacunas. Complejos clonales. Expresión antigénica
5. Posicionamiento del CAV-AEP. Cambios en las recomendaciones
6. Otros



Montserrat Soto. Galería Juana de Aizpuru

Posicionamiento CAV-AEP

AEP
Asociación Española de Pediatría

CAV
Comité Asesor de Vacunas

An Pediatr (Barc). 2019;90(1):56.e1–56.e9

analesdepediatría

www.analesdepediatria.org

ASOCIACIÓN ESPAÑOLA DE PEDIATRÍA

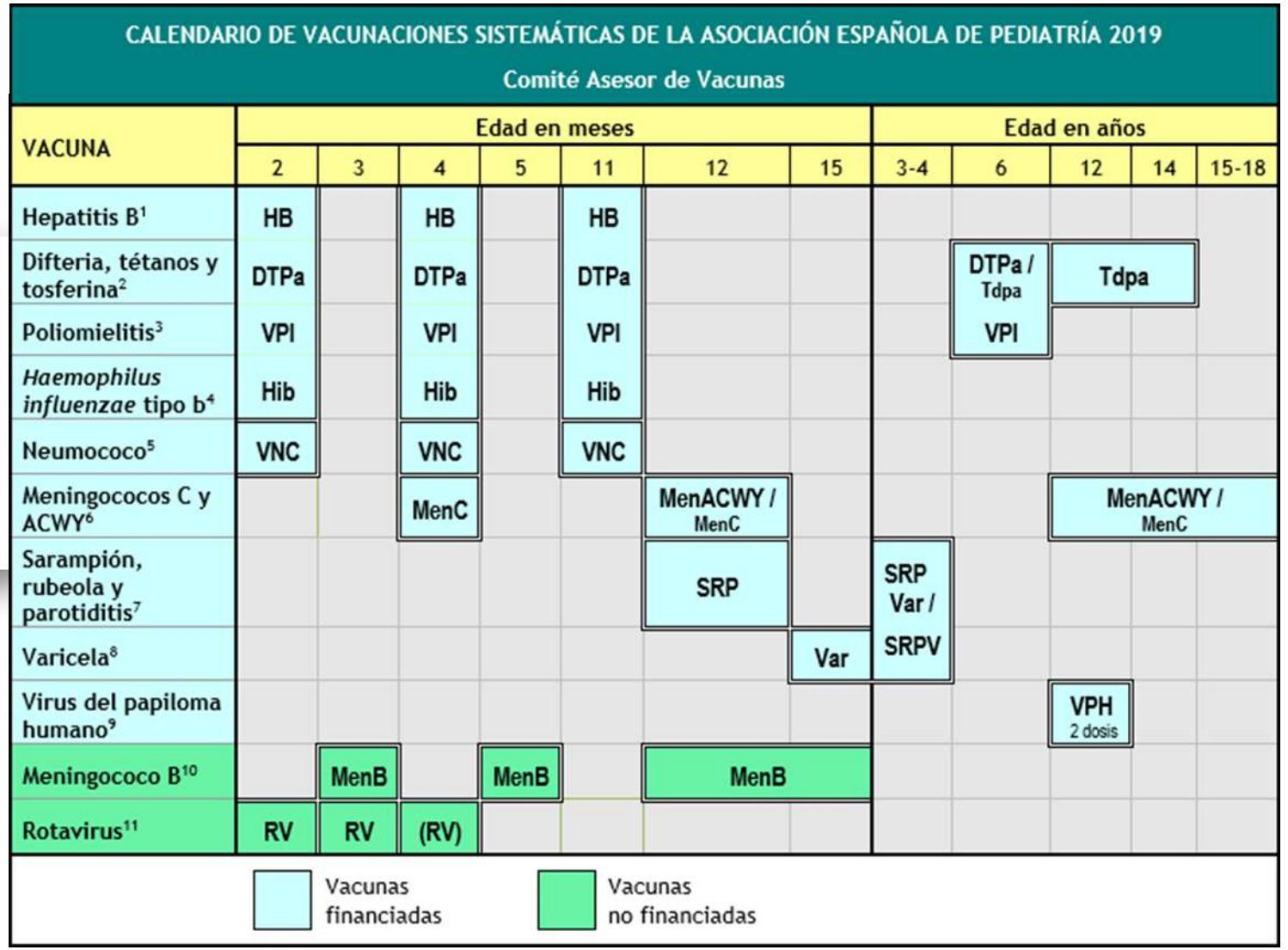
Calendario de vacunaciones de la Asociación Española de Pediatría: recomendaciones 2019

David Moreno-Pérez[a,b,*], Francisco José Álvarez García[c,d], Javier Álvarez Aldeán[e], María José Cilleruelo Ortega[f,g], María Garcés Sánchez[h,i], Nuria García Sánchez[j,k], Ángel Hernández Merino[l], María Méndez Hernández[m,n], Manuel Merino Moína[o,p], Abián Montesdeoca Melián[q] y Jesús Ruiz-Contreras[r,s], en representación del Comité Asesor de Vacunas de la Asociación Española de Pediatría (CAV-AEP)

Calendario de Vacunaciones de la Asociación Española de Pediatría.
Razones y bases de las recomendaciones 2019

Vacuna frente al meningococo B

Recomendación 2019: esta vacuna presenta un perfil de vacuna sistemática a administrar a lactantes a partir de los 3 meses de edad con una pauta 2 + 1. Para el resto de las edades pediátricas, incluyendo la adolescencia, el CAV-AEP aboga también por su uso, realizando una recomendación de tipo individual.



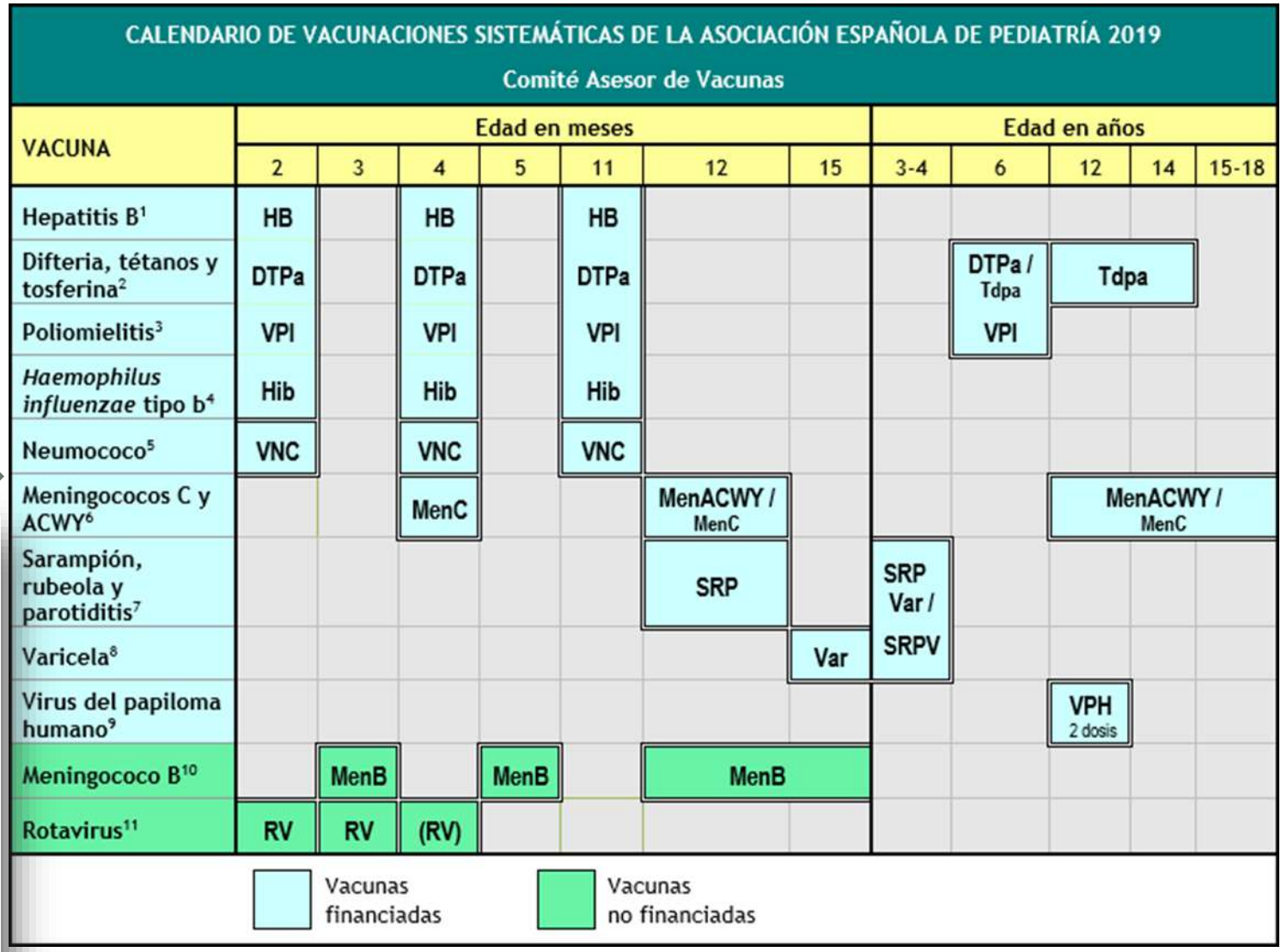
An Pediatr (Barc). 2019

Calendario de Vacunaciones de la Asociación Española de Pediatría.
Razones y bases de las recomendaciones 2019

Posibilidad de sustituir la primera dosis de **MenC por MenACWY** tras la próxima modificación de FT

Vacunación frente a meningococos C y ACWY

Recomendación 2019: se recomienda mantener la protección frente al meningococo C a los 4 meses de edad. Dada la incidencia ascendente de los serogrupos W e Y en España, el CAV-AEP recomienda proteger a los 12 meses de edad y a los adolescentes mediante la introducción en calendario sistemático de la vacuna MenACWY, aconsejándose un rescate progresivo hasta los 19 años. También, a los mayores de 6 semanas de vida con factores de riesgo de enfermedad meningocócica invasora (EMI) o que viajen a países de elevada incidencia.



An Pediatr (Barc). 2019

Vaccine 36 (2018) 4102–4111

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Immunogenicity and safety of MenACWY-TT, a meningococcal conjugate vaccine, co-administered with routine childhood vaccine in healthy infants: A phase III, randomized study

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[b] Hospital General de Durango, Durango, Mexico
[c] GSK, Wavre, Avenue Fleming 20 (W23), 1300 Wavre, Belgium

ABSTRACT

Background: Invasive meningococcal disease has a high burden in young children, particularly during infancy. We investigated the immunogenicity and safety of a quadrivalent meningococcal conjugated vaccine (MenACWY-TT) co-administered with routine vaccines in healthy infants.

Methods: In this phase IIIb study (NCT01340898) conducted in 2 centers in Lebanon and Mexico, 750 infants were randomized (2:1:1) to receive MenACWY-TT according to 3 schedules: 3+1 (at ages 2, 4, 6 and 15–18 months; group ACWY3+1); 1+1 (at 6 and 15–18 months; group ACWY1+1) or single-dose at 15–18 months (group ACWY1). All infants received PHiD-CV and DTPa-IPV/Hib at ages 2, 4, 6, 15–18 months. Immune responses to MenACWY-TT were assessed by rSBA and hSBA at 7 months (groups ACWY3+1, ACWY1+1) and pre- and post-vaccination at 15–18 months of age (all groups). Immune responses to co-administered vaccines, reactogenicity and safety were also evaluated.

Results: Immunogenicity of MenACWY-TT at 1 month post-primary vaccination was demonstrated in group ACWY3+1: the lower limit of the 95% confidence interval for the percentage of infants with rSBA titers ≥8 was >80% for each serogroup. At 7 months of age, ≥93.9% of MenACWY-TT-primed infants had rSBA titers ≥8. Post-MenACWY-TT vaccination at age 15–18 months, ≥96.3% of participants in all groups had rSBA titers ≥8, regardless of the number of doses received previously. The percentage of infants with hSBA titers ≥4 were ≥87.2% and ≥89.7% at post-primary and booster/single-dose vaccination, respectively. Immune responses to PHiD-CV and DTPa-IPV/Hib did not seem impacted by co-administration with MenACWY-TT in infancy. The incidence of all adverse events was similar among groups. Serious adverse events were reported for 63/750 children in all groups; none were considered vaccine-related by investigators.

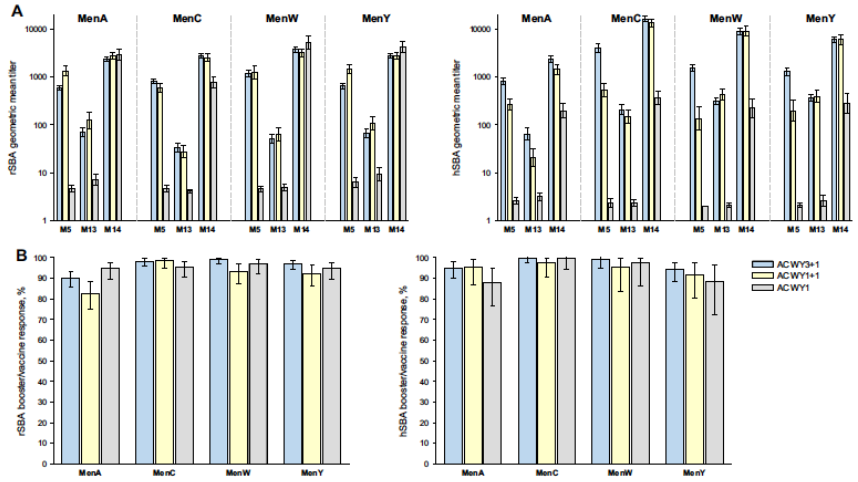
Conclusion: Primary vaccination with 3 or 1 dose(s) of MenACWY-TT when co-administered with routine pediatric vaccines in infants is immunogenic and well-tolerated.

PAUTA VACUNAL

2 + 4 + 6 + 15-18 meses (3 + 1)

6 + 15-18 meses (1 +1)

15-18 meses (0 + 1)



5. Conclusions

MenACWY-TT was immunogenic in healthy infants after 3 primary doses at 2, 4 and 6 months or after 1 dose at 6 months of age. Regardless of the primary vaccination schedule received, ≥96.3% of children had rSBA titers ≥ 8 after 1 dose of MenACWY-TT at 15–18 months of age, showing that immune response to MenACWY-TT vaccination in toddlers is not affected by the number of previously-administered doses. Co-administration of MenACWY-TT with DTPa-IPV/Hib and PHiD-CV during the first years of life was immunogenic, well-tolerated and no safety concerns were identified.

Our results support the potential use of MenACWY-TT in routine pediatric vaccination programs worldwide to ensure protection against IMD caused by 4 meningococcal serogroups at a very young age. However, the need for vaccinating infants, the age at vaccination and the number of administered doses should be dictated by geographic and epidemiological factors.

CONSEJO INTERTERRITORIAL DEL SISTEMA NACIONAL DE SALUD

CALENDARIO COMÚN DE VACUNACIÓN A LO LARGO DE TODA LA VIDA

Calendario recomendado año 2019

VACUNACIÓN	EDAD													
	Pre-natal*	0 meses	2 meses	4 meses	11 meses	12 meses	15 meses	3-4 años	6 años	12 años	14 años	15-18 años	19-64 años	≥ 65 años
Poliomielitis			VPI	VPI	VPI				VPI[a]					
Difteria-Tétanos-Pertussis	dTpa		DTPa	DTPa	DTPa				DTPa[a]		Td	Td[b]	Td[b]	Td
Haemophilus influenzae b			Hib	Hib	Hib									
Sarampión-Rubéola-Parotiditis						TV		TV				TV[c]	TV[c]	
Hepatitis B[d]		HB[d]	HB	HB	HB							HB[e]		
Enfermedad meningocócica C				MenC[f]		MenC				MenC		MenC[g]		
Varicela							VVZ	VVZ		VVZ[h]		VVZ[h]	VVZ[h]	
Virus del Papiloma Humano										VPH[i]		VPH[j]		
Enfermedad neumocócica			VNC1	VNC2	VNC3									VN[k]
Gripe	gripe													gripe anual

*Se administrará una dosis de vacuna frente a tosferina en embarazadas entre las semanas 27 y 36 de gestación. En temporada de gripe se vacunará a embarazadas en cualquier trimestre de gestación.

[a] Se administrará la vacuna combinada DTPa/VPI a los menores vacunados con pauta 2+1 cuando alcancen la edad de 6 años. Los menores vacunados con pauta 3+1 recibirán dTpa.

[b] Vacunar o completar vacunación en caso de no tener administradas 5 dosis durante la infancia y adolescencia

[c] Vacunar con dos dosis si susceptible

[d] Pauta 0, 2, 4, 11 meses. Se administrará la pauta 2, 4 y 11 meses siempre que se asegure una alta cobertura de cribado prenatal de la embarazada y la vacunación de hijos/as de madres portadoras de AgHBs en las primeras 24 horas de vida junto con administración de inmunoglobulina HB.

[e] En personas no vacunadas con anterioridad se administrarán 3 dosis con pauta 0, 1 y 6 meses

[f] Según la vacuna utilizada puede ser necesaria la primovacunación con una dosis (4 meses) o dos dosis (2 y 4 meses de edad).

[g] Se administrará 1 dosis en las personas no vacunadas después de los 10 años de edad.

[h] Personas que refieran no haber pasado la enfermedad ni haber sido vacunadas con anterioridad. Pauta con 2 dosis.

[i] Vacunar solo a las niñas con 2 dosis.

[j] Vacunar solo a las mujeres no vacunadas con anterioridad, con pauta de 3 dosis.

[k] Vacunación frente a neumococo a los 65 años de edad.

Calendario aprobado por el Pleno del Consejo Interterritorial del SNS el 15 de noviembre de 2018

GRUPO DE TRABAJO DEL MINISTERIO
DOCUMENTO VACUNACION MENINGOCOCICA 2019

Consejo Interterritorial
SISTEMA NACIONAL DE SALUD

GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

Calendario de vacunación de Melilla 2016-2017

CALENDARIO DE VACUNACIÓN INFANTIL A PARTIR DE 2016
MELILLA

VACUNAS	EDAD										
	0 MESES	2 MESES	4 MESES	11 MESES	12 MESES	15 MESES	24 MESES	3 AÑOS	6 AÑOS	12 AÑOS	14 AÑOS
Poliomielitis inyectable		VPI 1	VPI 2	VPI 3					VPI 4 (c)		
Difteria-Tétanos-Pertussis	*	DTPa 1	DTPa 2	DTPa 3					DTPa 4 (c)		Td 5
Haemofilus-influenza b		Hib 1	Hib 2	Hib 3							
Hepatitis B / Hepatitis A	HB (a)	HB 1	HB 2	HB 3		HA 1	HA 2				
Meningitis Meningocócica C			MMC 1		MMC 2					A,C,W,Y	
Neumococo		Neumo 1	Neumo 2	Neumo 3							
Sarampión-Rubeola-Parotiditis					TV 1 (b)			TV 2 (b)			
Varicela						VVZ 1		VVZ 2 (b)		VVZ (d) 1 y 2	
Virus Papiloma Humano										VPH (e)	

http://www.melilla.es/melillaportal/RecursosWeb/DOCUMENTOS/1/5_13218_1.pdf

CASTILLA Y LEÓN, PRIMERA EN INCORPORAR LA VACUNA FRENTE A LOS MENINGOCOCOS A, C, W, Y AL CALENDARIO INFANTIL

14 diciembre 2018

Versión para imprimir | Share | Twittear

Fuente: Elaboración propia a partir de varias fuentes.

Boletín Oficial de Castilla y León BOCYL

Núm. 241 Viernes, 14 de diciembre de 2018 Pág. 49230

I. COMUNIDAD DE CASTILLA Y LEÓN

D. OTRAS DISPOSICIONES

CONSEJERÍA DE SANIDAD

ORDEN SAN/1332/2018, de 30 de noviembre, por la que se aprueba el Calendario Oficial de Vacunaciones Sistemáticas a lo largo de la vida de las personas para la Comunidad de Castilla y León.

CALENDARIO OFICIAL DE VACUNACIONES SISTEMÁTICAS PARA TODA LA VIDA DE CASTILLA Y LEÓN

	Prenatal	2 meses	4 meses	11 meses	12 meses	15 meses	3 años	6 años	12 años	14 años	15-59 años (1)	60-64 años (1)	65-69 años	70 y más años
Hepatitis B infantil (2)		HB	HB	HB										
Difteria-Tétanos	dTpa	DTPa	DTPa	DTPa				dTpa - DTPa-VPI (3)		Td			Td	
Tosferina														
Polio		VPI	VPI	VPI										
***Haemophilus influenzae* tipo b**		Hib	Hib	Hib										
Neumococo		VNC13	VNC13	VNC13									VNC13 (4)	
													VNP23 (5)	
Meningococo			MC-C		MC-ACYW				MC-ACYW					
Sarampión-Rubéola-Parotiditis					SRP		SRPV							
Varicela						VVZ			VVZ (6)					
Virus del papiloma humano									VPH9 (7)					
Gripe	VIG anual											VIG anual		

redacción médica

AUTONOMÍAS / CANARIAS

Canarias, primera autonomía en incluir Bexsero en su calendario vacunal

La región lo ha anunciado tras una reunión del Comité Asesor de Vacunas

Conrado Domínguez, gerente del SCS; junto a José Manuel Baltar, consejero de Sanidad de Canarias.

LUN 18 FEBRERO 2019. 12.40H | REDACCIÓN MÉDICA

Canarias se convierte en la primera comunidad autónoma en introducir la vacuna Bexsero (4CMenB) en su calendario vacunal. Todo ello ha sido anunciado tras la reunión del **Comité Asesor de Vacunas**, en el que están representados todas las **sociedades científicas**, para presentar la propuesta de incorporación de nuevas vacunas en el Calendario Vacunal para todas las edades de la vida de la Comunidad Autónoma de Canarias. Además, se ha anunciado también la mejora de la oferta vacunal frente al Virus del Papiloma Humano con la incorporación de una vacuna frente a 9 genotipos del VPH.

VACUNACIÓN ›

Castilla y León se une a Canarias y financiará la vacuna contra la meningitis B

Esta comunidad dará el paso aunque no haya acuerdo en la Comisión de Salud Pública organizada por el Ministerio de Sanidad el 14 de marzo. La medida beneficiará a 16.000 niños

POLÍTICA SANITARIA

La AEP aplaude la decisión de Castilla y León de incluir ‘Bexsero’ en su calendario

La Asociación Española de Pediatría (AEP) celebra que cada vez más comunidades autónomas se muestren partidarias de incluir 'Bexsero' o la vacuna contra la meningitis B en su calendario vacunal. Trars el anuncio de Canarias, Castilla y León ha mostrado su intención de hacerlo.

En resumen

1. La EMI es una enfermedad poco frecuente, con elevada morbimortalidad
2. Epidemiología variable de la EMI
    1. Serogrupo B estable
    2. Serogrupos W e Y en ascenso
3. Vacunas disponibles
    1. Monovalentes MenC
    2. Monovalentes MenB
    3. Monovalentes MenA
    4. Tetravalentes ACWY
4. Cambios en la estrategia de vacunación
5. Desarrollo de nuevas vacunas

Early evidence of expanding W ST-11 CC meningococcal incidence in Spain

J Infect. 2016;73:296-7

This situation has been under special surveillance in Spain because its special economic and cultural relationship with Latin America etc that could suggest a potential risk of transmission of strains W: P1.5,2 ST-11CC to our country.

Review

OPEN ACCESS

Enter B and W: two new meningococcal vaccine programmes launched

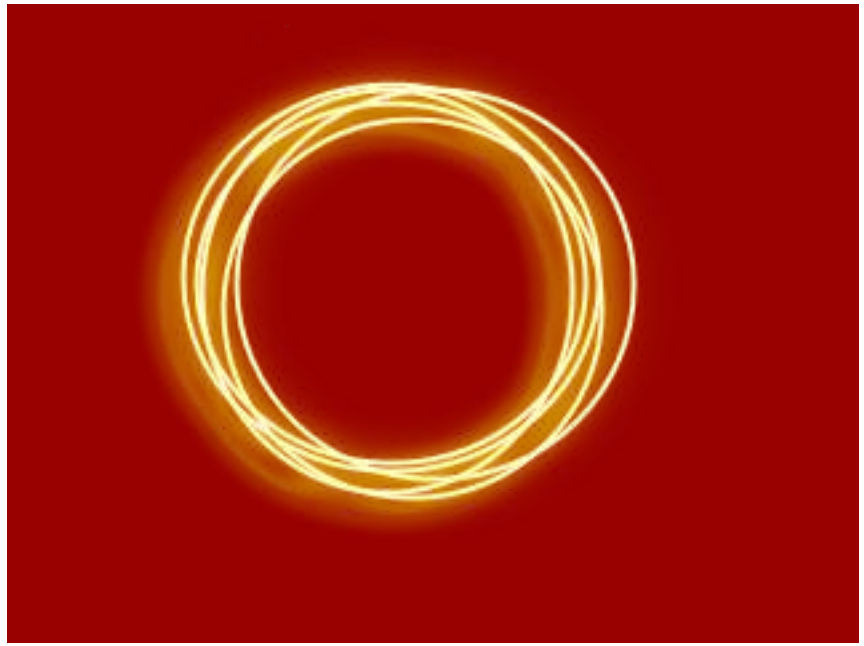
Shamez N Ladhani,[1] Mary Ramsay,[1] Ray Borrow,[2] Andrew Riordan,[3] John M Watson,[4] Andrew J Pollard[5]

Ladhani SN, et al. Arch Dis Child.2016;101:91-95

Rates of meningococcal disease vary over time as a result of

VIGILANCIA EPIDEMIOLÓGICA

Although the incidence of meningococcal disease has remained low for more than 10 years, the reasons for the change in epidemiology are unknown. Therefore, high-quality disease surveillance remains important to detect potential changes in epidemiology that might affect vaccine policy decisions.



Cerrando el círculo a la enfermedad meningocócica

GRACIAS!!!!