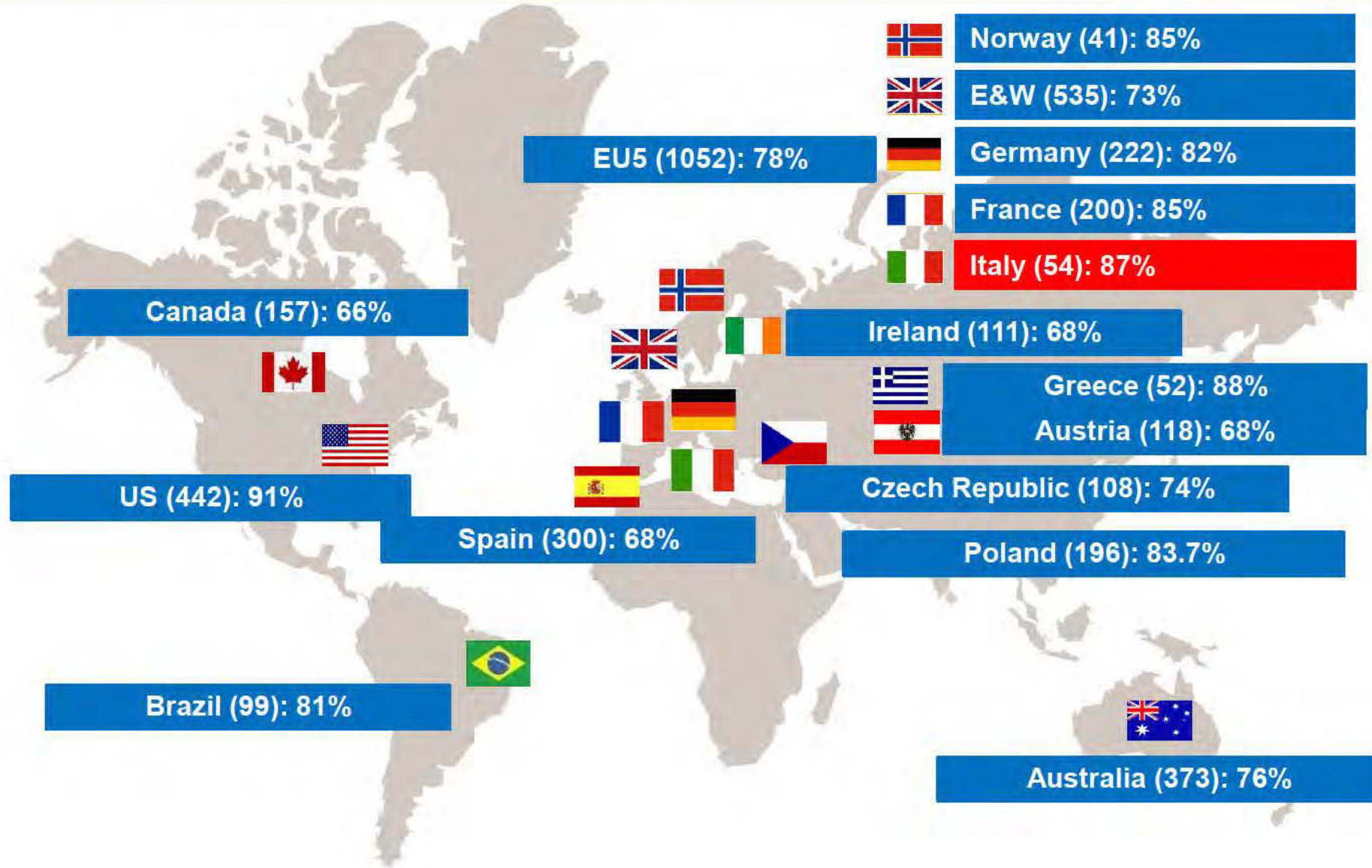
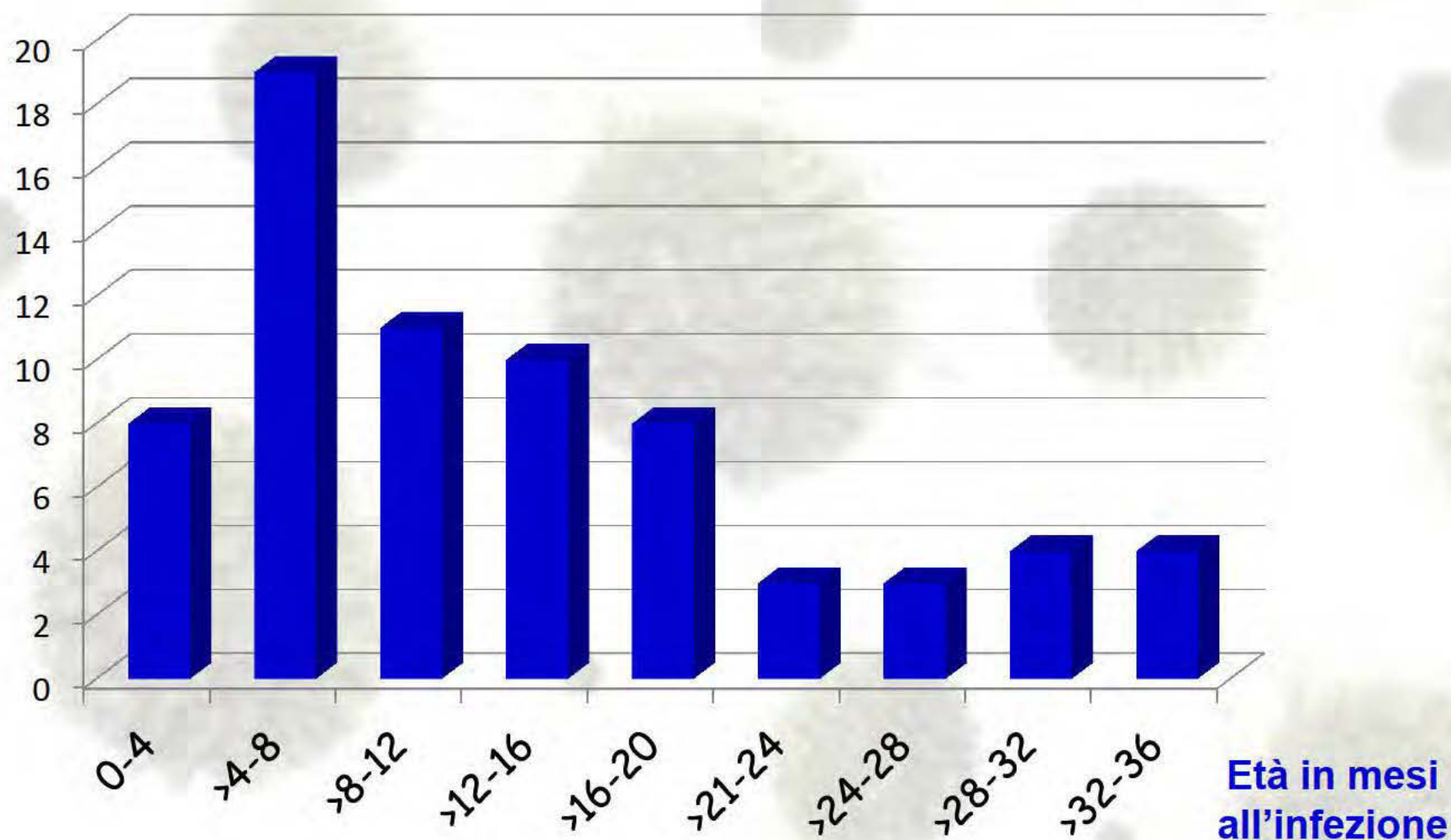


La copertura di MenB nei diversi Paesi è stata stimata tramite MATS (66-91% coverage)



Distribuzione dei casi di meningite/sepsi da MenB in Italia per età



Approvazione EMA in 31 Paesi europei



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 November 2012
EMA/CHMP/669278/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Bexsero

Meningococcal group B Vaccine (rDNA, component, adsorbed)

**Il 16 novembre 2012 EMA ha
rilasciato la Positive Opinion sul
vaccino contro il meningococco B**

**Il 14 Gennaio 2013 la Commissione
Europea ha autorizzato
l'immissione sul mercato del
vaccino contro il meningococco B**



Procedura Nazionale



Determina AIFA → 28 maggio 2013

Pubblicazione in GU → 14 giugno 2013



CLASSIFICAZIONE AI SENSI DELL'ART. 12, COMMA 5, LEGGE 8 NOVEMBRE 2012 N. 189 DI
MEDICINALI PER USO UMANO APPROVATI CON PROCEDURA CENTRALIZZATA

IL DIRETTORE GENERALE

Farmaci di nuova registrazione mediante procedura centralizzata.

BEXSERO

Codice ATC **Principio Attivo**

J07AH09 Meningococco B, vaccino multicomponente

Titolare NOVARTIS VACCINES AND DIAGNOSTICS S.R.L.

GUUE 22/02/2013 – corrigendum 02.05.2013

Scheda tecnica

4. INFORMAZIONI CLINICHE

4.1 Indicazioni terapeutiche

Bexsero è indicato per l'immunizzazione attiva di soggetti di età pari o superiore ai 2 mesi contro la malattia meningococcica invasiva causata da *Neisseria meningitidis* di gruppo B.

Approvazione in altri Paesi

Australia → 14 agosto 2013

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2013-PI-02131-1>



Canada → 9 dicembre 2013

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd_smd_2014_bexsero_147275-eng.php



Epidemiologia di MenB in Canada/Quebec

**Il sierogruppo B causa circa 110 casi di IMD/anno in Canada (1)
Dal 2002 al 2009 l'incidenza media annuale è di 0.23/100.000 (dati IMPACT) (1)**

**Il 48% dei casi di MenB nel periodo 2002-2009 si sono verificati in Quebec, la provincia con il 23% della popolazione canadese. (1)
Nel periodo 2006-2013, il 78% di tutti i casi di IMD in Quebec sono stati causati da MenB
L'incidenza nei soggetti con età ≤ 20 anni è di 2.1/100,000 abitanti (periodo 2006-2013)**

La regione di Saguenay-Lac-Saint-Jean è quella più colpita dalla malattia.

Negli ultimi 12 mesi, il tasso di infezione in soggetti con età ≤ 20 anni è di 12.04/100 000 abitanti, ovvero 7 volte più alto, se comparato a quello dell'intero Quebec (2)

(1) *Expert Rev. Vaccines* 12(5), 505–517 (2013);

(2) (2) SUCCESSFUL OPERATION First wave of vaccination against meningococcal B; Saguenay, June 19, 2014

Campagna Vaccinale in Quebec



Santé et Services sociaux Québec

Home Site map Contact us Quebec's portal Français

Search OK

Vaccination > Home

Vaccination

The best protection!

Vaccines stimulate our defense cells to produce substances called antibodies in what is an entirely natural protective reaction. These antibodies protect a vaccinated individual against disease caused by real germs.

Whether for you or your child, vaccination is a major ally.

Targeted Meningococcal Serogroup B Vaccination Campaign in the Saguenay-Lac-Saint-Jean Region

For a number of years, the number of people infected with meningococcal serogroup B has been much higher in the Saguenay-Lac-Saint-Jean region than in other Québec regions, relative to the population. The decision to implement this vaccination campaign in the Saguenay-Lac-Saint-Jean region is based on experts' recommendation due to its unique situation and to availability of a vaccine.

This meningococcal serogroup B vaccination campaign will run from May 5, 2014, to December 31, 2014. It targets individuals age 2 months to 20 years old who live or go to school in the Saguenay-Lac-Saint-Jean region. Vaccination is voluntary and free of charge.

Visit the page [Targeted Meningococcal Serogroup B Vaccination Campaign in the Saguenay-Lac-Saint-Jean Region](#) to find out more.

Get the Facts!

You have questions about vaccination? A health professional has recommended a vaccination to you. You aren't sure whether you should agree to the vaccination or refuse.

Home
Vaccination Schedule
Diseases
Vaccines
Immunoglobulin
FAQs
Documentation
Travel Health
Useful Links
Compensation

Questions and answers
Get the facts
Pneumococcal infections
VPH Vaccination program

- Offerta gratuita su base volontaria per tutti i **soggetti 2 mesi-20 anni e per i soggetti a rischio**
- A Giugno 2014 (conclusione della prima parte della campagna) **81%** soggetti “target → **45,638** hanno già ricevuto una prima somministrazione di vaccino MenB.

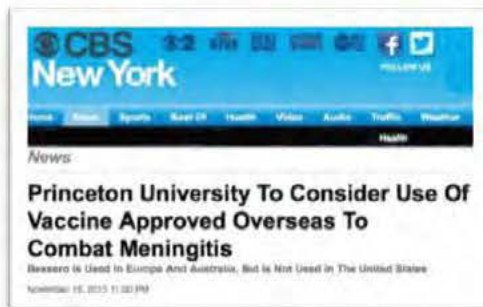
Princeton



- 8 casi

1. The first case was a female student who was away from campus for spring recess and developed symptoms of meningococcal disease on March 22, 2013 when returning to the area. This student has recovered.
2. The second case was a visitor on Princeton University campus from April 6-8, 2013 who was diagnosed with bacterial meningitis after returning to another state. This case is being followed by another state's health department.
3. The third case is a male student diagnosed with bacterial meningitis on May 7. This student has recovered.
4. The fourth case is a male student who resides out of state. The case developed symptoms on May 19, 2013 on his way home for summer recess. This case has recovered.
5. The fifth case is a male student who developed symptoms on June 29, 2013 while traveling abroad. This student has recovered.
6. The sixth case is a female student who developed symptoms of meningococcal disease on October 1, 2013. This student has recovered.
7. The seventh case is a male student who developed symptoms of meningococcal disease on November 8, 2013. This student is recovered.
8. The eighth case is a female student who developed symptoms of meningococcal disease on November 20, 2013. This student is recovered.

Men B Vaccine: Princeton



MenB Vaccine: Princeton



MenB Vaccine: Princeton



VACCINE

CLINIC

MENINGITIS B VACCINE CLINIC

FIRST DOSE
December 9, 10, 11 and 12
Noon to 8 p.m.
First Campus Center
Level B multipurpose rooms

- Wait times are expected
- Two doses are needed for maximum protection. A second dose is expected to be available in February.

WHO CAN GET THE VACCINE

- All undergraduate students
- Graduate students living in the Graduate College, Graduate College Annexes and the undergraduate dorms
- University community members who have certain medical conditions*

* Problems with their spleen (including sickle cell disease) or complement pathway disorder (a specific type of immune deficiency). Persons with these conditions should check the University's meningitis information website for further instructions.

COST

- Free

REQUIRED

- Sign a vaccine consent form
- Students under 18: Bring permission form signed by parent/guardian
- Bring your Princeton University I.D.

web.princeton.edu/sites/emergency/meningitis.html

- The Meningitis B vaccine helps protect against Type B meningitis, the strain causing the outbreak at Princeton University.
- Meningitis can be fatal and the progression of disease can be rapid.
- The Centers for Disease Control and Prevention (CDC) recommends eligible campus groups get vaccinated.

MenB Vaccine: Princeton



talk to a real person
855-374-4687



chat with a real person
LIVE CHAT NOW

Menge Shirts

Group Sign-up Sheet

Welcome!

Please enter the quantity and sizes you want before December 28th! Princeton Students: I will contact you when the shirts arrive with information for pick-up times and locations. When you pick up your shirt, please come with cash or pay via Venmo (I'm listed as Solveig Gold). Others Customers: I will be in touch with you individually about shipping and payment. Generally, you will pay via Venmo or send a check to my campus address. Feel free to send me an email if you have any questions!

Solveig Gold (slgold@princeton.edu)

What We're Ordering



Sign-up Status

181 People
Have Already Signed Up

Sign-up is Closed

Please contact Solveig Gold if you have questions.

View Sizing Line-UpSM

- Product: American Apparel 50/50 T-shirt
- Sizes: XS-2XL

MenB Vaccine: Santa Barbara



Barbara students diagnosed with meningitis

Aaron Loy had both feet amputated due to illness

POSTED: 12:56 PM, Dec 3, 2013

UPDATED: 8:13 PM, Dec 3, 2013



MenB Vaccine: Santa Barbara



Meningitis B Vaccine Clinic

The serogroup B vaccine helps protect against the type of meningococcal disease causing the outbreak at UC Santa Barbara. Meningitis can be fatal and the progression of disease can be rapid. The Centers for Disease Control and Prevention (CDC) recommends eligible campus groups get vaccinated.

[studenthealth.sa.ucsb.edu/
Meningitishealthalert.aspx](http://studenthealth.sa.ucsb.edu/Meningitishealthalert.aspx)



WHEN CAN I GET THE FIRST DOSE OF VACCINE?

Monday, February 24, Noon-6 p.m. and February 25-March 7, weekdays, 10 a.m.-6 p.m., at the MAC (Multi-Activity Court), Recreation Center

- Wait times are expected.
- Two doses are needed for maximum protection. A second dose is expected to be available in spring quarter.

WHO CAN GET THE VACCINE?

- All undergraduate students, and University Immersion Program students
- Faculty, staff and graduate students living in UCSB-owned dormitory-style residence halls or who have certain medical conditions*

**Those without a spleen or who have problems with their spleen (including sickle cell disease) or persistent complement component deficiencies (C5-C9, properdin, factor H, factor D).*

WHAT ELSE DO I NEED TO KNOW?

- A signed consent form (available at the clinic) is required.
- Bring your UCSB Access card or photo ID.
- Students under 18: Bring signed "Parent/Legal Guardian Permission Form."
- More information is available at the Student Health website.

HOW MUCH DOES THE VACCINE COST?

- There is no cost to those receiving the vaccine.

Vaccinazione nei Campus USA, Università di Princeton e Santa Barbara

- **PRINCETON**
- Il 90% degli studenti del college Princeton è stato vaccinato con due dosi di Bexsero



- **SANTA BARBARA**
 - 51% degli studenti ha ricevuto la prima dose di vaccino
 - 37% degli studenti ha ricevuto la seconda dose



In totale **21,000** dosi somministrate

ACIP- meeting febbraio 2014

<http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2014-02/04-Mening-Patel.pdf>

ACIP Home Page

Recommendations

Meetings

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Vaccines Home > ACIP Home Page > ACIP Meetings > ACIP Meeting Information

ACIP Presentation Slides: February 2014 Meeting

February 26-27, 2014

February 26, 2014

Welcome

- Opening Remarks (6 pages)
Dr. L. Pickering
Dr. J. Tarrille

Influenza

- New Influenza vaccine work group (8 pages)
Dr. D. Caillat-Culot
- Introduction (3 pages)
Dr. A. Kramarz
- Influenza activity update (1, 22 MB, 21 pages)
Dr. L. Finelli
- Interim estimates of 2013-2014 seasonal influenza vaccine effectiveness (19 pages)
Dr. B. Ramsey
- Effectiveness of Live-Attenuated vs. Inactivated Influenza Vaccines for Healthy Children (GRADE) (27 pages)
Dr. L. Grijakowski
- Interim Influenza Vaccine Safety Update (21 pages)
Dr. H. Cano
- LAIV vs. IIV Comparative Safety Studies in Children (22 pages)
Dr. C. Walter
- Safety of Live-Attenuated vs. Inactivated Influenza Vaccines for Healthy Children (GRADE) (13 pages)
Dr. L. Grijakowski
- LAIV supply update (8 pages)
Dr. K. Coelingh
- Annual Influenza Recommendations (3 pages)
Dr. V. Chakravarti

Meningococcal Vaccine

- Introduction (7 pages)
Dr. L. Rubin
- Meningococcal Disease Among Men Who Have Sex with Men (MSM) (18 pages)
Dr. J. Meitell
- Meningococcal Disease Among Men Who Have Sex with Men (MSM) (20 pages)
Dr. J. Meitell
- Outbreaks of Serogroup B Meningococcal Disease on University Campuses – 2013 (10 pages)
Dr. M. Patel

Pneumococcal Conjugate Vaccine (PCV)

- Introduction (10 pages)
Dr. V. Barnard
- Update on Effectiveness and Impact of PCV13 use among U.S. Children (13 pages)
Dr. W. Roane
- GRADE for 3-dose PCV13 schedule (56 pages)
Dr. S. Tomasz
- Considerations for a 3-dose PCV13 schedule for infants (1 MB, 44 pages)
Dr. T. Arslan

Yellow Fever Vaccine

- Introduction and ACIP Japanese Encephalitis (JE) and Yellow Fever (YF) Vaccines Work Group (25 pages)
Dr. J. Baccin
Dr. E. Staples

Vaccine Supply

- Vaccine supply update (6 pages)
Dr. J. Sanfilippo

On this page

- Welcome
- Influenza
- Meningococcal Vaccines
- Pneumococcal Conjugate Vaccine (PCV)
- Yellow Fever Vaccine
- Vaccine Supply
- General Recommendations
- Safety of Tdap
- HPV Vaccine
- Smallpox Vaccine

Contact ACIP

Advisory Committee on Immunization Practices (ACIP)
1600 Clifton Road, N.E., Mailstop A27
Atlanta, GA 30333
1-404-639-8636
acip@cdc.gov

Contact Us:

Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333
800-CDC-INFO (800-232-4636)
TTY: (888) 232-6343
Contact CDC-PR

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Outbreaks of Serogroup B Meningococcal Disease on University Campuses – 2013

Manisha Patel, MD MSc

Medical Officer

Meningitis and Vaccine Preventable Diseases Branch

National Center for Immunization & Respiratory Diseases
Division of Bacterial Diseases



ACIP- meeting Febbraio 2014 : Dati di Safety

<http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2014-02/04-Mening-Patel.pdf>

Safety Follow-Up

- ❑ **Mandatory reporting of all serious adverse events (SAEs) to FDA**
 - Include death, a life-threatening adverse event (AE), hospitalizations, substantial disruption in the ability to conduct normal life functions, or a congenital anomaly/birth defect
- ❑ **To date, rate of SAEs reported is 2.0/1,000 vaccinees following the first dose and 0.2 /1,000 vaccinees following the second dose**
 - No SAEs have been determined to be causally related to rMenB
- ❑ **No concerning patterns among other types of AEs reported**

Vaccino MenB: breakthrough therapy



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

April 1, 2014

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Our Reference: IND 11561

**GRANT BREAKTHROUGH
THERAPY DESIGNATION**

National Foundation for Infectious Diseases



Addressing the Challenges of Serogroup B Meningococcal Disease Outbreaks on Campuses:

A report by the National Foundation for Infectious Diseases

Addressing the Challenges of serogroup B meningococcal Disease Outbreaks on Campuses. A report By NFID; May 2014

Challenges and Recommendations

Licensure of meningococcal serogroup B vaccines will have the single greatest impact on improving responses to future outbreaks.

Once the serogroup B vaccines are licensed, the CDC Advisory Committee on Immunization Practices (ACIP) will provide recommendations for their use in endemic and outbreak circumstances.

However, because of the extreme nature and epidemiology of meningococcal disease, the changing epidemiology, and the experience of recent outbreaks, the panel did advance some thoughts about the potential ways serogroup B meningococcal vaccines might be used.

The logic of adding serogroup B prevention to current routine immunization strategies was discussed. If invasive meningococcal disease is severe enough to warrant routine immunization with one of the currently available vaccines, and the current high vaccine coverage rates would argue that healthcare professionals (HCPs) and parents believe it is, then we must give equal weight to preventing disease caused by all serogroups, not just those in the current quadrivalent vaccines. The panel recognized the public health challenges of adding vaccine doses for adolescents. The panel concluded that a CDC recommendation that goes beyond outbreak control will provide a possible solution, vaccination. It may also facilitate insurance coverage for vaccinations.

Increased efforts needed to educate and raise awareness among HCPs about invasive meningococcal disease presentation.

There was a spectrum of clinical presentations in the two recent college outbreaks. Clinicians who were more alert to the possibility of invasive meningococcal disease appeared more likely to make a rapid diagnosis. Since this disease is rare, clinicians, especially younger ones, may have little to no personal experience in diagnosing it. We must, therefore, increase efforts to educate HCPs on all of the potential clinical markers for the disease.

Even in the setting of a known outbreak, clinicians failed to make diagnoses of disease, because of the absence of expected (or anticipated) clinical markers or failure to recognize markers. Situational awareness must be improved among HCPs so that they have invasive meningococcal disease in the differential diagnosis during campus outbreaks. Decision-making tools incorporated into the electronic medical record, along with electronic information flow between public health professionals and

clinicians that support these tools can provide powerful educational messages in real-time during an encounter.

Meningococcal disease incidence is well known to be cyclical. If US incidence increases again, our public health and healthcare systems need to be prepared. This includes making sure younger clinicians know how to recognize, diagnose, and treat cases, and report them promptly to public health authorities.

Educational resources need to be readily available for the public when outbreaks occur.

Educating affected populations about risk reduction and convincing college students to minimize risk may mean an undesirable change in lifestyle to many. Students are unlikely to alter their social behaviors except in cases where their fear is heightened (e.g., during an outbreak), so it is essential to reach them as quickly as possible after a case is reported.

It is extremely difficult to deliver definitive messages in the face of such an uncertain disease. An evidence-based social marketing campaign that addresses both vaccination and healthy behaviors can be developed for ready use during outbreaks to help universities provide reassurance and accurate information in a timely manner. These campaigns can also contain materials that can be used proactively before an outbreak occurs.

The FDA should communicate clearly about the new licensure pathway for meningococcal serogroup B vaccines.

A new "breakthrough therapy" pathway has been established by the FDA and serogroup B meningococcal vaccines are the first vaccines to be granted review under this new procedure. The FDA should communicate clearly about its process and licensure steps, as well as anticipated timing, so that the concerned public is informed.

In this case, data from geographical locations with much higher incidence of serogroup B disease may prove useful, facilitating rapid FDA assessment of vaccine safety and efficacy.

Media need to be engaged in a thoughtful and positive way by all stakeholders.

Media coverage can heighten public fear and may not always provide accurate and balanced information that communicates what public health officials know and

JCVI position statement on use of Bexsero® meningococcal B vaccine in the UK

March 2014

Recommendation

JCVI recommended a programme for use of the MenB vaccine with the NHS immunisation schedule at 2, 4, 12 months of age (2+1) in a carefully planned programme. Given the vaccine only demonstrated cost-effectiveness at a low price, plans for implementation should anticipate a sustainable and cost-effective programme.

The JCVI did not recommend a 5-12 month catch up as it had not been specifically considered in the cost-effectiveness analysis. When assessing 1-4 year old catch-up, in view of the marginal cost-effectiveness of even the base programmes (i.e. without catch up), the JCVI considered that the priority should be the implementation of the primary immunisation programme. JCVI further advised that once a MenB vaccination programme was established in infants, and once the MenC vaccination programmes in adolescents and those entering university were established (programmes which would provide indirect protection of infants against MenC disease) that the infant dose of MenC currently given at three months of age should be removed from the schedule.

JCVI further advised that a targeted carriage study be undertaken in adolescents to assess the impact of Bexsero® on the acquisition of meningococcal carriage. Such a study should significantly reduce uncertainty associated with the impact of Bexsero® on the acquisition of meningococcal carriage in adolescents, and guide future decision making by the Committee on the impact and cost-effectiveness of an adolescent programme in the UK.

JCVI agreed to review the impact of an infant programme, (should a cost-effective price be agreed on); evidence on the impact of Bexsero® on carriage in teenagers; the cost-effectiveness of an adolescent programme; the MenC vaccination programme for teenagers; and the merits of reducing the number of doses of MenC vaccinations provided in infancy, within the next two years.

JCVI

21 March 2014

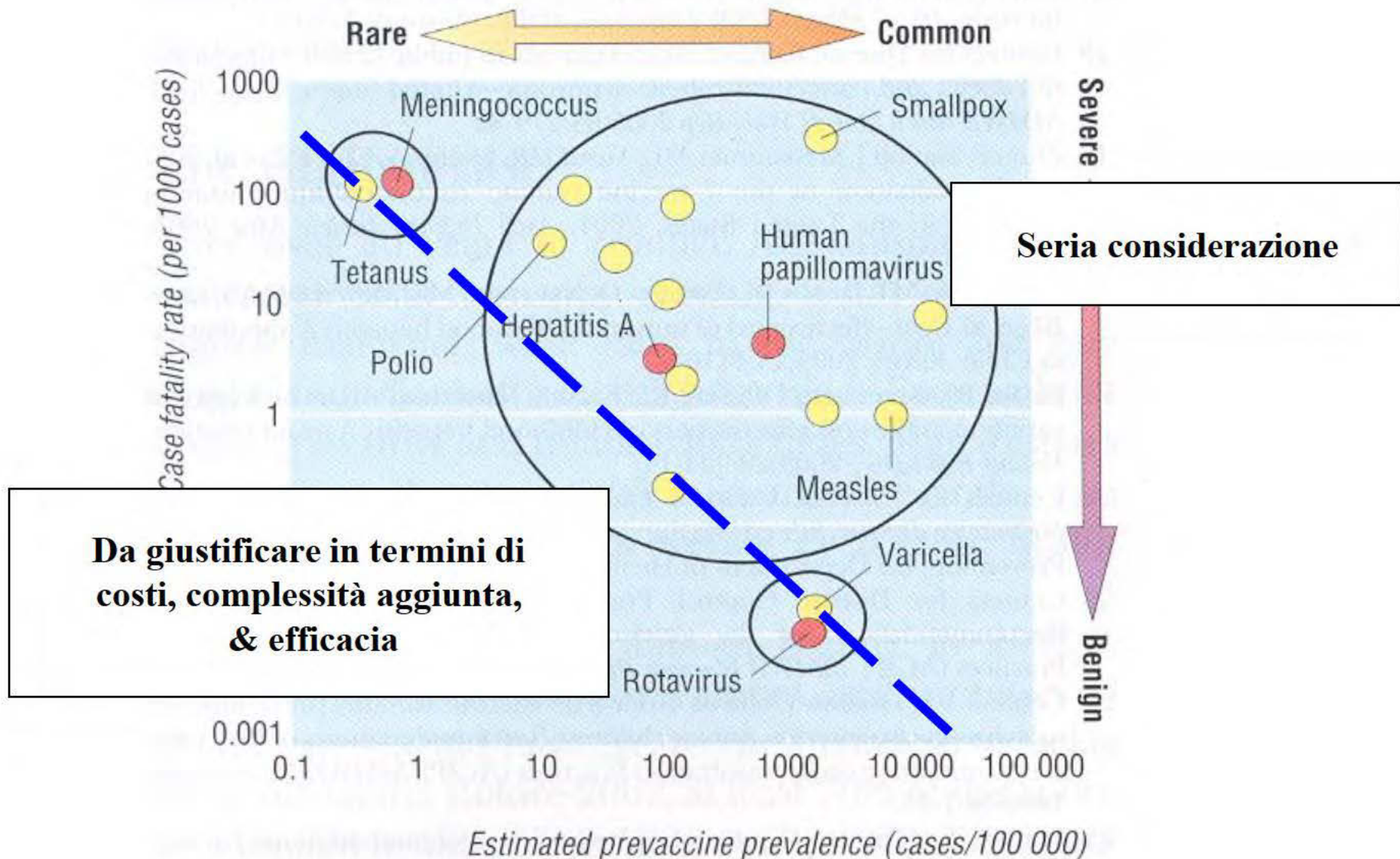


Fig 2 Mortality and prevaccine prevalence of vaccine preventable diseases in the United States. Recently recommended and future candidate vaccines shown in red ^{11 22-25}

Il Vaccino MenB

« *Problema?* »

Opportunità

Indicazioni su numero di dosi e loro intervalli

Gruppo di età	Immunizzazione primaria	Intervallo tra dosi	Richiamo
Lattanti da 2 a 5 mesi	Tre dosi da 0,5 ml ciascuna con la prima dose somministrata all'età di 2 mesi	Almeno 1 mese	Sì, una dose tra i 12 e i 23 mesi
Lattanti da 6 a 11 mesi	Due dosi da 0,5 ml ciascuna	Almeno 2 mesi	Sì, una dose nel secondo anno di vita con un intervallo di almeno 2 mesi tra il ciclo primario e la dose di richiamo
Bambini da 12 a 23 mesi	Due dosi da 0,5 ml ciascuna	Almeno 2 mesi	Sì, una dose nell'intervallo compreso tra 12 e 23 mesi tra il ciclo primario e la dose di richiamo
Bambini da 2 a 11 anni	Due dosi da 0,5 ml ciascuna	Almeno 2 mesi	Non è stata stabilita la necessità di una dose di richiamo
Adolescenti e adulti > 11 anni	Due dosi da 0,5 ml ciascuna	Almeno 1 mese	Non è stata stabilita la necessità di una dose di richiamo

Schedule → Proposte

Lattanti 2-5 mesi (schedule 3+1)							Sedute aggiuntive ¹ (in rosso)
SENZA CO-SOMMINISTRAZIONE DI 3 VACCINI NELLA STESSA SEDUTA							
Opzione A. Mix	3°	4°	5°	6°	8°	11°	13°- 15°
	Esa MenB	Pneumo ² MenB	Esa Pneumo	MenB		Esa Pneumo	MPRV MenC ³ MenB
Opzione B. Intercalata	3°	4°	5°	6°	8°	11°	13°- 15°
	Esa Pneumo	MenB	Esa Pneumo	MenB	MenB	Esa Pneumo	MMRV MenC MenB
CON CO-SOMMINISTRAZIONE DI 3 VACCINI NELLA STESSA SEDUTA							
Opzione C. Cosomministrata	3°	4°	5°	6°	8°	11°	13°- 15°
	Esa Pneumo MenB		Esa Pneumo MenB	MenB		Esa Pneumo	MPRV MenC MenB
Opzione D. Cosomministrata parziale	3°	4°	5°	6°	8°	11°	13°- 15°
	Esa Pneumo	MenB	Esa Pneumo MenB	MenB		Esa Pneumo	MPRV MenC MenB
Bambini 6-23 mesi (schedula 2+1)⁴							
	3°	4°	5°	6°	8°	11°	13°- 15°
	Esa Pneumo		Esa Pneumo	MenB	MenB	Esa Pneumo	MPRV MenC MenB

Proposta del Board SItI e del 'Calendario per la Vita' sull'inserimento del vaccino anti-meningococco B nel calendario delle vaccinazioni dell'infanzia

3° mese	4° mese	5° mese	6° mese	11° mese	13° mese	14° mese- 23° mese
Esavalente + PCV13 <i>Ad inizio 3° mese (61° giorno di vita)</i>		Esavalente + PCV13 <i>Dopo 15 giorni dalla seconda dose di MenB ad inizio 5° mese (121° giorno di vita)</i>		Esavalente + PCV13		
					MPR o MPRV	
MenB <i>Dopo 15 giorni da Esavalente + PCV (76° giorno di vita)</i>	MenB <i>Dopo 1 mese dalla prima dose MenB (106° giorno di vita)</i>		MenB <i>Dopo 1 mese dalla seconda dose Men B , ad inizio 6° mese (151° giorno di vita)</i>		MenB*	
						MenC

* In eventuale co-somministrazione con altri vaccini del 2° anno di vita, in funzione dei calendari regionali

Vantaggio: effettuazione delle 3 dosi del ciclo di base con Men B in tempi rapidi, rispetto dell'attuale calendario per le vaccinazioni di routine, facilità per il genitore di rammentare il successivo appuntamento

Svantaggio: 3 sedute aggiuntive in tempi brevi

In caso di ritardo al successivo appuntamento possibilità di proporre la simultanea somministrazione di 3 vaccini (Esavalente + Pneumo + Men B)

COMUNICATO STAMPA



Da SIItI, SIP, FIMP e FIMMG l'appello a offrire gratuitamente il vaccino contro il meningococco B a tutti i lattanti italiani

Inserire il nuovo vaccino anti-meningococco B tra quelli offerti gratuitamente e attivamente ai lattanti. È la proposta che arriva dal Board del 'Calendario per la Vita', composto da Società Italiana di Igiene, Medicina Preventiva e Sanità Pubblica (SIItI), Società Italiana di Pediatria (SIP), Federazione Italiana Medici Pediatri (FIMP) e Federazione Italiana Medici di Medicina Generale (FIMMG). "Le patologie invasive da meningococco, pur non frequenti, costituiscono una seria minaccia alla salute e sono, tra le malattie prevenibili mediante vaccino, quelle percepite come più drammatiche dalla popolazione - si legge in un documento condiviso da SIItI, SIP, FIMP e FIMMG -. Il verificarsi anche di relativamente pochi casi di malattia rappresenta un evento drammatico, gravato da un'elevata probabilità di morte e di sequele permanenti. La vaccinazione contro il meningococco B rappresenta una necessità epidemiologica, ma anche etica e comunicativa non eludibile. Per tali ragioni, il Board del 'Calendario per la Vita' raccomanda il suo utilizzo per la vaccinazione gratuita di tutti i lattanti". Certo la scelta della collocazione delle dosi di meningococco B da inoculare rappresenta "un problema di non facile risoluzione, considerate le contrastanti necessità di effettuare 4 somministrazioni nel volgere di pochi mesi, di non effettuare più di 2 iniezioni simultaneamente e, nel limite del possibile, di evitare le co-somministrazioni del vaccino anti-meningococco B con altri vaccini, visto l'incremento delle febbri di grado moderato/elevato conseguente alla co-somministrazione", ma non riscontrabile dopo la sola vaccinazione contro meningococco B. Pur lasciando ai decisori territoriali la valutazione finale della schedula migliore in funzione dell'offerta vaccinale locale e delle sue tempistiche, le Società scientifiche e le Federazioni che hanno condiviso il documento in oggetto ritengono utile "suggerire uno schema di inserimento della vaccinazione anti-meningococco B nel 'Calendario della Vita', che rappresenta una modalità concreta di introduzione di questa nuova fondamentale possibilità preventiva". La sequenza di vaccinazione che viene raccomandata è la seguente:

Calendario Vaccinale per la Vita 2014 (Siti, SIP; FIMP, FIMMG)

Vaccino	0gg-30gg	3° mese	4° mese	5° mese	6° mese	7° mese	11° mese	13° mese	15° mese	⇌	6° anno	12°-18° anno	19-49 anni	50-64 anni	> 64 anni
DTPa		DTPa		DTPa			DTPa				DTPa**	dTpaIPV	1 dose dTpa*** ogni 10 anni		
IPV		IPV		IPV			IPV				IPV				
Epatite B	EpB-EpB*	Ep B		Ep B*			Ep B						3 Dosi: <i>Pre Esposizione</i> (0, 1, 6 mesi) 4 Dosi: <i>Post Esposizione</i> (0, 2, 6 sett. + booster a 1 anno) o <i>Pre Esposizione imminente</i> (0, 1, 2, 12)		
Hib		Hib		Hib			Hib								
Pneumococco		PCV13		PCV13			PCV13	PCV13 ^{AA}			PCV13/PPV23 (vedi note)		PCV13		
MPRV								MPRV			MPRV				
MPR								MPR			oppure MPR	MPR oppure MPR	2 dosi MPR**** + V (0-4/8 settimane)		
Varicella									V		+ V				
Meningococco C								Men C o MenACWY	Men C o MenACWY			MenACWY coniugato 1dose			
Meningococco B		Men B	Men B		Men B			Men B	Men B						
HPV												HPV*: 2-3 dosi (in funzione di età e vaccino); fino a età massima in scheda tecnica			
Influenza							Influenza ^{oo}					1 dose all'anno	1 dose all'anno		
Herpes Zoster															1 dose#
Rotavirus		Rotavirus##													
Epatite A									EpA###			EpA###	2 dosi (0-6-12 mesi)		

Cosomministrare nella stessa seduta		Opzioni di cosomministrazione nella stessa seduta o somministrazione in sedute separate
Somministrare in seduta separata		Vaccini per categorie a rischio

Regione Basilicata



1° delibera regionale in Italia N. 5 - BOLLETTINO UFFICIALE DELLA REGIONE BASILICATA 24-2-2014

REGIONE BASILICATA

DIPARTIMENTO SALUTE
SICUREZZA E SOLIDARIETÀ SOCIALE
SERVIZI ALLA PERSONA E ALLA COMUNITÀ
UFFICIO POLITICHE DELLA PREVENZIONE,
SANITÀ PUBBLICA, MEDICINA DEL LAVORO,
SICUREZZA NEI LUOGHI DI VITA E LAVORO

001/07/1.2014/001
gabriele.concilio@regione.basilicata.it

Inoltre, per i soggetti che hanno ricevuto il ciclo primario di immunizzazione prima dei 2 anni di età, è prevista la somministrazione di una dose di richiamo (booster).

Strategia vaccinale

In merito alla strategia vaccinale da adottare la Regione Basilicata concide e raccomanda la seguente modalità intercalata di somministrazione del vaccino antimeningococcico B per l'anno 2014:

- 61° giorno (3° mese) ESA-PCV;
- 75°/90° giorno (3° mese + 15/30 giorni) **Meningococco B**;
- 121° giorno ESA-PCV (5° mese);
- 135°/150° giorno **Meningococco B** (5° mese + 15/30 giorni);
- 181°/210° giorno **Meningococco B** (7° mese + 15/30 giorni);
- 11° mese ESA-PCV;
- dopo il 13° mese **Meningococco B**.

Il vantaggio di questa proposta risiede:

- nel conferire un'adeguata protezione prima del picco di casi di Meningococco B;
- limitare eventuali complicazioni legate alla reattogenicità;
- utilizzare la possibilità di effettuare la co-somministrazione dei tre vaccini come recupero della seduta vaccinale eventualmente persa o dove necessario per problemi organizzativi e di compliance;
- sfruttare la prima seduta vaccinale (ESA+PCV) per informare i genitori riguardo la successiva vaccinazione antimeningococcica;
- nel poter meglio gestire l'inserimento di ulteriori nuove vaccinazioni, quali l'antirrotavirus.

3° mese (2 mesi)	3°- 4° mese (3 mesi)	5° mese (4 mesi)	5°-6° mese (5 mesi)	7°-8° mese (6 mesi)	11° mese (10 mesi)	Dopo il 13° mese
Esa		Esa			Esa	
PCV13		PCV13			PCV13	MenC
	MenB		MenB	MenB		MenB

3+1 intercalata

Regione Puglia



Regione Puglia

Deliberazione della Giunta Regionale

N. 958 DEL 20-05-2014

Commissione Regionale Vaccini. Modifica Calendario Regionale per la vita 2012 - DGR 241/2013. Approvazione nuovo Calendario Vaccinale per la vita 2014.

3° mese (2 mesi)	3° + 15gg	4° mese (3 mesi)	5° mese (4 mesi)	6° mese (5 mesi)	11° mese (10 mesi)	Dopo il 13° mese
Esa			Esa		Esa	
PCV13			PCV13		PCV13	MenC
	MenB	MenB		MenB		MenB

3+1 intercalata