Meningococcen

TOM VERCRUYSSE

AZ SINT-LUCAS GENT

Meningococcal disease : waarom is immunisatie belangrijk ?

- Zeer destructieve infectie
  - Pediatrische populatie (tienmaal meer bij -2jarigen dan in algemene bevolking)
  - Voordien gezond
  - Hyperacuut
  - Mortaliteit/morbiditeit quasi onveranderd sinds jaren ‘70

- Verwekker en Incidentie
- Klinisch beeld
- Diagnostiek
- Behandeling
- Vaccinatie

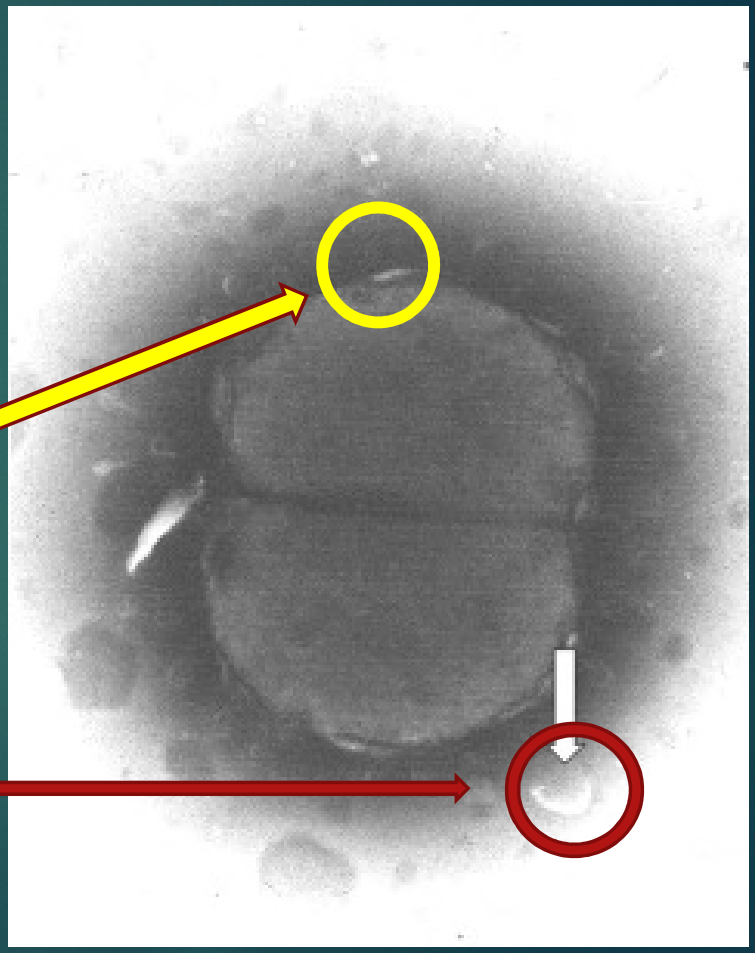
Verwekker en Incidentie

Meningococcal disease

- **Neisseria meningitidis**
  - **1805** (Vieusseux) : *fièvre cérébrale maligne non contagieuse*

    1887 (Weichselbaum) : *diplococcus*

    intracellularis meningitis
  - **Gram negatieve diplococ**
    - Anaeroob
    - Fimbria : binding aan CD46 receptoren
    - Polysaccharide kapsel
      - Resistent aan fagocytose
      - 13 serotypes, waarvan 6 dominante : A,B,C, W-135, X en Y
    - Lipopolysacharide in kapsel = endotoxine
      - Release van inflammatoire mediatoren

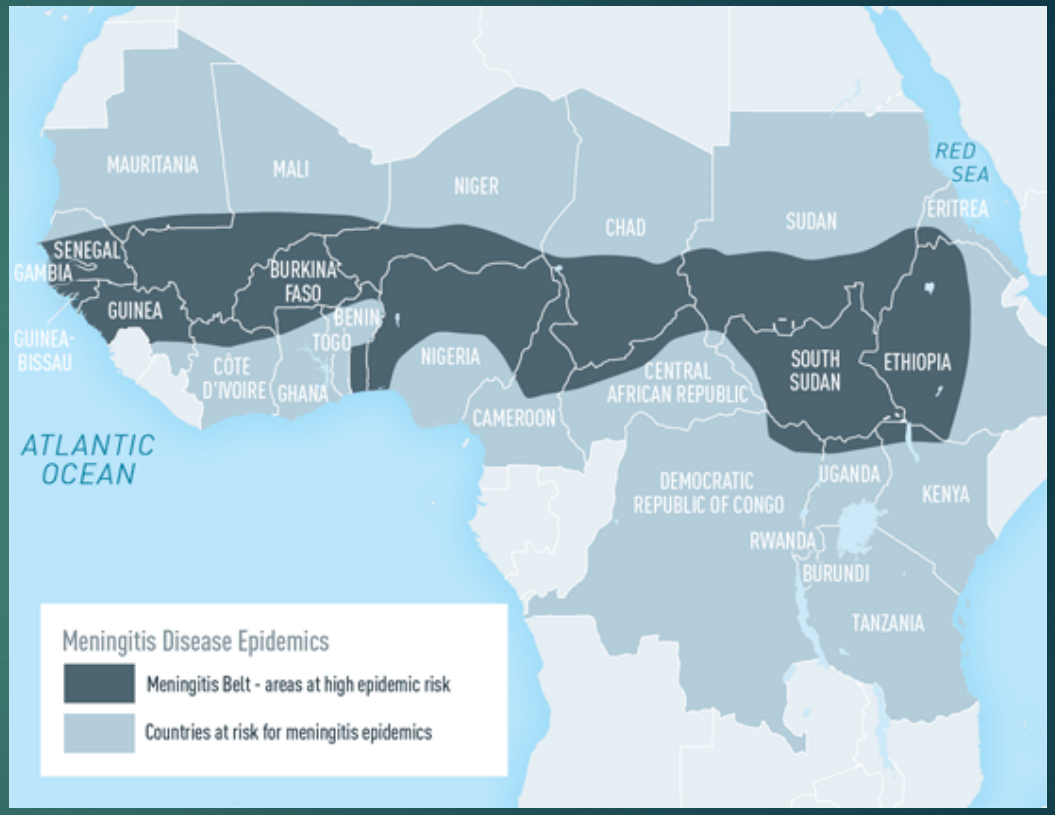


Verwekker en Incidentie

- Mens is enige natuurlijke gastheer
  - Naso-faryngeaal
  - Anale mucosa
  - Conjunctiva
  - Urogenitale tractus
- Asymptomatische drager
  - 2%-4,5% bij kinderen onder 5 jaar
  - Piek van 20-25% adolescenten – jongvolwassenen
  - 8% 50-jarige volwassenen
- Infectie via droplets (aërosol)
  - Overleeft niet / close contact

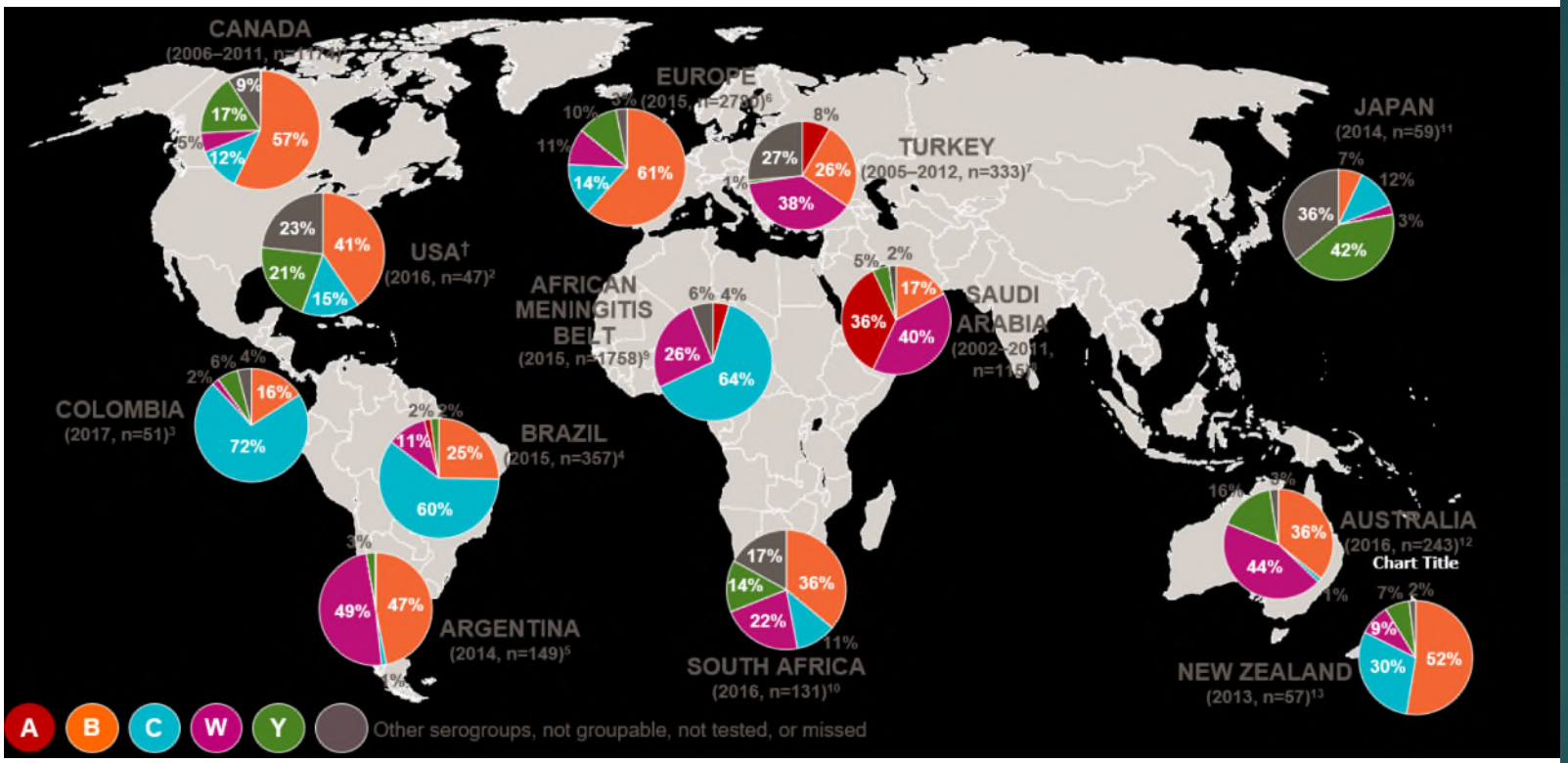
Verwekker en Incidentie

- Incidentie
  - Wereldwijd : 500,000/jaar
  - Epidemisch : ‘African meningitis belt’
    - 1200/100,000
  - Endemisch : Noord-Amerika, Europa en Australia
    - 0,3-3/100,000



Five *Neisseria meningitidis* serogroups cause the majority of IMD, which vary across countries and regions*

Verwekker en Incidentie



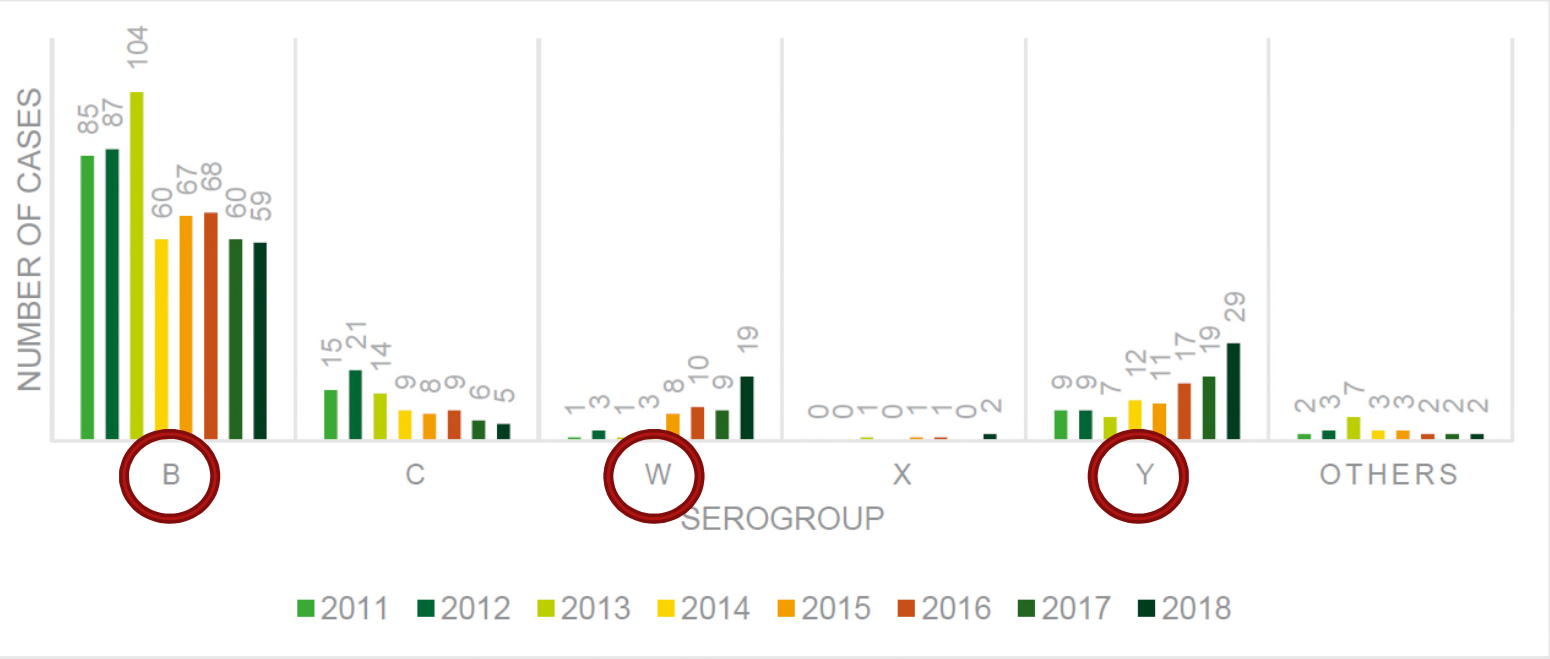
*Serogroup distribution cannot be directly compared across countries due to variability in surveillance data availability; †USA: 23% 'other' serogroups includes serogroup W and non-groupable; surveillance data cover only some areas of the USA, representing ~44.2 million people;[2] IMD, invasive meningococcal disease

Figure adapted from: 1. Li YA *et al*. *Can Commun Dis Rep* 2014;40(9):160–171; 2. Active Bacterial Core surveillance (ABCs). Surveillance reports, *Neisseria meningitidis*, 2016. Centers for Disease Control and Prevention. https://www.cdc.gov/abcs/reports-findings/survreports/mening16.pdf; 3. Vigilancia por laboratorio *Neisseria meningitidis* (aislaminetos invasores) periodo 1987–2017. Instituto Nacional de la Salud. Grupo de Microbiologia. 2018. https://www.ins.gov.co/buscador-eventos/Informacin%20de%20laboratorio/Informe%20Vigilancia%20por%20Laboratorio%20de%20N%20%20meningitidis%202017.pdf; 4. Ministry of Health / SVS – Notifiable Diseases Information System – SINAN Net. http://tabnet.datasus.gov.br/cgi/tabcgi.exe?sinannet/cnv/meninbr.def; 5. Servicio Bacteriología Clínica-Departamento Bacteriología-INEI-ANLIS Dr.C.G. Malbrán-ARGENTINA. SIREVA II. http://antimicrobianos.com.ar/ATB/wp-content/uploads/2015/09/Tablas-vigilancia-SIREVA-II-Nm-2014-Argentina1.pdf; 6. ECDC. Surveillance Report: Annual Epidemiological Report for 2015, 1999–2015. https://ecdc.europa.eu/sites/portal/files/documents/AER_for_2015-meningococcal-disease.pdf; 7. Ceyhan M *et al*. *Hum Vaccin Immunother* 2014;10:2706–2712; 8. Memish Z *et al*. *Euro Surveill* 2013;18:pii=20581; 9. WHO. 2016. *Wkly Epidemiol Rec* 2016;91:209–216; 10. National Institute for Communicable Diseases. GERMS–South Africa Annual Report 2016. http://www.nicd.ac.za/wp-content/uploads/2017/03/GERMS-SA-AR-2016-FINAL.pdf; 11. Fukusumi M *et al*. *Vaccine* 2016;34:4068–4071; 12. Australian Meningococcal Surveillance Programme annual report 2016. http://www.health.gov.au/internet/main/publishing.nsf/Content/52063507BA07755ECA25823300191E9B/$File/cdi4104-i.pdf; 13. Lopez L *et al*. The epidemiology of meningococcal disease in New Zealand in 2013. Institute of Environmental Science and Research Ltd (ESR), 2014. https://surv.esr.cri.nz/PDF_surveillance/MeningococcalDisease/2013/2013AnnualRpt.pdf (all weblinks accessed Feb. 2020)

PM-BE-BEX-PPT-200018 - July 2020

Belgium from 2011 to 2018:
Evolution of IMD confirmed cases per serogroups

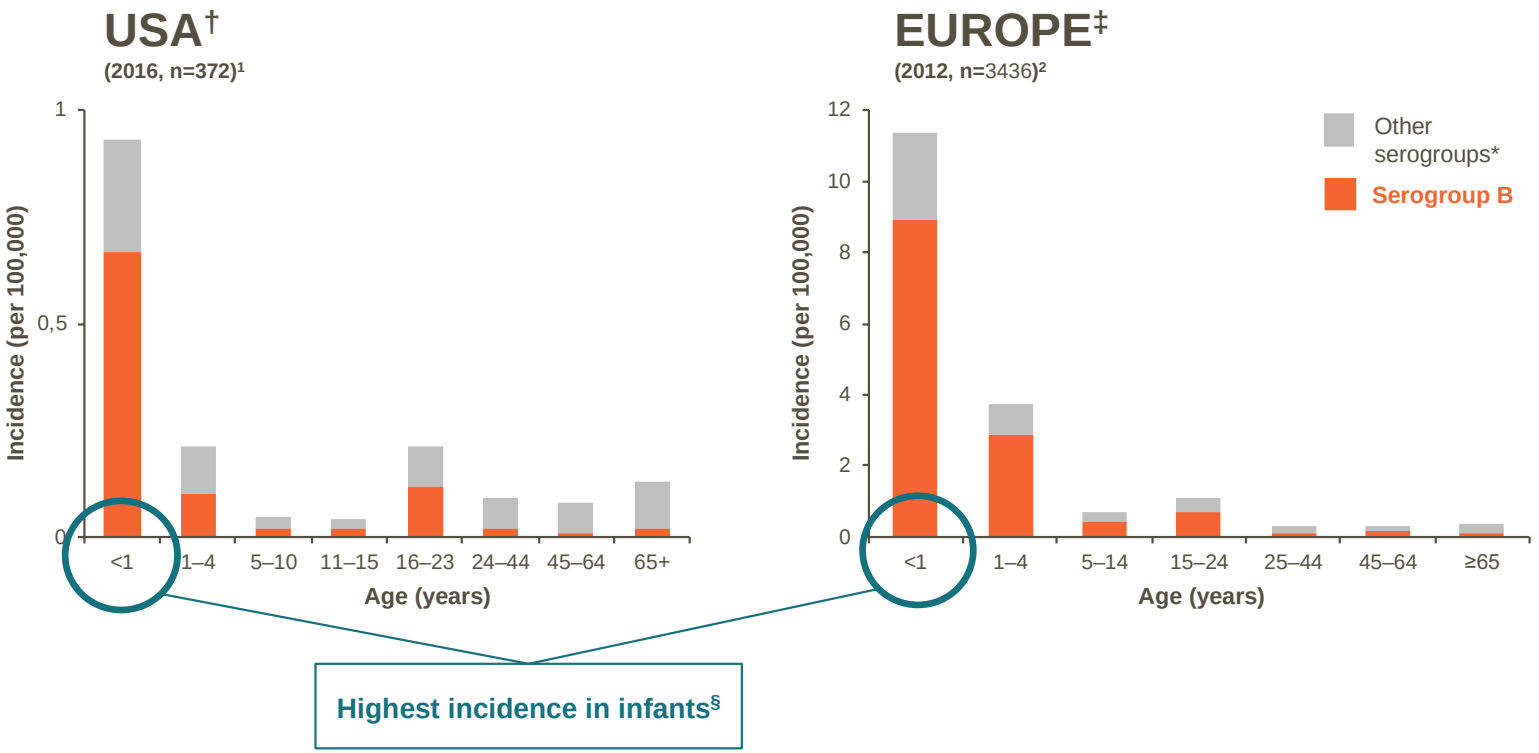
Verwekker en Incidentie



Adapted from Surveillance épidémiologique des infections invasives à méningocoques – 2018 – Sciensano available at https://epidemio.wiv-isp.be/id/pages/publications.aspx Accessed Feb. 2020

MenB incidence is generally highest in infants and young children, with a smaller peak in adolescents

Verwekker en Incidentie



The same results were first published in CDC, 2017. http://www.cdc.gov/meningococcal/surveillance/ (left figure) and the European Centre for Disease Prevention and Control (ECDC). Surveillance report, 2012. http://ecdc.europa.eu/en/publications/Publications/Surveillance%20of%20IBD%20in%20Europe%202012.pdf (right figure)

*All other serogroups, not groupable, not tested or missed; †Unknown serogroup (20%) and other serogroups (5%) excluded;

‡Contributing countries: Austria, Belgium, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the UK

§In Europe, MenB risk is more than 10-times higher in infants than in adolescents and young adults[2]

1. Centers for Disease Control and Prevention (CDC), 2017. Enhanced Meningococcal Disease Surveillance Report, 2016. https://www.cdc.gov/meningococcal/downloads/NCIRD-EMS-Report.pdf (accessed Feb. 2020); 2. European Centre for Disease Prevention and Control (ECDC), 2015. Surveillance of invasive bacterial diseases in Europe, 2012. http://ecdc.europa.eu/en/publications/Publications/Surveillance%20of%20IBD%20in%20Europe%202012.pdf (accessed Feb. 2020)

Dataset (right figure) provided by ECDC based on data provided by WHO and Ministries of Health from the affected countries; graph has been independently created by GSK from the original data

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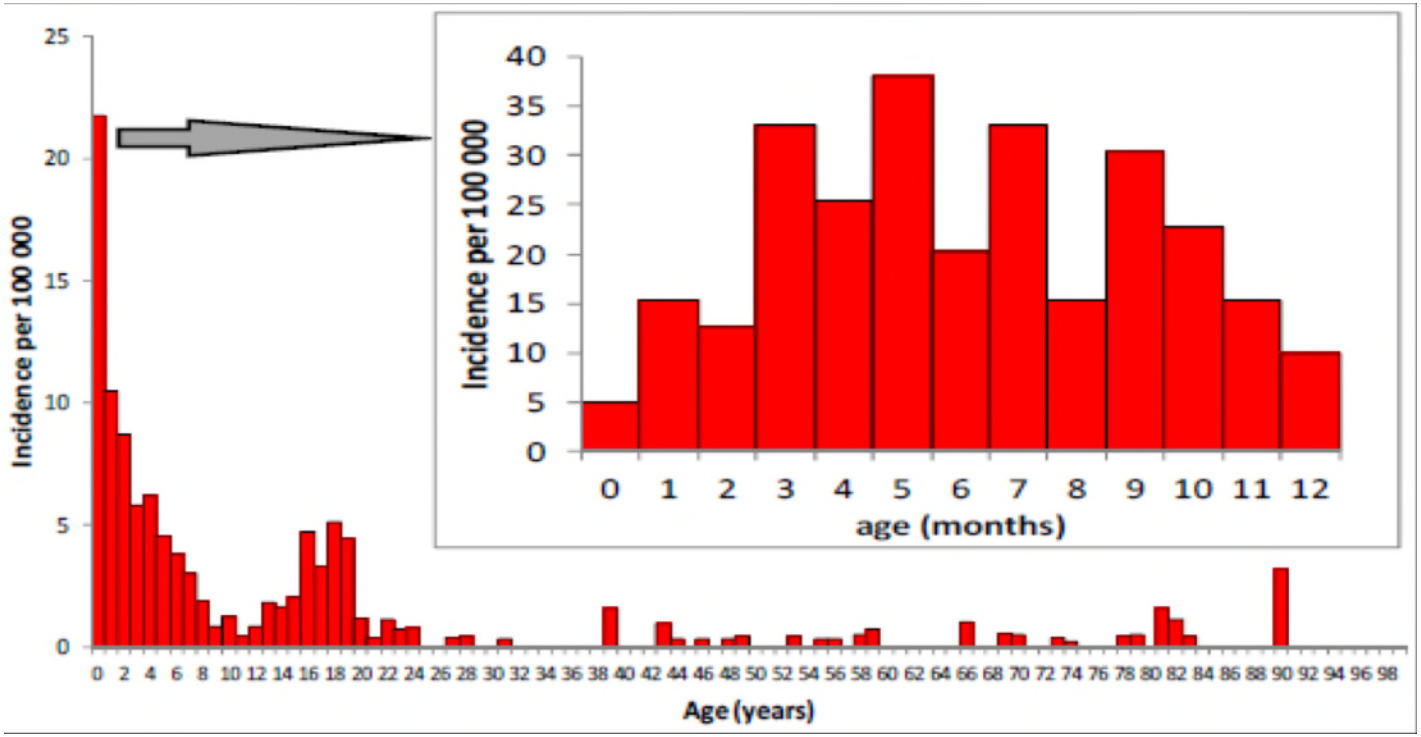
Incidence of serogroup B cases by year of age In Belgium

Average 2009-2010



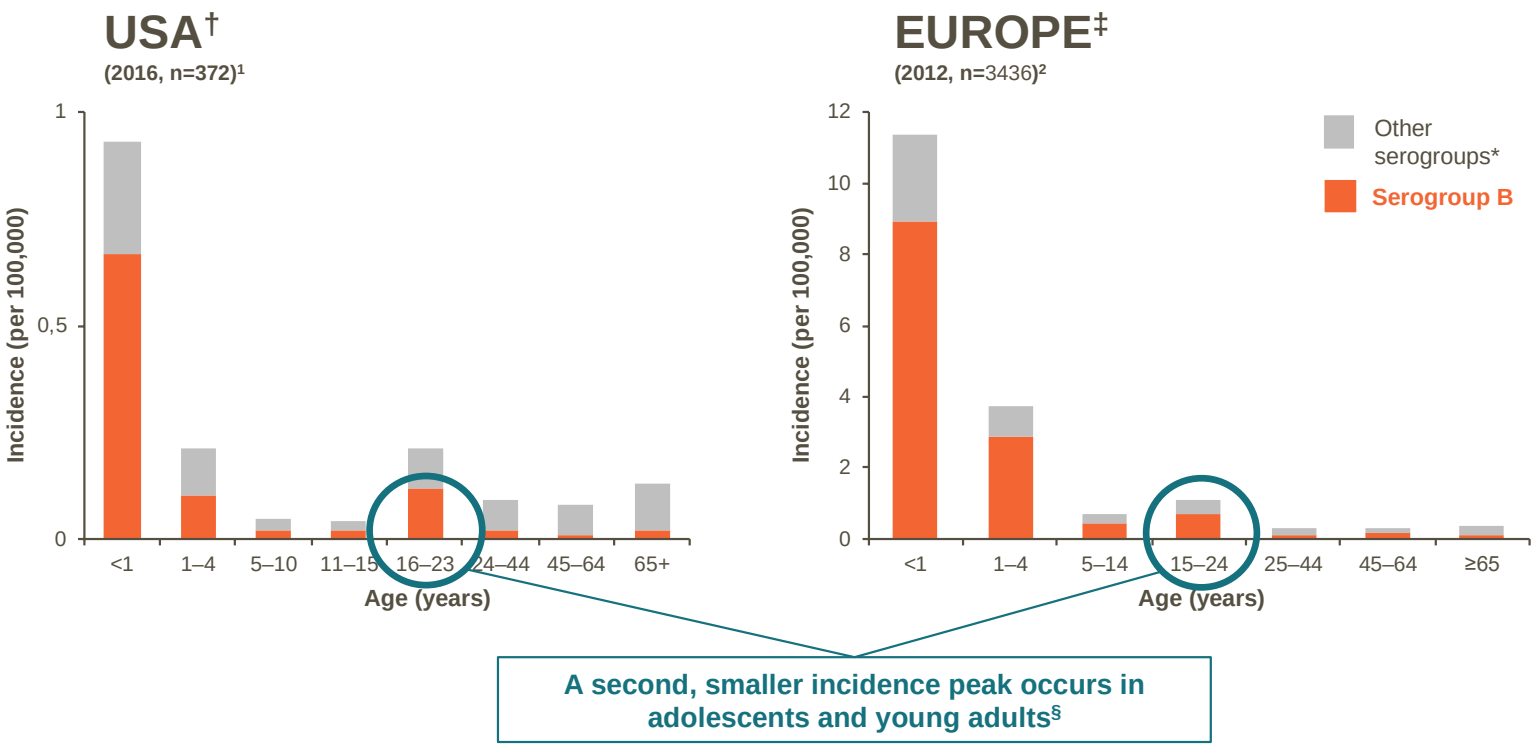
Incidence is highest under 1 year old with a peak between **3 to 9 months**

Verwekker en Incidentie

(Figure adapted from) Hanquet G, Christensen H, Agnew E, Trotter C, Robays J, Dubois C, Devriese S, Van De Sande S, Thiry N. A quadrivalent vaccine against serogroup B meningococcal disease: a cost-effectiveness study. Health Technology Assessment (HTA) Brussels: Belgian Health Care Knowledge Centre (KCE). 2014. KCE Reports 231.D/2014/10.273/77

MenB incidence is generally highest in infants and young children, with a smaller peak in adolescents

Verwekker en Incidentie



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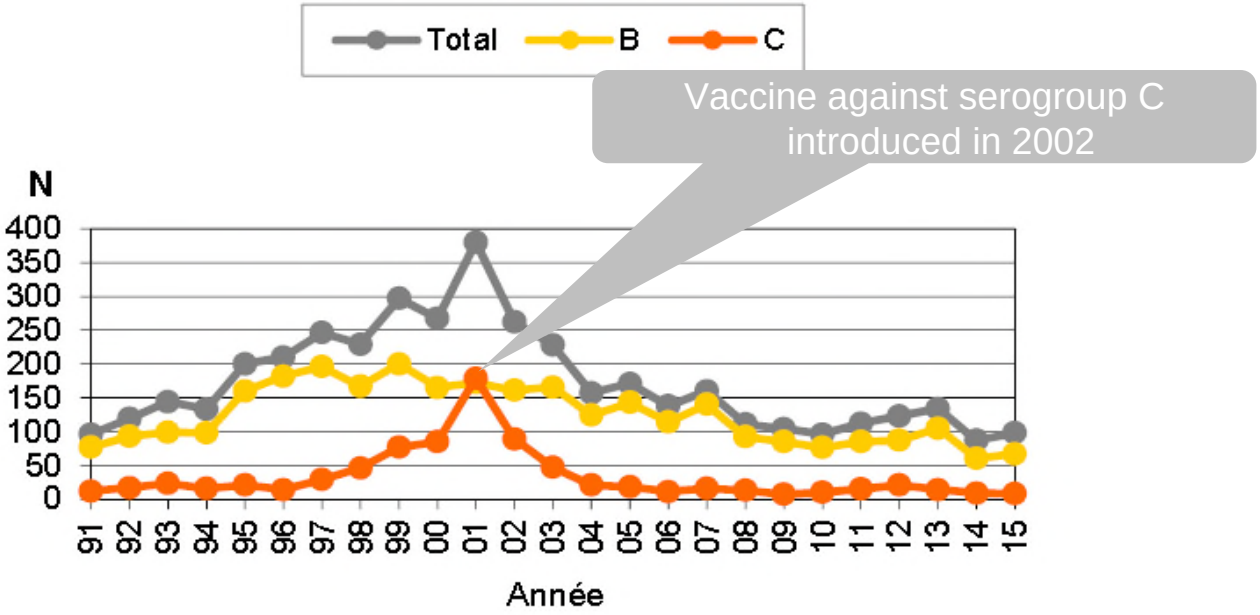
Impact of meningococcal C vaccination in Belgium[1]



Substantial reduction of serogroup C (in all age groups) after introduction of vaccination. There is **no clear link** with decreasing trend of serogroup B

Verwekker en Incidentie

1. (Figure adapted from) ISP-WIV (Sciensano). Centre National de Référence des Neisseria meningitidis. Rapport annuel 2015. http://bacterio.wiv-isp.be/reporting/reportspdf/Rap%20An%20Neis%202015%20Fr%20couv.pdf [Accessed Feb. 2020]

Belgium 2019:
Sciensano report for Q4 2019

Verwekker en Incidentie

Key messages:

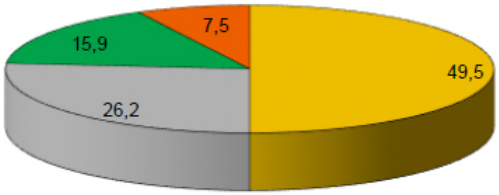
In 2019, 107 confirmed cases (annual incidence = 0,94/100.000) – comparable to 2018

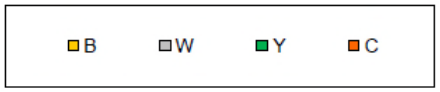
Serogroup B in 49,5% of cases, W in 26,2%, Y in 15,9% and C in 7,5%

14 deaths (4 B, 4 W, 3 C and 3 Y) (CFR = 13,1%);

45,8% cases in Flanders, 43,0% in Wallonia and 11,2% in Brussels

31.0% of cases in children < 5 years, and 9.3% in adolescents aged 15-19 years





Sciensano report 4th trimester 2019 – https://www.sciensano.be/sites/default/files/t4_2019_sciensano_1.pdf last consulted 14/07/2020

België 2020:
Sciensano rapport voor Q4 2020

Verwekker en Incidentie

Hoofdpunten:

En 2020, 55 bevestigde gevallen (jaarlijkse incidentie = 0,48/100.000)

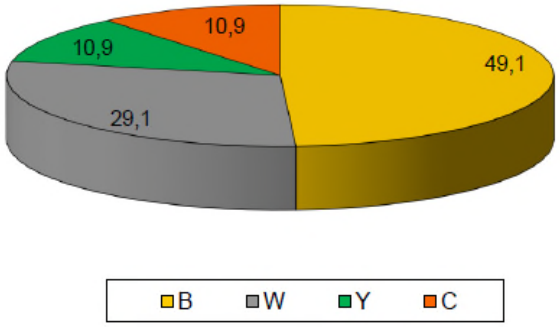
Serogroep B in 49,1% van de gevallen, W in 29,1%, Y in 10,9% en C in 10,9%

2 sterfgevallen (1 W en 1 C) (CFR = 3,6%);

50.9 % van de gevallen in Vlaanderen, 30.9% in Wallonië en 18,2% in Brussel

38.2% bij kinderen < 5 jaar en 9.1% bij adolescenten tussen 15 en 19 jaar

Het aantal gevallen waargenomen in 2020 was beduidend lager dan 2019 (n =107). De Covid-19 pandemie met de bijhorende maatregelen hebben duidelijk een effect gehad op de verspreiding van invasieve meningokokken infecties.



Sciensano rapport 4ème trimestre 2019 – https://www.sciensano.be/en/health-topics/meningitis/numbers#meningitis-in-belgium consulted in March 2021

CFR: Case Fatality Rate

- Verwekker en Incidentie
- Klinisch beeld
- Diagnostiek
- Behandeling
- Vaccinatie

IMD is an acute, serious illness that can be easily misdiagnosed and requires urgent medical attention

Easily misdiagnosed

Early symptoms resemble common viral illnesses[1]

Rapid disease course

Can progress to **death** within **24–48 hrs**[1,2]

Acute serious illness

Characterised by septicaemia and/or meningitis[2]

High mortality:[2]
Without treatment: **up to 50%**[2]
With treatment: **~8–15%**

1. Thompson MJ *et al. Lancet* 2006;367:397–403
2. World Health Organization (WHO), 2018. Meningococcal meningitis. Fact sheet no. 141. http://www.who.int/mediacentre/factsheets/fs141/en (accessed Feb. 2020)

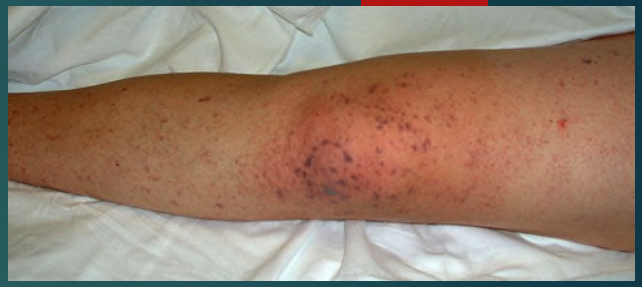
IMD, invasive meningococcal disease

Klinisch beeld

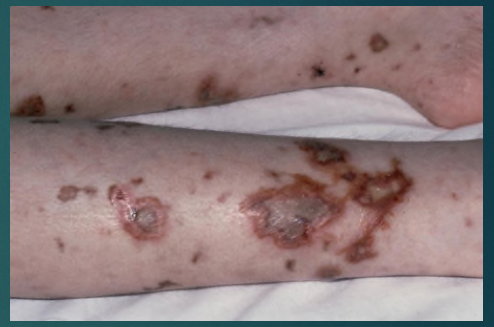
- Incubatieperiode 2-10 dagen (gem 3-4 d)
- Prodromi : zoals bij virale BLWI : keelpijn, hoest, coryza, otalgie
- Klinische presentatie verschilt naargelang de leeftijd

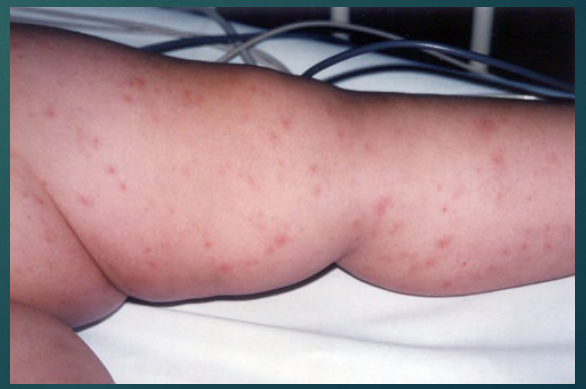
Klinisch beeld

- Meningitis (15 %)
  - koorts, hoofdpijn +++, braken, meningeale prikkeling (>2 jaar) , bulging fontanel,lethargie, fotofobie,…



- Meningococcemie (25 %)
  - Hyperacuut, koorts, asthenie, BWZ daling, intense myalgie onderste ledematen
  - Petechiën (drukplaatsen) , purpura/ soms initieel maculopapulair of urticarieel
  - Drie vroege tekenen van sepsis bij meningococcen!!
    - Pijn benen
    - Koude extremiteiten
    - Bleke, gebloemde huid





- 60 % Meningitis-sepsis !!

Klinisch beeld

- Primaire pneumonie
- Septische arthritis (C,W) : adolescenten, knie of heup
- Chronische meningococcemie
  - Laaggradige koorts, maculopapulair exantheem, arthralgie-arthritis
  - Weken tot maanden
- Primaire pericarditis (C,W)
- Zeldzaam conjunctivitis, osteomyelitis, epiglottitis, cellulitis,…

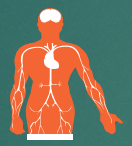
Up to 20% of IMD survivors may have sequelae[1]

Klinisch beeld

Orthopaedic[2–4]

- Limb loss
- Hemiparesis
- Skin loss
- Growth plate arrest

Systemic[2,5]



- Chronic organ damage
- Adrenal failure
- Immune disorders

Sensorial[2,6,7]

- Hearing loss
- Visual impairment

Neurological[2,5,6,7,8]

- Brain abscess
- Seizures
- Motor deficits
- Stroke

Cognitive / psychiatric[3,6,8]

- Cognitive impairment
- Neurodevelopment deficits
- Neuropsychiatric disorders

Some sequelae do not become evident until years after the illness, when routine follow-up has ceased[3,4,6,8]

1. World Health Organization (WHO). 2018. Meningococcal meningitis. Fact sheet no. 141. http://www.who.int/mediacentre/factsheets/fs141/en (accessed Feb. 2020); 2. Granoff DM et al. In: Kleigman RM et al, eds. Nelson Textbook of Pediatrics, 19th ed. Philadelphia, PA: Saunders Elsevier; 2011:929–935; 3. Judge D et al. Intensive Care Med 2002;28:648–650; 4. Belthur MV et al. J Bone Joint Surg Br 2005;87-B:236–240; 5. Brandtzaeg P. In: Frosch M, et al, eds. Handbook of Meningococcal Disease: Infection Biology, Vaccination, Clinical Management. Weinheim, Germany: Wiley-VCH Verlag GmbH & Co. KGaA; 2006:427–479; 6. Bedford H et al. BMJ 2001;323:533–536; 7. Singhi PD et al. In: Helfaer MA et al, eds. Rogers' Handbook of Pediatric Intensive Care. Philadelphia, PA: Lippincott, Williams & Wilkins; 2009:500–519; 8. Anderson V et al. J Pediatr Psychol 2004;29:67–81

- Verwekker en Incidentie
- Klinisch beeld
- Diagnostiek
- Behandeling
- Vaccinatie

Diagnostiek

Klinisch beeld

- Abrupte koorts met fulminant ziektebeeld
- Toxisch aspect / Verlaagd bewustzijn
- Petechiën, purpura
- Meningeale prikkeling
- Meningococcensepsis triade

GEEN UITSTEL BEHANDELING !!

Technische onderzoeken

- Bloedonderzoek
  - CRP elevatie/ Leucocytose met linksverschuiving of leucopenie/ thrombocytopenie
  - Cultuur
- Lumbaalpunctie
  - Leucorachie (>1000 wbc/mm^3)
  - Lage glucorrachie (<40 mg dl of $gluc^{LV}/gluc^{ser}$ <0,4)
  - Hoge proteïnorrachie (>50mg/dl)
  - Microscopie rechtstreeks / PCR
- Andere : keelkweek, urineonderzoek, kweek huidletsels,…

- Septische shock
- Recent convulsies
- Intracraniële hypertensie
- Verlaagd bewustzijn
- Huidinfectie op punctieplaats

- Verwekker en Incidentie
- Klinisch beeld
- Diagnostiek
- Behandeling
- Vaccinatie

Behandeling

- Meningococcensepsis
  - IV AB (derde generatie cefalosporine) : cefotaxime/cetriaxone
  - IV vocht
  - IV inotropica (adrenaline)
  - Zuurstof
  - Intubatie – gecontroleerde ventilatie
    - Minder nood aan zuurstof
    - Arteriële CO2 niveau : intracraniële druk

- Verwekker en Incidentie
- Klinisch beeld
- Diagnostiek
- Behandeling
- Vaccinatie

Recommendations SHC* July 2019

Vaccinatie

Vaccination	Context
Men ACWY • At 15 months • At 15-16 years (with Tdap) + Catch up 15-19 yoa until 2024)	• Increasing incidence Y and W (BE + other countries) • Age distribution of cases • Herd effect on infants/adolescents • Waning immunity MenC

MenB
• No UMV
• Recommended on individual basis for:
  • Children from 2 months to 5 years
  • Adolescents 15-19 years
  • Risk groups
	Confirmation of proven efficacy and no major side effects
	
	Low incidence MenB
	• Need for early vaccination at the age of 2 months together with routine vaccines: this requires prophylactic paracetamol against high risk of fever
	• 3 shots at the same time requires high acceptance from parents and vaccinators and may lead to lower vaccinaton coverage for routine vaccines
	• Poor cost-effectiveness (expensive vaccine, rare disease)
	• No herd immunity, no effect on carriage

Reevaluation will occur to take into account efficacy data & epidemiology	

SHC: Superior Health Council (Conseil Supérieur de la Santé, Hoge Gezondheidsraad)

https://www.health.belgium.be/fr/avis-9485-vaccination-contre-le-meningocoque Feb. 2020

Recommendations SHC* July 2019

Vaccinatie

Schedule for children < 1year

Scheme	Dose 1	Dose 2	Booster	Comment
Best	8 weeks (2 M)	16 weeks (4 M)	11-14 months	With routine V + paracetamol
Alternative	10 weeks (2.5 M)	18 weeks (4.5 M)	11-14 months	Alone, no paracetamol
	12 weeks	20 weeks (5 M)	11-14 months	With routine V + paracetamol

≠ label

For children below 6 months, need min 6 months between primary series and booster

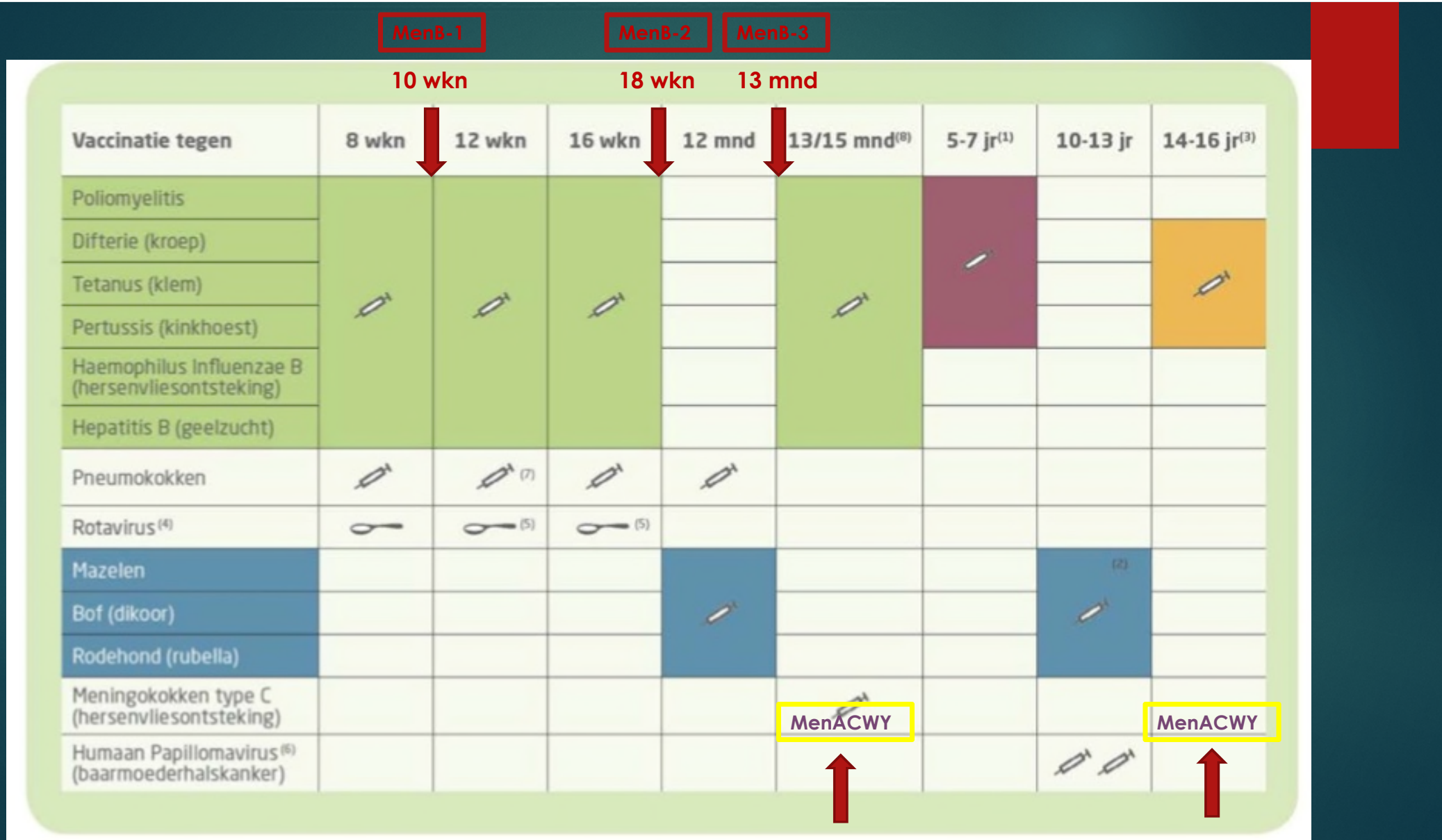
Schedule for other ages

Age group (1st dose)	Primary vaccination	Interval between doses	Booster
6 to 11 months	2 doses	min 2 months	during 2nd year, one dose at least 2 months after last dose 1st vaccination
12 to 23 months	2 doses	min 2 months	one dose at least 12 to 23 months after primary vaccination
2 to 5 years	2 doses	min 2 months	"Consider a booster dose if continued risk of exposure based on official recommendations"
Adolescents (aged 11 to 19)	2 doses	1min 1 month	

3 vaccinaties

2 vaccinaties

https://www.health.belgium.be/fr/avis-9485-vaccination-contre-le-meningocoque accessed Feb. 2020


MenB-1
MenB-2
MenB-3
10 wkn
18 wkn
13 mnd
Vaccinatie tegen
8 wkn
12 wkn
16 wkn
12 mnd
13/15 mnd(8)
5-7 jr(1)
10-13 jr
14-16 jr(3)
Poliomyelitis
Difterie (kroep)
Tetanus (klem)
Pertussis (kinkhoest)
Haemophilus Influenzae B (hersenvliesontsteking)
Hepatitis B (geelzucht)
Pneumokokken
(7)
Rotavirus(4)
(5)
(5)
Mazelen
Bof (dikoor)
Rodehond (rubella)
(2)
Meningokokken type C (hersenvliesontsteking)
MenACWY
MenACWY
Humaan Papillomavirus(6) (baarmoederhalskanker)

4CMenB has a clinically acceptable safety profile

Vaccinatie

Infants and children (up to 10 years)

Very common AEs (≥1/10):
Eating disorders, sleepiness, unusual crying, headache, diarrhoea, vomiting, rash, arthralgia, fever (≥38°C), injection-site tenderness, erythema, swelling, induration, irritability

Fever and systemic reactions in infants:
When administered alone, the frequency of fever with 4CMenB is similar to that of routine infant vaccines*

When administered with other infant vaccines,*† a higher rate of fever and systemic reactions observed versus routine vaccines alone

Adolescents (from 11 years of age) and adults

Very common AEs (≥1/10): Malaise, headache, nausea, myalgia, arthralgia, injection-site pain, swelling, induration, erythema

*PCV7 and DTaP/IPV/Hib/HepB
†Separate vaccinations can be considered when possible. Separate injection sites must be used if more than one vaccine is administered at the same time
AE, adverse event; DTaP/IPV/Hib/HepB, diphtheria, tetanus, acellular pertussis/inactivated polio vaccine/*Haemophilus influenzae* type b/hepatitis B; PCV7, pneumococcal (7 serotypes)

4CMenB SmPC.

Current immunisation programmes with 4CMenB

Vaccinatie

As of October 2020

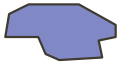
UK[1]
08/2015:
2m, 4m, 12m

Andorra[2]
02/2016:
2m, 4m, 13m

Ireland[3]
10/2016:
2m, 4m, 12m

Italy[4,5]
01/2017:
3m, 4m, 6m, 13m

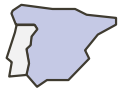
San Marino[6]
01/2017:
4m, 6m, 7m, 13m-14m



Lithuania[7]
01/2018:
2m, 4m, 12m-15m

South Australia[8]
09/2018: 2m, 4m, 12m
& catch-up for 1-4 y (2d)
02/2019: Adolescents

USA[9]
Adolescents
2d, ≥1 month apart



Spain[10]
06/2019 (Castilla y León):
3m, 5m, 12m
07/2019 (Canarias):
3m, 5m, 15m

Malta[11]
12/2019: 2m, 4m, 13m

Czech Republic[12]
05/2020: covered for
infants up to 6mo

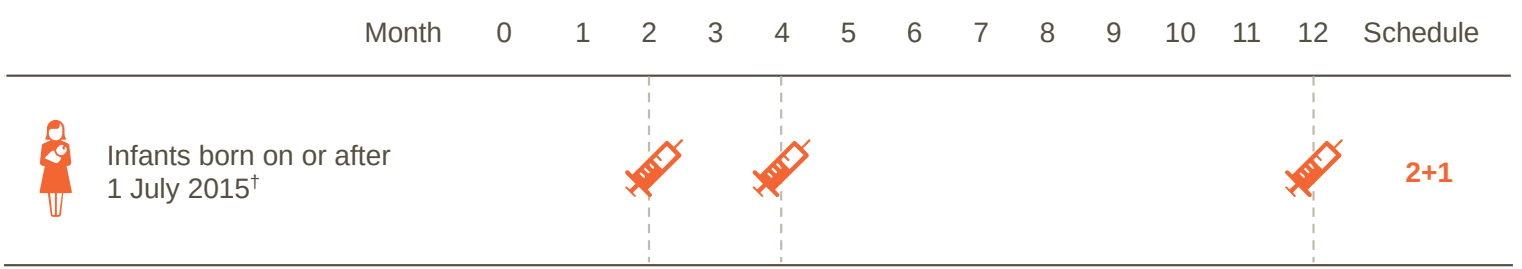
Portugal[13]
10/2020:
2m, 4m and 12 m

For references, refer to slide notes

4CMenB was introduced into the UK national immunisation programme in September 2015[1,2]

Vaccinatie

The programme uses a **2+1*** immunisation schedule, administered at 2, 4 and 12 months[1†]



Parents advised to give three doses of **prophylactic paracetamol** to infants at Doses 1 and 2[2,3]

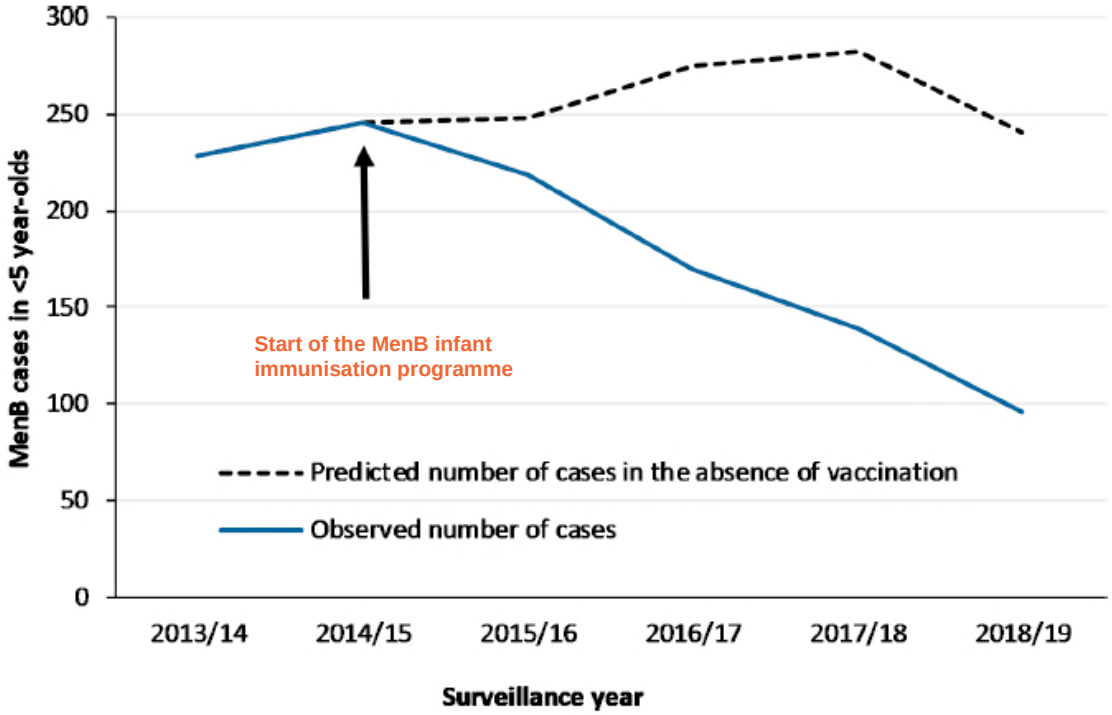
Co-administered with **routine vaccines** (DTaP/IPV/Hib/HepB, rotavirus, PCV13, MMR, Hib/MenC)[4,5‡]

*The 2+1 dosing schedule recommended by JCVI was not consistent with the licensed indication for this age group;[2,4] †For infants born 1 May–30 June 2015 who had their 2 month vaccinations before 1 September 2015, 4CMenB was added to vaccination schedule at 3 and/or 4 months ('catch-up cohort'); ‡HepB vaccine introduced into UK vaccination schedule in Autumn 2017 and MenC vaccine removed for infants aged 3 months in July 2016[6,7]

1. Parikh SR *et al. Lancet* 2016;388:2775–2782; 2. Ladhani SN *et al. Arch Dis Child* 2016;101:91–95; 3. Public Health England, 2018. Using paracetamol. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/483408/9413-paracetamol-menB-2page-A4-08-web.pdf; 4. Joint Committee on Vaccination and Immunisation (JCVI), 2014. JCVI position statement on use of 4CMenB® meningococcal B vaccine in the UK. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/294245/JCVI_Statement_on_MenB.pdf; 5. Public Health England, 2018. Routine childhood immunisations, 2018. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/696501/Complete_immunisation_schedule_April2018.pdf; 6. Torjesen I. *BMJ* 2017;358:j3357; 7. Public Health England, 2016. MenC infant schedule letter. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/512311/2016_MenC_infant_schedule_letter-FINAL__1_.pdf (all URLs accessed Feb. 2020)

PM-BE-BEX-PPT-200018 – July 2020

MenB cases in children under 5 years of age during 2013/2014–2018/2019 surveillance years in England



MenB cases in children < 5 years of age during 2013/2014–2018/2019 surveillance years in England (solid line) compared with MenB cases predicted by trends among unvaccinated childhood cohorts (dashed line) over the same period

Adapted from Isitt C, et al. Arch Dis Child 2020;0:1–7. doi:10.1136/archdischild-2019-318047

Vaccinatie

Summary

4CMenB prevented 1 case of MenB every 4 days

Introduction of 4CMenB to the UK NIP has been very successful, with **coverage >88%** (2+1 schedule)

From Sept 2015–2018, **277 cases were prevented (1 every 4 days)** in the vaccine-eligible cohort, irrespective of vaccination status, number of doses received, and strain coverage[1]

Substantial reduction in MenB disease, with a **vaccine impact of 75%** observed across all fully eligible age cohorts in vaccine-eligible infants and children[1]

Sustained protection for at least 2 years after the 12-month booster[1]

After **3 million doses administered**, the safety profile of 4CMenB in real-world use is **consistent** with that established in clinical trials[2,3]

NIP, national immunisation programme

1. Ladhani S. et. Al. N Engl J Med 2020;382:309-17. DOI: 10.1056/NEJMoa1901229; 2. Bryan P *et al. Lancet Child Adolesc Health* 2018;2:395–403; 3. Bettinger JA. *Lancet Child Adolesc Health* 2018;2:380–381

Vaccinatie

Vragen ?

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