# Ms Kim Hunter

GSK

Medical Science Liaison - Vaccines

Saturday, August 10, 2019

(Room 1)

11:40 - 12:20 Meningococcal Vaccination Issues

# “B informed”
# Update on Meningococcal Disease and Vaccination in New Zealand

**Kim Hunter-Robb**
**Medical Science Liaison - Vaccines**

# Disclaimer

- GlaxoSmithKline (GSK) can only recommend the use of treatments in accordance with the approved Data Sheet information.

- Please review the Data Sheet before prescribing. Data Sheet is available at http://www.medsafe.govt.nz/profs/Datasheet/datasheet.htm

# Agenda:

- Invasive meningococcal disease and meningitis
- NZ history and latest epidemiology
- Available meningococcal vaccines and new infant dosing indication
- Co-administration and tolerability

# Invasive Meningococcal Disease (IMD) and meningitis

# IMD is an acute, serious illness caused by a bacteria called *Neisseria meningitidis*[1–3]

## 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[3]

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

Up to **20%** of IMD survivors may have **sequelae**[2]

IMD, invasive meningococcal disease

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 April 2018); 3. Centers for Disease Control (CDC), 2015. Meningitis pink book. https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/mening.pdf (accessed April 2018)

# *Neisseria meningitis* remains a leading cause of bacterial meningitis and septicaemia worldwide

## *Haemophilus influenzae type b (Hib)*[1,2]

**Virtually eliminated** across most industrialised nations due to widespread vaccination

## *Streptococcus Pneumoniae*[3,4]

Childhood **incidence greatly reduced** after PCV7 vaccine introduction (USA and Europe)

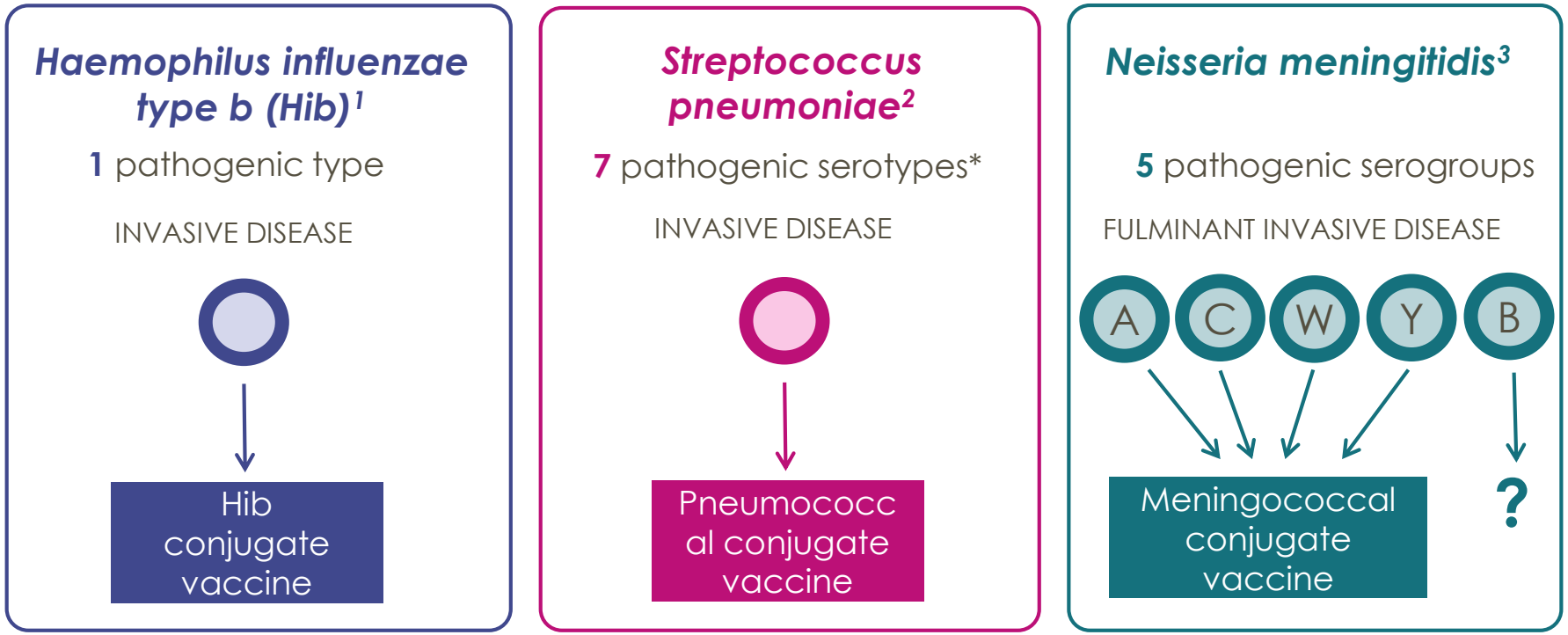
## *Neisseria meningitidis*[5,6]

Invasive meningococcal disease (IMD) remains a **primary cause of bacterial meningitis and septicaemia** worldwide

1. Watt JP, *et al*. *J Pediatr* 2003;143(Suppl 6):S163–187; 2. World Health Organization (WHO), 2012. *Haemophilus influenzae* type b (Hib) factsheet. http://www.wpro.who.int/mediacentre/factsheets/fs_20120220_hib/en/ (accessed April 2018); 3. Weil-Olivier C*, et al*. *BMC Infect Dis* 2012;12:207; 4. Black S, et al. *Pediatr Infect Dis J* 2007;26:771–777; 5. Stoddard J, *et al. Hum Vaccin* 2010;6:219–33; 6. World Health Organization (WHO), 2015. Immunization, vaccines and biologicals: meningococcal meningitis. http://www.who.int/immunization/diseases/meningitis/en (accessed April 2018)

# Several conjugate vaccines have been successfully developed against meningitis-causing bacteria

Vaccines have been based on the **polysaccharide capsule** of pathogenic strains[1–3]

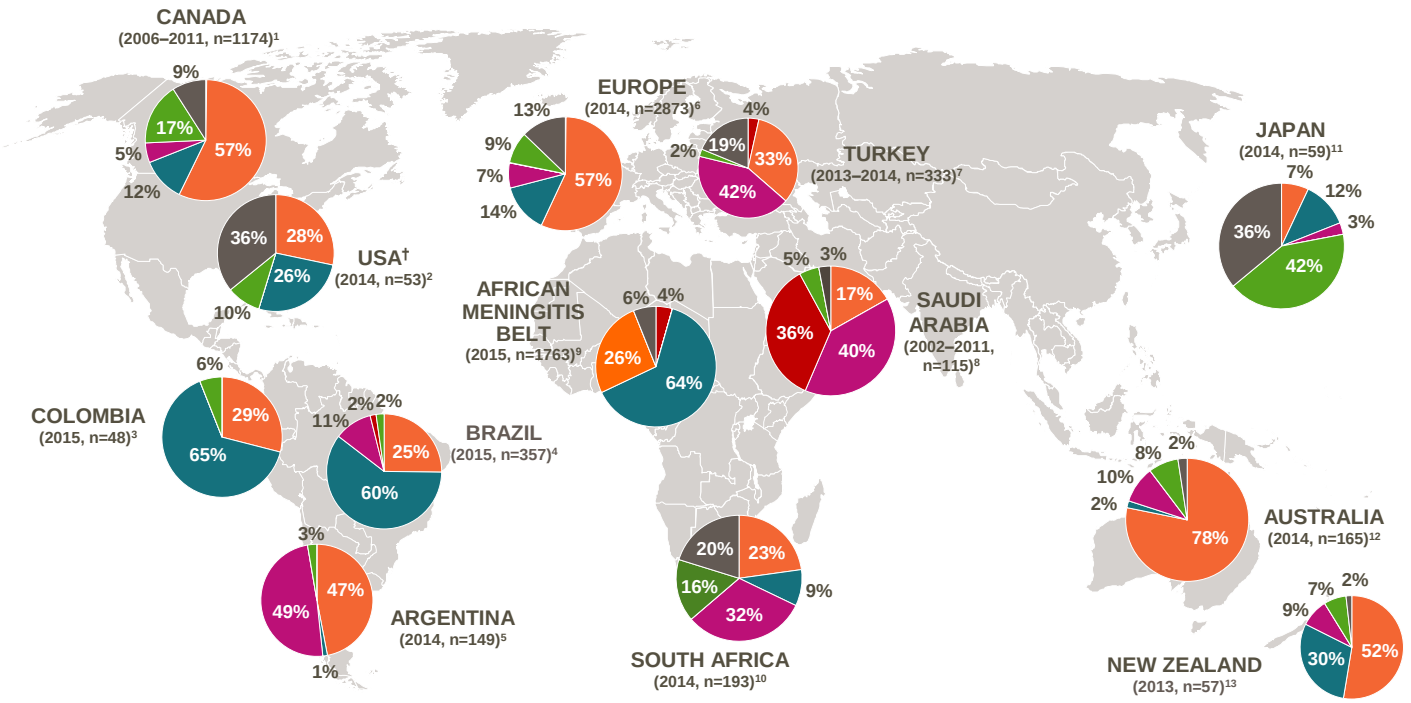



However, the polysaccharide capsule of **serogroup B** is poorly immunogenic[3–5]

*Pneumococcal conjugate vaccines contain polysaccharides from 7 serotypes, which cause 65–80% of invasive disease in developed countries`


1. Watt JP, *et al*. *J Pediatr* 2003;143(Suppl 6):S163–187; 2. World Health Organization (WHO), 2018. Biologicals: pneumococcal disease. http://www.who.int/biologicals/vaccines/pneumococcal/en/ (accessed April 2018); 3. Girard MP, *et al. Vaccine* 2006;24:4692–4700; 4. Finne J, *et al*. *J Immunol*. 1987;138:
4402–4407; 5. Wyle FA, *et al*. *J Infect Dis* 1972;126:514–521.

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

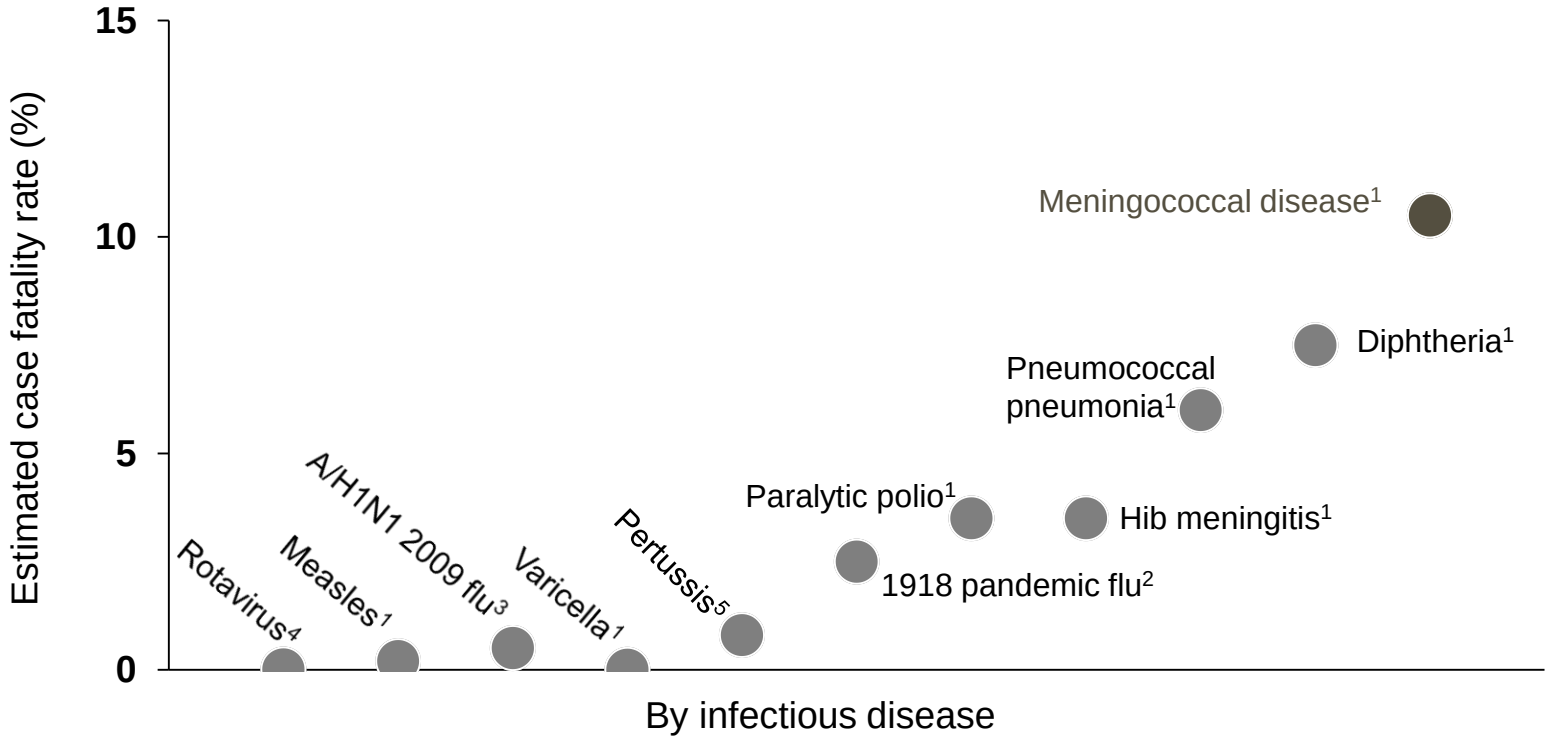



A B C W Y — Includes serogroup X, other serogroups, not groupable, not tested, or missed

Serogroup data are across all age groups; Percentages may not total 100 due to rounding
*Serogroup distribution cannot be directly compared across countries due to variability in surveillance data availability; †USA: 36% 'other' serogroups includes serogroup W and non-groupable; surveillance data cover only some areas of the USA, representing ~43.5 million people;[2] IMD, invasive meningococcal disease

See refs in notes

# IMD is associated with a higher case fatality rate compared with other VPDs




NB: Meningococcal disease and Hib meningitis: despite appropriate antimicrobial therapy; paralytic polio: in children; 1918 pandemic flu: in young adults; varicella: in children and adolescents; A/H1N1 2009 flu: worldwide; measles: US, 1985–1992; rotavirus: US general population; pertussis: infants <6 months of age, US, 2001–2003.

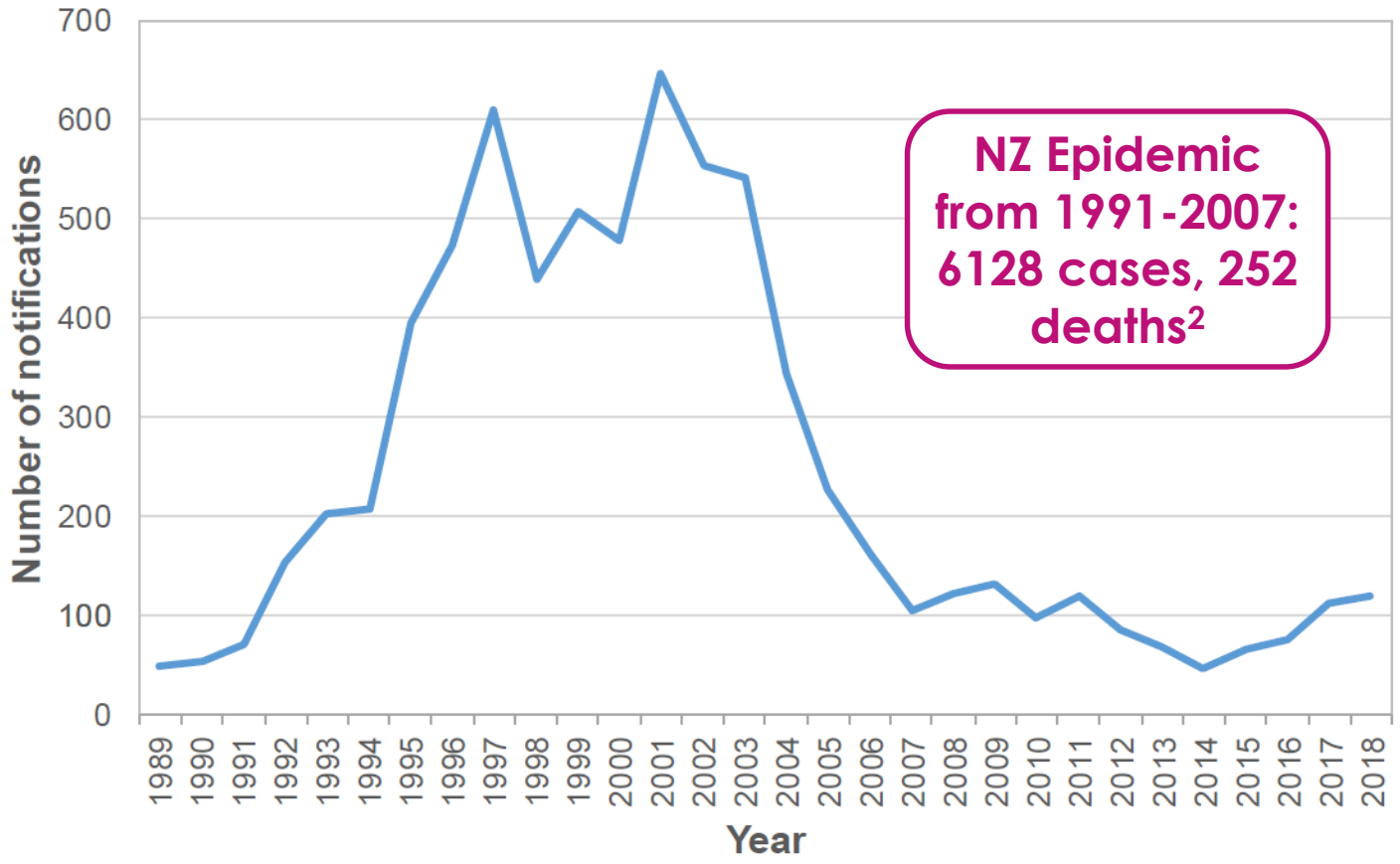

1. Centers for Disease Control and Prevention (CDC). *Epidemiology and Prevention of Vaccine-Preventable Diseases*. 12th ed. Atkinson W, et al, eds. Washington, DC: Public Health Foundation; 2012. http://www.cdc.gov/vaccines/pubs/pinkbook/index.html#chapters; 2. Taubenberger JK, et al. *Emerg Infect Dis.* 2006;12:15-22; 3. Pandemic H1N1 2009 Overview. CIDRAP website. http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/biofacts/h1n1_panview.html; 4. Gerba CP, et al. *Wat Res*. 1996:30;2929-2940; 5. Centers for Disease Control and Prevention (CDC). *MMWR Morb Mortal Wkly Rep*. 2005;54:1283-1286.


IMD = invasive meningococcal disease VPDs = vaccine preventable diseases

# NZ history and latest epidemiology

# IMD incidence in NZ is unpredictable and can change rapidly

## Meningococcal disease notifications by year, 1989–2018[1]

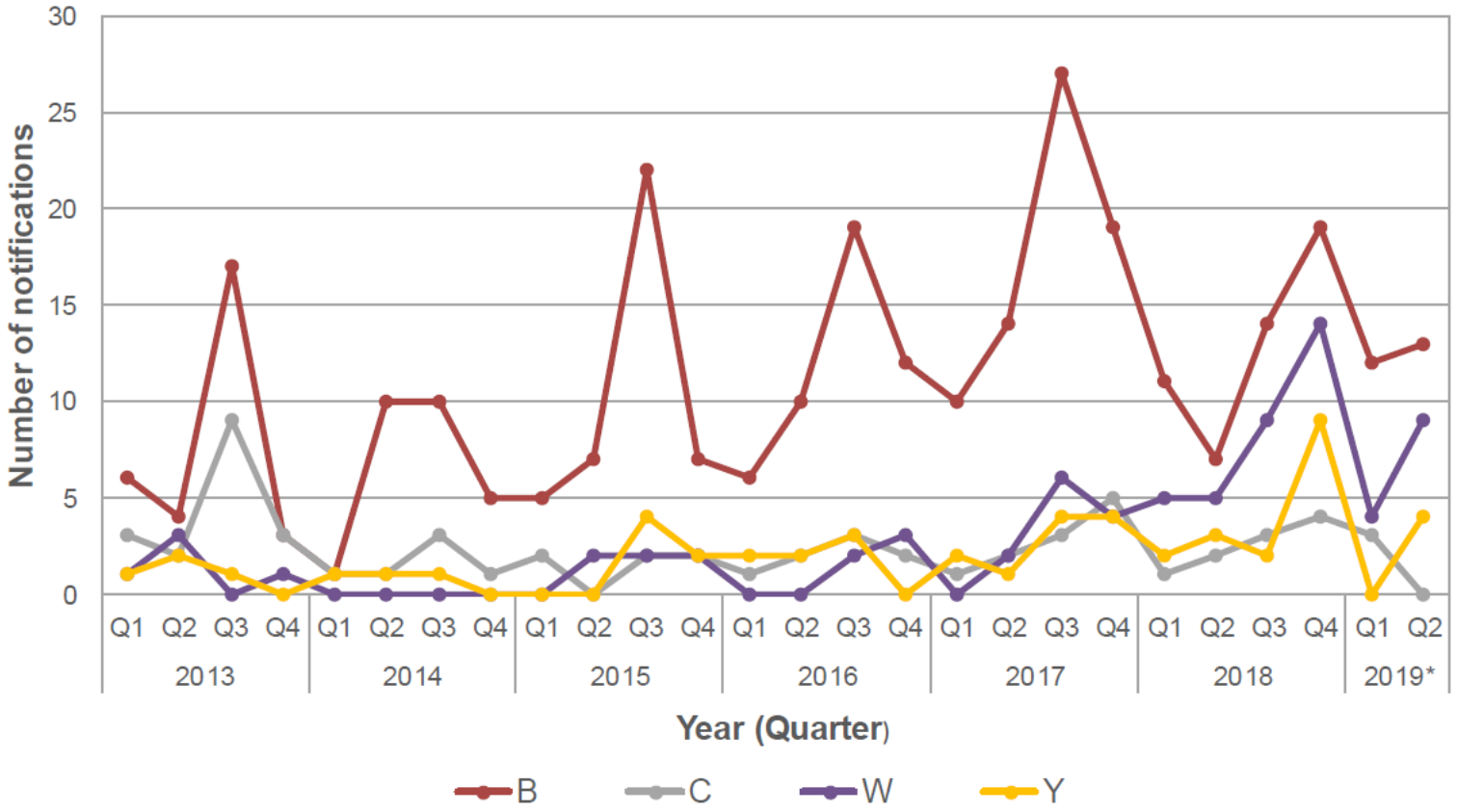




1. The Institute of Environmental Science and Research. Invasive Meningococcal Disease Report Q2 2019. Accessed July 2019, available at: https://surv.esr.cri.nz/surveillance/Meningococcal_disease.php 2. Martin, D. and L. Lopez, *The epidemiology of meningococcal disease in New Zealand in 2007*. May 2008: Wellington

# Annual number of cases has been increasing since 2014

Meningococcal disease notifications by group by quarter by year 2013-2019*

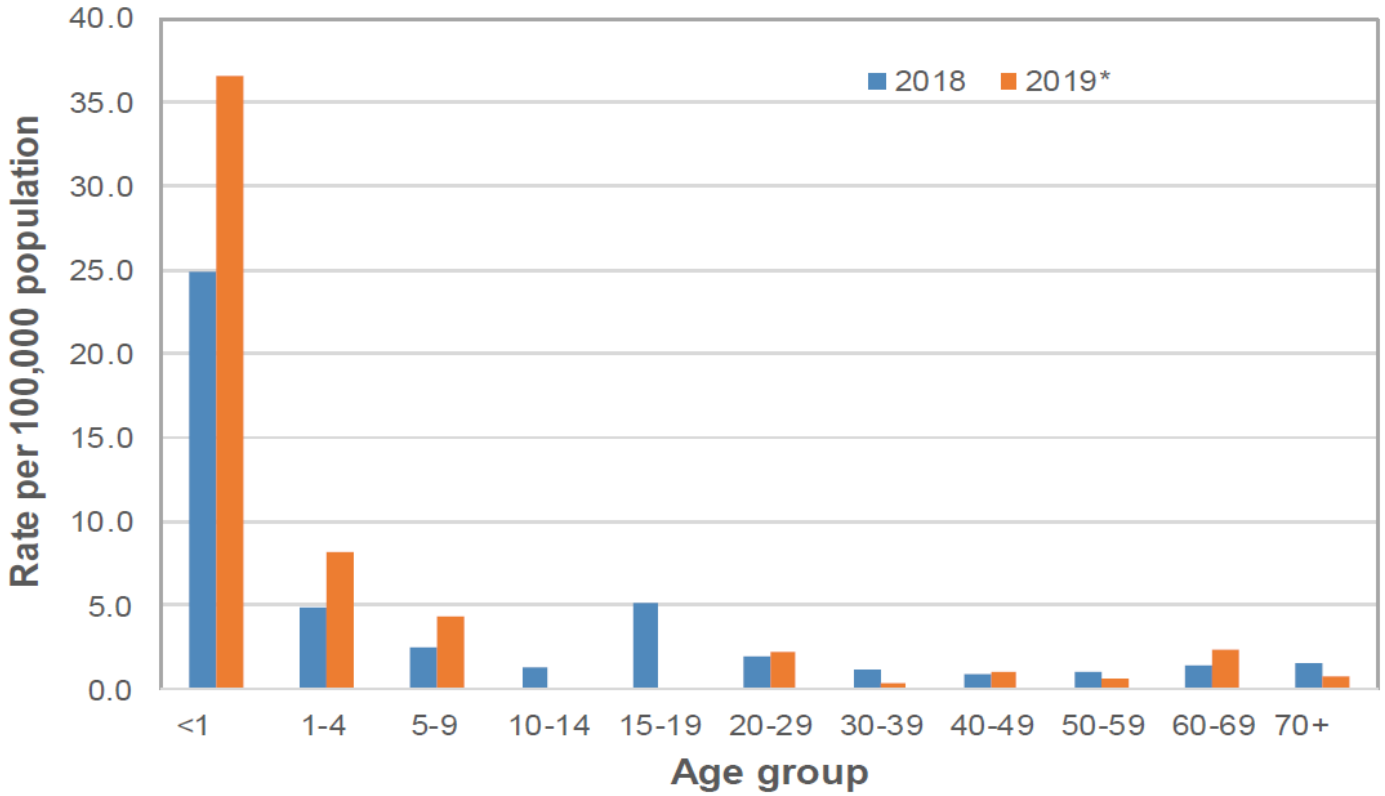



*Cases reported up to 30 June 2019 only.

The Institute of Environmental Science and Research. Invasive Meningococcal Disease Report Q2 2019. Accessed July 2019, available at: https://surv.esr.cri.nz/surveillance/Meningococcal_disease.php

# Highest notification rates of disease in <1 year olds

**Figure 3. Meningococcal disease notifications rate by age group, 2018 and 2019***

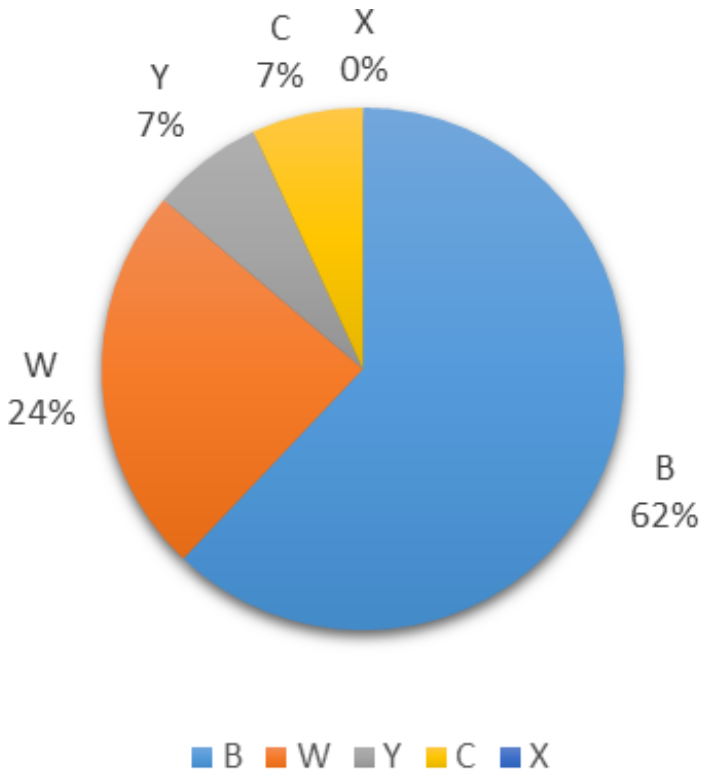



*Cases reported up to 30 June 2019 only. Annualised rate using quarter 1 and 2 notifications.

The Institute of Environmental Science and Research. Invasive Meningococcal Disease Report Q2 2019. Accessed July 2019, available at: https://surv.esr.cri.nz/surveillance/Meningococcal_disease.php

# Group B caused 62% of cases in 0 – 4yrs 2018*

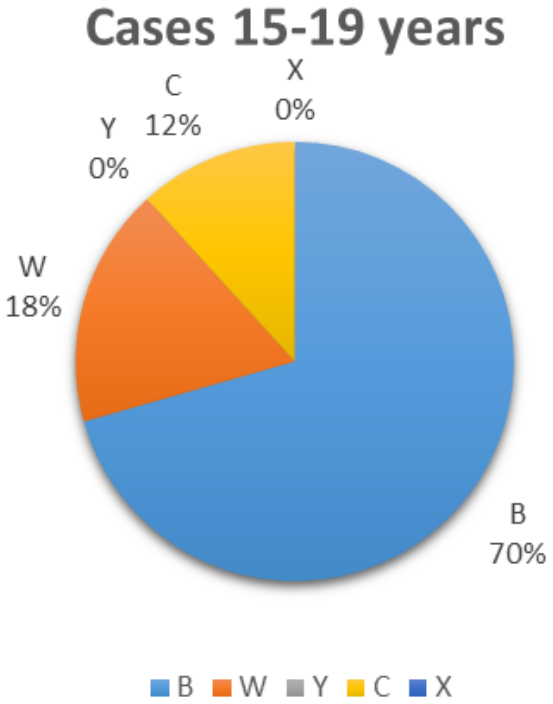
## Distribution of serogroups 0-4 yrs 2018*

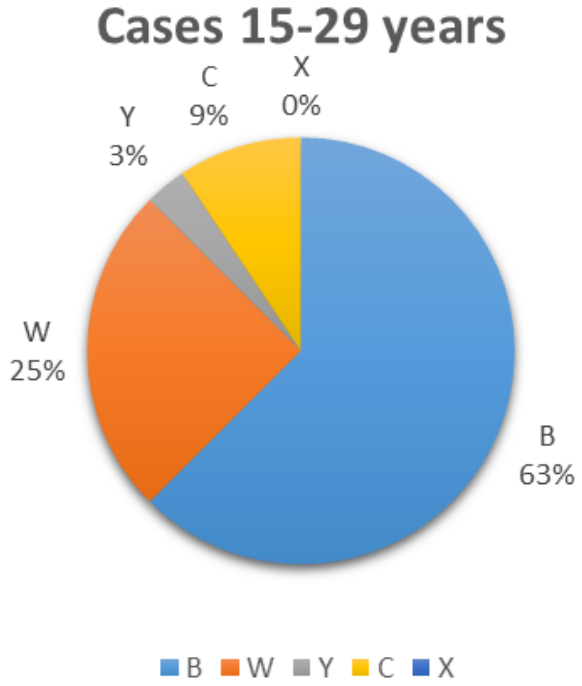



*of those serogrouped

The Institute of Environmental Science and Research. Invasive Meningococcal Disease Report Q2 2019. Accessed July 2019, available at: https://surv.esr.cri.nz/surveillance/Meningococcal_disease.php

# Group B causes majority of disease in 15 – 29 yrs in 2018*



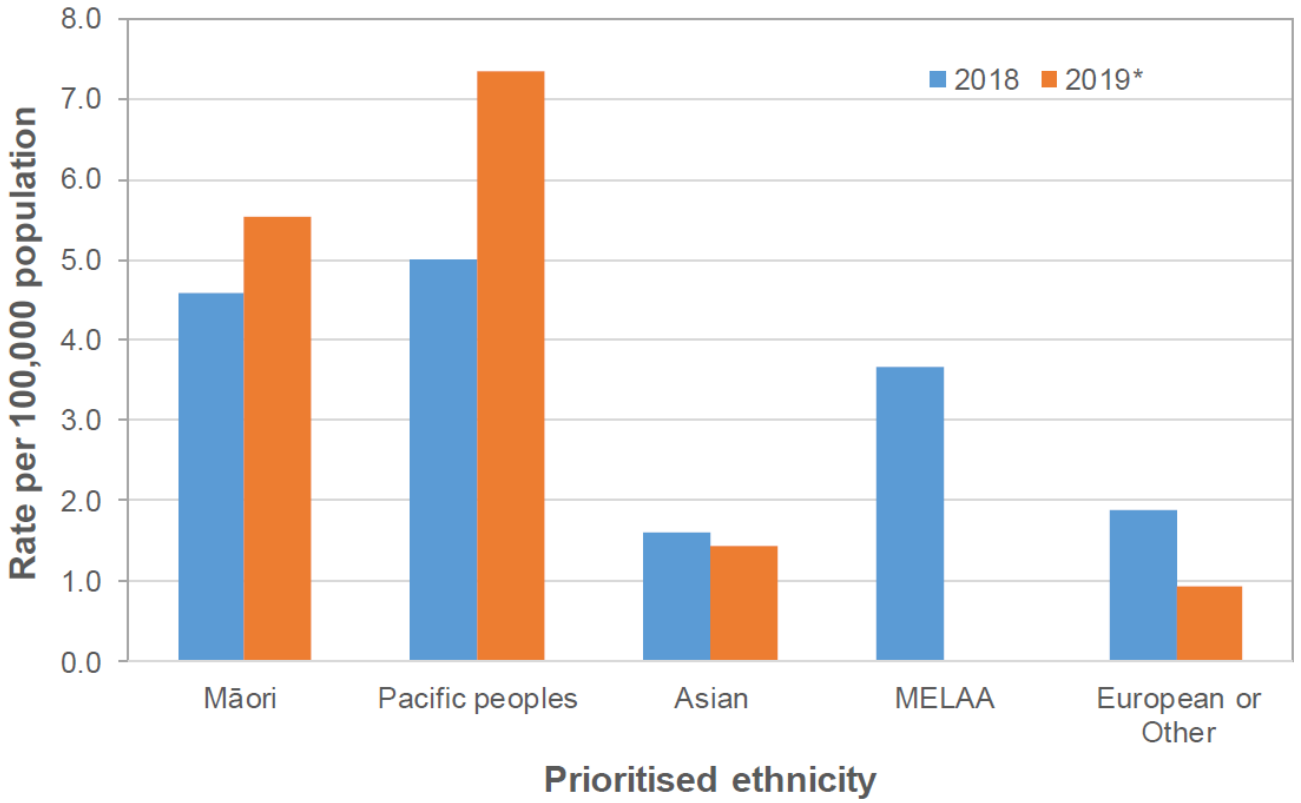




*of those serogrouped

The Institute of Environmental Science and Research. Invasive Meningococcal Disease Report Q2 2019. Accessed July 2019, available at: https://surv.esr.cri.nz/surveillance/Meningococcal_disease.php

# Greatest burden of disease is in Māori and Pacific

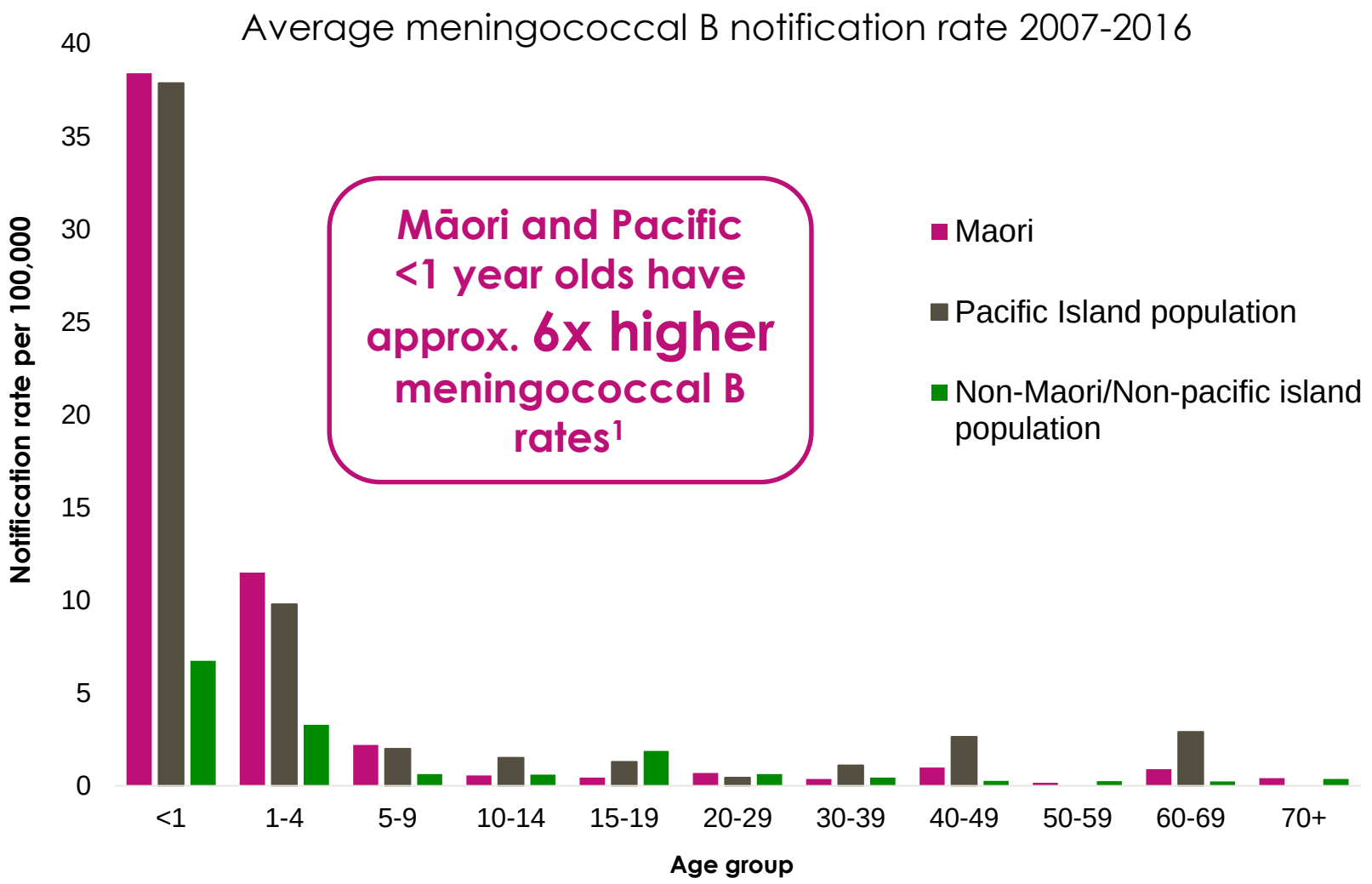
**Figure 4. Meningococcal disease notifications rate by ethnicity, 2018–2019***




MELAA - Middle Eastern/Latin American/African.
*Cases reported up to 30 June 2019 only. Annualised rate using quarter 1 and 2 notifications.

The Institute of Environmental Science and Research. Invasive Meningococcal Disease Report Q2 2019. Accessed July 2019, available at: https://surv.esr.cri.nz/surveillance/Meningococcal_disease.php

# Māori and Pacific Island populations are disproportionately impacted by meningococcal B disease in NZ




1. The Institute of Environmental Science and Research, Meningococcal disease epidemiology data request. GSK. 2017.

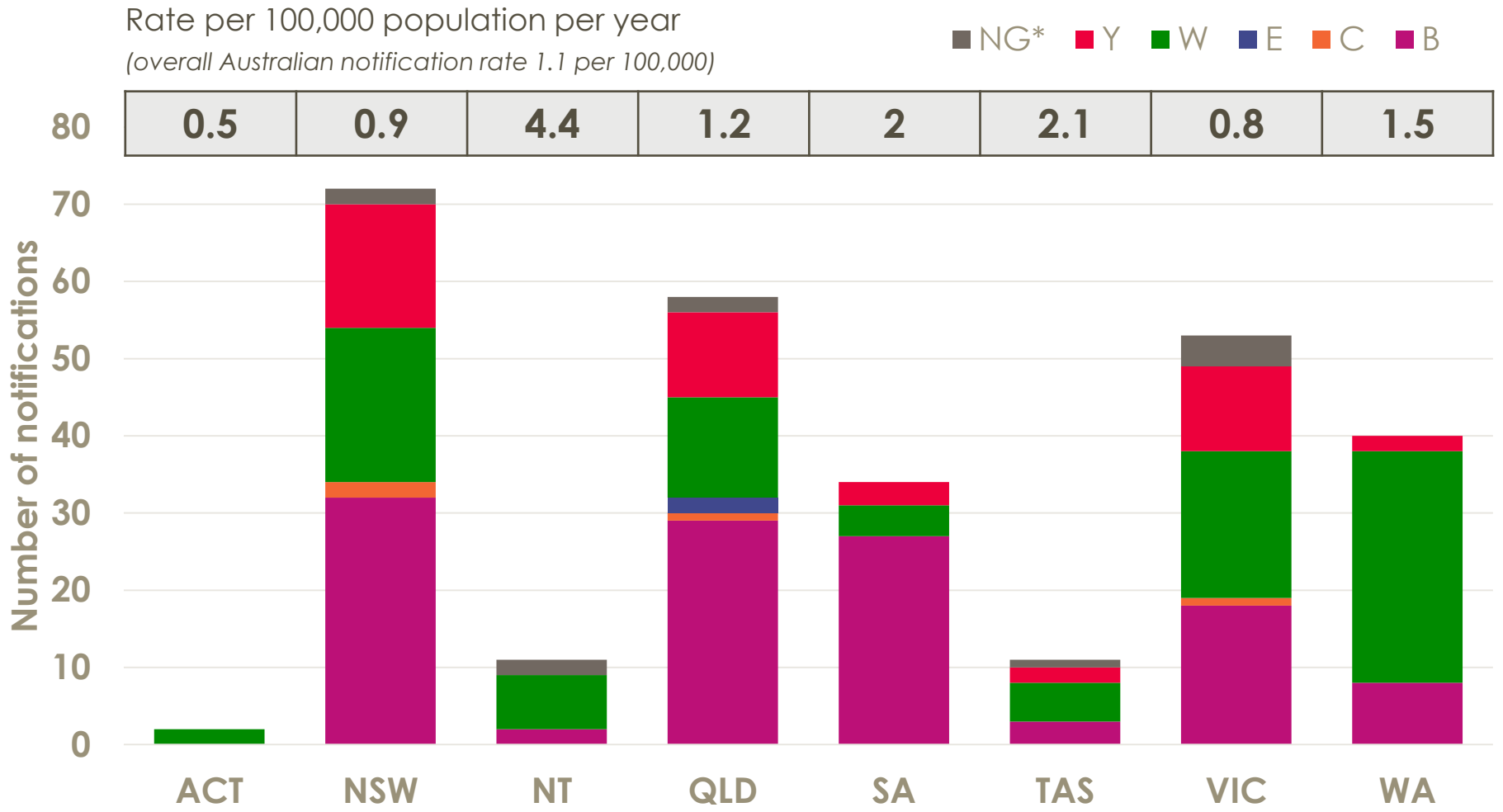
# NZ has a high rate of IMD compared with other countries worldwide*

| Country | Year | Notification rate | Source |
|---|---|---|---|
| New Zealand | 2018 | 2.5 | **ESR Invasive Meningococcal Disease Report 23 November 2018** https://surv.esr.cri.nz/PDF_surveillance/MeningococcalDisease/2018/QuarterlyreportMen23_11_2018.pdf |
| Australia | 2017 | 1.6 | Australian Government Department of Health Invasive meningococcal disease National surveillance report 31 December 2017 https://www.health.gov.au/internet/main/publishing.nsf/Content/5FEABC4B495BDEC1CA25807D001327FA/$File/31-Mar18-IMD-Surveillance-report.pdf |
| US | 2017 | 0.11 | CDC Enhanced Meningococcal Disease Surveillance report, 2017 https://www.cdc.gov/meningococcal/downloads/NCIRD-EMS-Report-2017.pdf |
| England | 2017 - 2018 | 1.0 | **Public Health England Invasive meningococcal disease in England: annual laboratory confirmed reports for epidemiological year 2017 to 2018** https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/751821/hpr3818_IMD.pdf |



*Some countries have an IMD vaccination programme in place

# IMD in Australia: Breakdown by State or Territory, 2018[1]




Adapted from the Department of Health, 2018[1]

*NG includes where meningococcal isolates could not be identified ('not groupable'), other isolates not grouped and where serogroup was not known.


1. Department of Health. Invasive Meningococcal Disease National Surveillance Report. Quarter 4, 2018. 1 October to 31 December 2018 http://www.health.gov.au/internet/main/publishing.nsf/Content/5FEABC4B495BDEC1CA25807D001327FA/$File/1Oct-31Dec19-qrt3-IMD.pdf [Accessed April 2019]

# Summary - the number of cases of IMD has been increasing since 2014

- The total number of reported cases for 2018 is 120 cases with 10 deaths. This is higher than the 112 cases and 9 deaths reported in 2017.
- From 1 January to 30 June 2019, 50 cases of invasive meningococcal disease were reported, compared with 42 cases for the same period in 2018
- The group was identified in 45 of the cases; 25 (54.3%) were group B, 13 (28.3%) were group W, four (8.7%) were group Y, three (6.5%) were group C
- As compared with the first two quarters of 2018, the proportion of group W has increased (from 27.0% to 28.3%) and the proportion of group B cases has increased (from 48.6% to 54.3%)
- Two deaths has been reported this year to date

The Institute of Environmental Science and Research. Invasive Meningococcal Disease Report Q2 2019. Accessed July 2019, available at: https://surv.esr.cri.nz/surveillance/Meningococcal_disease.php

# Available meningococcal vaccines and new infant dosing indication

# Meningococcal vaccination in New Zealand[1,2]


- There is no single vaccine that offers protection against all bacterial serogroups that cause meningococcal disease

- There are three types of meningococcal vaccines used in New Zealand currently
  1. Meningococcal C conjugate vaccines
  2. Quadrivalent meningococcal conjugate vaccines
  3. Multicomponent meningococcal group B vaccine (recombinant, adsorbed)

- There is no vaccine to protect against serogroup X

- There are no meningococcal vaccines included in the National Immunisation programme

1. NZ Ministry of Health Immunisation Handbook: https://www.health.govt.nz/system/files/documents/publications/immunisation-handbook-2017-may17-v3.pdf [Accessed Jan 2018]

# Meningococcal vaccines available in New Zealand[1]

## Monovalent meningococcal C vaccines

| Vaccine | Indication | Dosing schedule | Protects against |
|---|---|---|---|
| NeisVac-C®[1] | ≥8 weeks | <12 months, 2 doses^<br>>12 months, 1 dose | Serogroup C |

^At least 2 months apart. Booster dose to be given in the second year of life

## Quadrivalent meningococcal conjugate vaccines

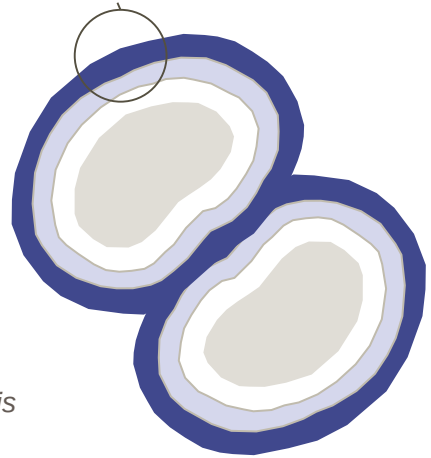
| Vaccine | Indication | Dosing schedule | Protects against |
|---|---|---|---|
| Menactra®[2] | ≥9 months-55 years | 9-23 months, 2 doses^<br>2-55 years, 1 dose | Serogroups A,C,$W_{135}$,Y |
| Nimenrix®[3] | ≥12 months- 55 years | All ages, 1 dose | Serogroups A,C,$W_{135}$,Y |

^At least 3 months apart.


1. NeisVac-C Datasheet, Pfizer http://www.medsafe.govt.nz/profs/datasheet/n/NeisVacCinj.pdf [Accessed: Jan 2018]
2. Menactra Datasheet, Sanofi Aventis http://www.medsafe.govt.nz/profs/Datasheet/m/menactrainj.pdf [Accessed: Jan 2018]
3. Nimenrix Datasheet, Pfizer http://www.medsafe.govt.nz/profs/Datasheet/n/nimenrixinj.pdf [Accessed: Jan 2018]

# Why was a multicomponent approach to Meningococcal B vaccine development needed?

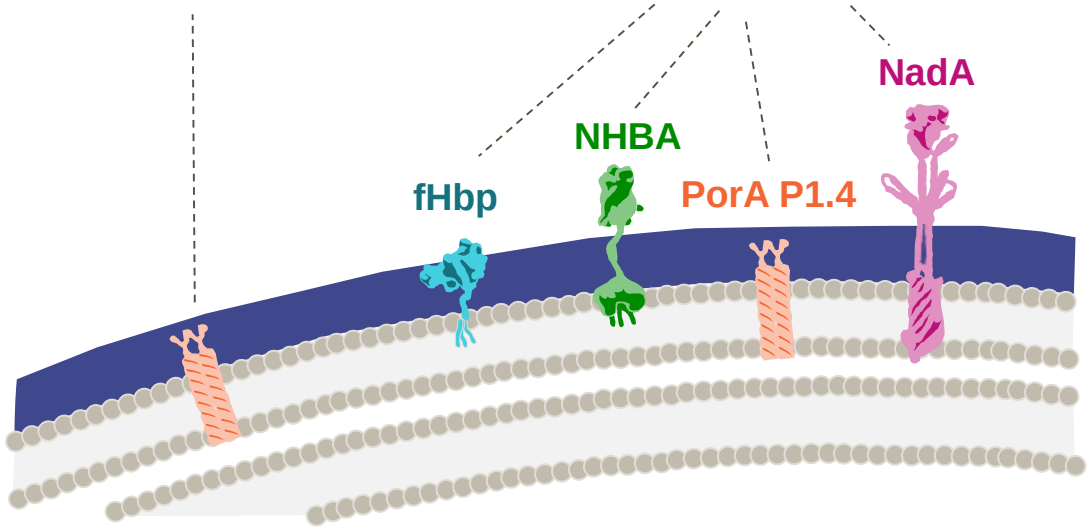
The **polysaccharide capsule** is **poorly immunogenic**[1,2]



*Neisseria meningitidis*

A **single** subcapsular **protein component** (e.g. OMV) is susceptible to **antigenic variability**[3,4]

**Multiple** components enable **broad coverage** across a number of strains[5]




fHbp, Factor H binding protein; NadA, *Neisseria* adhesin A; NHBA, *Neisseria* heparin-binding antigen; OMV, outer membrane vesicle; PorA, Porin A; OMV, outer membrane vesicle
Images of antigenic components of 4CMenB adapted by permission from Springer Nature: Drugs, A Multi-Component Meningococcal Serogroup B Vaccine(4CMenB): The Clinical Development Program, O'Ryan M et al, Copyright 2014

1. Finne J *et al. J Immunol* 1987;138:4402–4407; 2. Wyle FA *et al. J Infect Dis* 1972;126:514–521; 3. Sadarangani M *et al. Lancet Infect Dis* 2010;10:112–124; 4. Tan LK *et al. N Engl J Med* 2010;362:1511–1520; 5. Donnelly J *et al. Proc Natl Acad Sci U S A* 2010;107:19490–19495

# Bexsero Indication

Multicomponent Meningococcal group B Vaccine (recombinant, adsorbed)

Bexsero is indicated for active immunisation against invasive disease caused by *N. meningitidis* group B strains.

Bexsero is indicated for vaccination of individuals from 2 months of age and older.

The use of Bexsero should be in accordance with official recommendations.


1. GSK New Zealand. Bexsero Data Sheet, July 2018. Available at http://www.medsafe.govt.nz/profs/Datasheet/datasheet.htm

# Bexsero dosing – new indication

| | 2 – 5 months old* | 6 – 11 months old | 12 months – 23 months old | 2 – 50 years old^ |
|---|---|---|---|---|
| PRIMARY IMMUNISATION | 2 doses~, ≥2 months apart | 2 doses, ≥2 months apart | 2 doses, ≥2 months apart | 2 doses, ≥1 month apart |
| BOOSTER | Second year of life<br>1 dose in the second year of life with an interval of at least 6 months between the primary series and the booster dose | Second year of life<br>1 dose in the second year of life with an interval of at least 2 months between the primary series and the booster dose | Need not established | Need not established |

*Bexsero* can be administered at the same time as other vaccines, including those on the National Immunisation Schedule.[2]

Refer to the *Bexsero* Data Sheet and local Immunisation Advisory Centre recommendations before prescribing.[1,2]

**Note:** Each dose is 0.5 mL. *The safety and efficacy of the vaccine in infants <8 weeks has not yet been established and there is no data available. ~Alternative schedule available - refer to Data Sheet. ^No data available in individuals above 50 years of age.


**1.**GlaxoSmithKline NZ. Bexsero Data Sheet 2018. Available at: http://www.medsafe.govt.nz/profs/Datasheet/b/bexseroinj.pdf Accessed:17 May 2019.
**2.**Immunisation Advisory Centre. Bexsero®: A vaccine to protect against meningococcal group B disease. Available at: http://www.immune.org.nz/sites/default/files/resources/Written%20Resources NonprogrammeVaccineBexseroImac20181109V01Final. pdf Accessed: 24 April 2019.

# The MenB vaccination programme was implemented to reduce MenB disease in early childhood in the UK[1]

**January 2013[2]**

BEXSERO® approved in UK

**March 2014[3]**

JCVI recommendation (BEXSERO® at 2, 4 and 12 months of age*)

**September 2015[1]**

Implementation into NHS immunisation programme

## Implementation of the MenB programme[1,3–5]

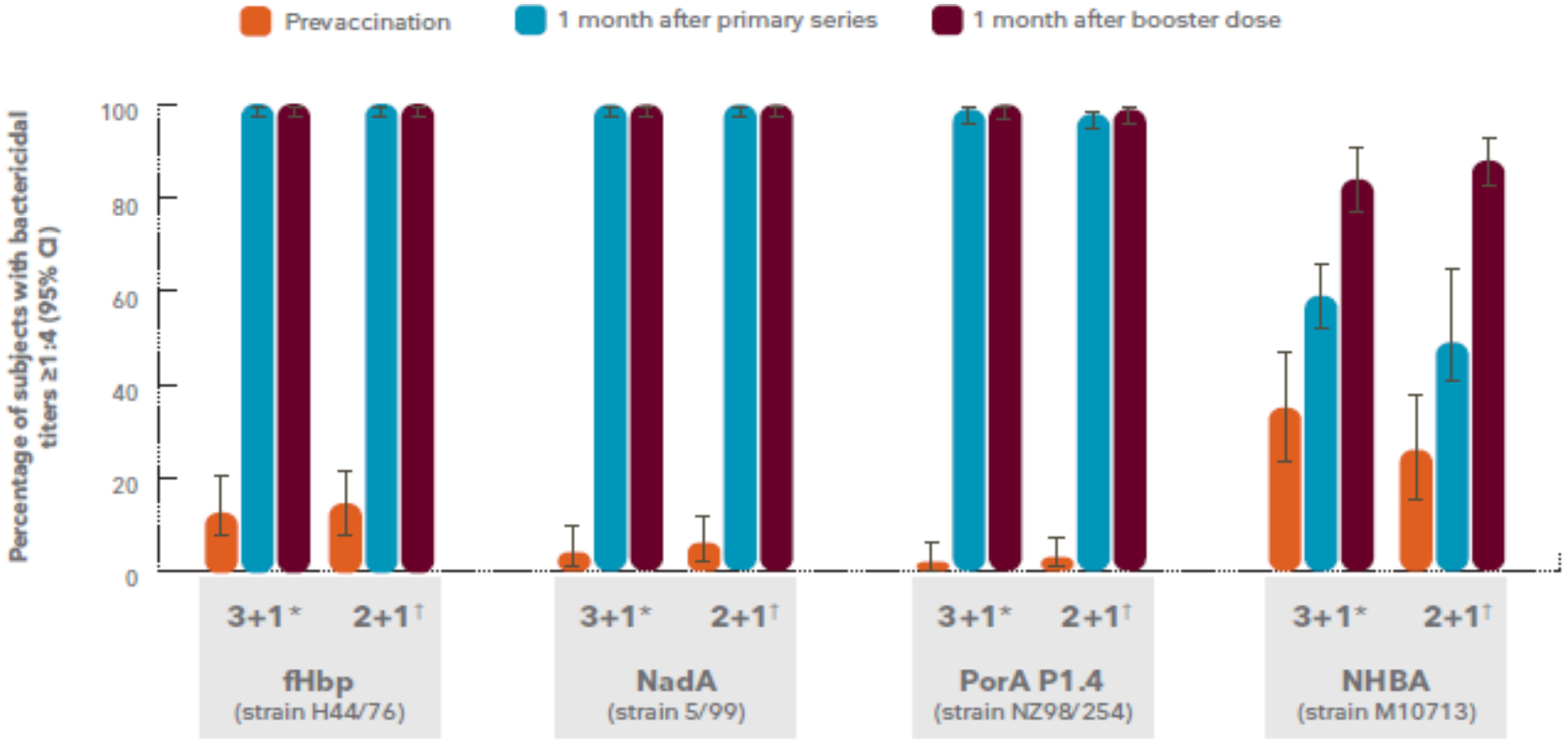
- Three doses of BEXSERO® as part of the primary immunisation schedule at 2, 4 and 12 months of age (2+1 schedule)[1,3,4*]
- A catch-up schedule offered to 3- and 4-month-olds[4]
- BEXSERO® was coadministered with routine vaccines[1,4]
- Paediatricians made aware that, in clinical trials, some post-vaccination fevers resulted in attendance at medical facilities[1,3]
- Therefore, parents advised to give paracetamol with BEXSERO® to infants aged 2 and 4 months[1,5]

*Note: The dosing schedule recommended by JCVI was not consistent with the licensed indication for this age group[2,3]
JCVI, Joint Committee on Vaccination and Immunisation; NHS, National Health Service

1. Ladhani SN *et al. Arch Dis Child* 2016;101:91–5; 2. BEXSERO® UK SmPC. https://www.medicines.org.uk/emc/history/28407#version7 (Accessed September 2016);
3. JCVI 2014. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/294245/JCVI_Statement_on_MenB.pdf (Accessed September 2016);
4. Parikh, Sydel R *et al. The Lancet* October 2016 http://dx.doi.org/10.1016/S0140-6736(16)31921-3 (Accessed October 2016); 5. PHE 2015. Using paracetamol.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/483408/9413-paracetamol-menB-2page-A4-08-web.pdf (Accessed September 2016)

# Infant response to vaccination with Bexsero

Percentage of infants with hSBA titres considered to be protective[1]

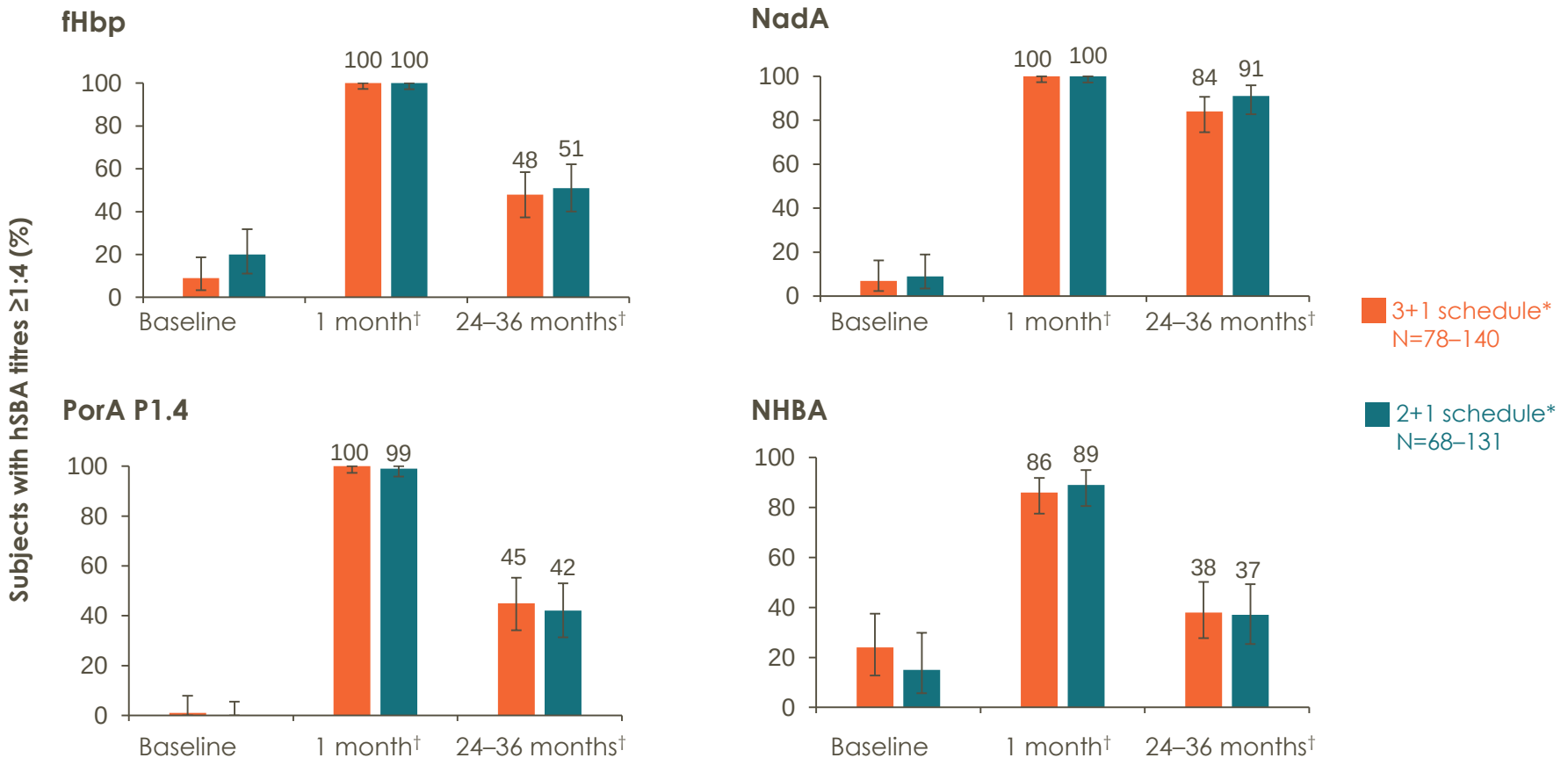



* For the 3+1 dosing schedule, infants received BEXSERO at 2½, 3½, and 5 months, with a booster at 11 months.
† For the 2+1 dosing schedule, infants received BEXSERO at 3½ and 5 months, with a booster at 11 months.
CI = confidence interval; hSBA = human complement serum bactericidal activity; fHbp = factor H binding protein; NadA = Neisserial adhesin A; PorA P1.4 = porin A protein; NHBA = *Neisseria* heparin binding antigen.

- **87% to 100%** of infants achieved titres considered to be protective one month after the booster with the 2+1 schedule[2]
- **83% to 100%** of infants achieved titres considered to be protective one month after the booster with the 3+1 schedule[1]
- Persistence of protective antibodies 24-36 months post-vaccination with a reduced 2+1 schedule was similar to that of the 3+1 schedule[3]

1. Martinón-Torres F et al. *Vaccine*. 2017;35(28):3548-3557 2. GlaxoSmithKline. BEXSERO. European public assessment report, Annex I: Summary of product characteristics. 3. Martinón-Torres F et al. *J Infect*. 2018;76(3):258-269.

# Immunogenicity and persistence of BEXSERO in infants was similar with a 2+1 and 3+1 schedule*

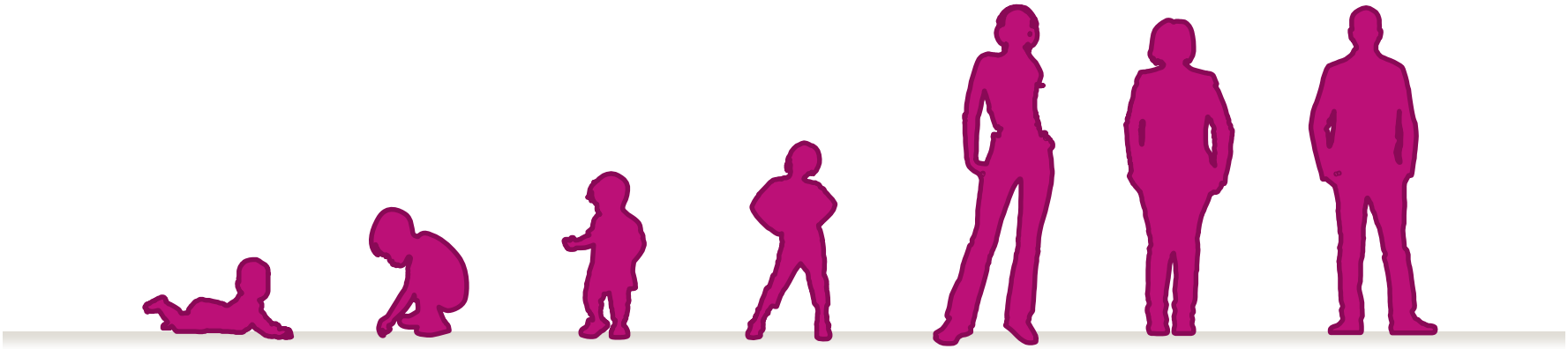



The same results were first published in Martinón-Torres F *et al*. *J Infect* 2018;76:258–269
*For the licensed 3+1 schedule, patients received BEXSERO at 2½, 3½, 5, and 11 months and for the reduced 2+1 schedule, at 3½, 5, and 11 months
†Immune response measured post-last dose; Baseline data extrapolated from graphs in the supplementary appendix of the publication
fHbp, factor H binding protein; hSBA, serum bactericidal assay using human complement; NadA, *Neisseria* adhesin A; NHBA, *Neisseria* heparin-binding antigen; PorA, porin A

1. Martinón-Torres F *et al*. *J Infect* 2018;76:258–269
The graph has been independently created by GSK from the original data

# Co-administration and tolerability

# *Bexsero* can be co-administered with a number of routine vaccines



Immune response to **routine vaccines was unaffected** by co-administration of *Bexsero*

- ✓ Diphtheria
- ✓ Tetanus
- ✓ Acellular pertussis
- ✓ *Haemophilus influenzae* type b
- ✓ Inactivated poliomyelitis
- ✓ Hepatitis B

- ✓ Measles
- ✓ Mumps
- ✓ Rubella
- ✓ Varicella

- ✓ Heptavalent pneumococcal conjugate

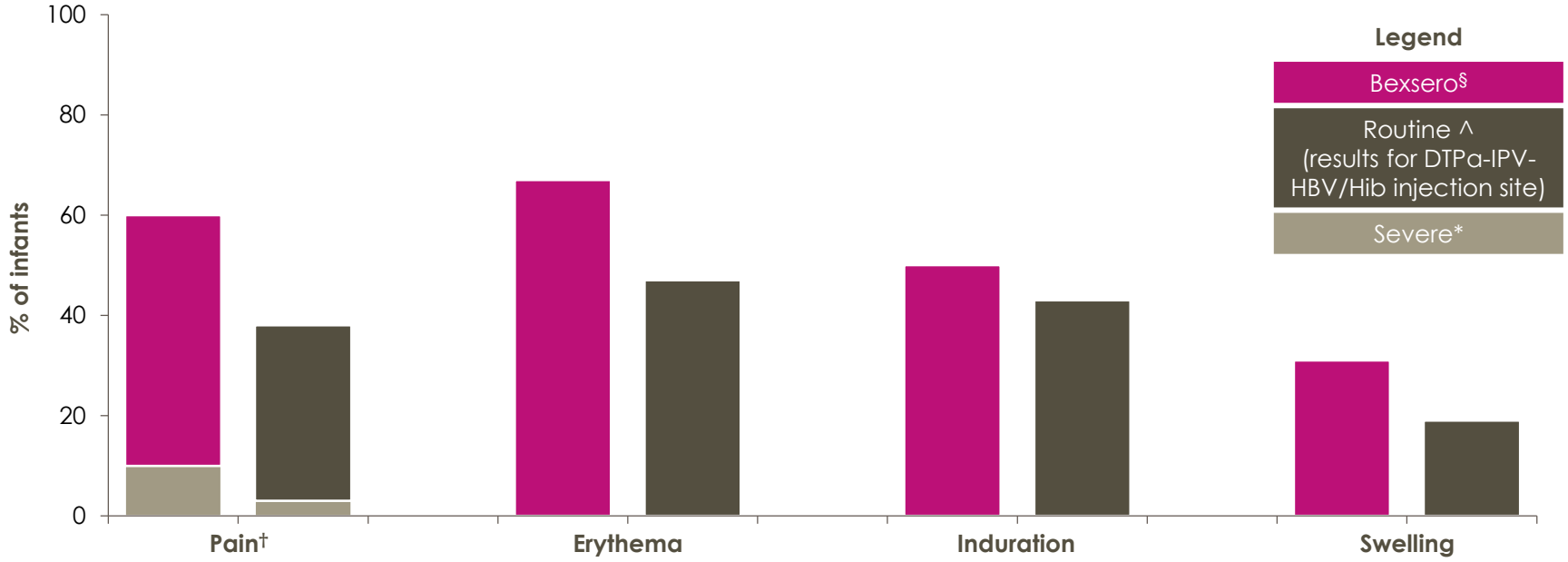
- ✓ Meningococcal group C-CRM conjugate

– Co-administration of B*exsero* with vaccines other than those mentioned above has not been formally studied
Inconsistent results were seen across studies for responses to inactivated poliovirus type 2 and pneumococcal conjugate serotype 6B, and lower antibody titres to the pertussis pertactin antigen were also noted; these findings do not suggest clinically significant interference

1. GSK New Zealand. *Bexsero* Data Sheet, July 2018. Available at http://www.medsafe.govt.nz/profs/Datasheet/datasheet.htm

# Bexsero tolerability in infants

## Bexsero tolerability compared to routine vaccines (PCV7 and DTPa-IPV-HBV/Hib)
## Results post dose 1: Local reactions (reported in the 7 days post vaccination)




*Adapted from Gossger et al, 2012[1]

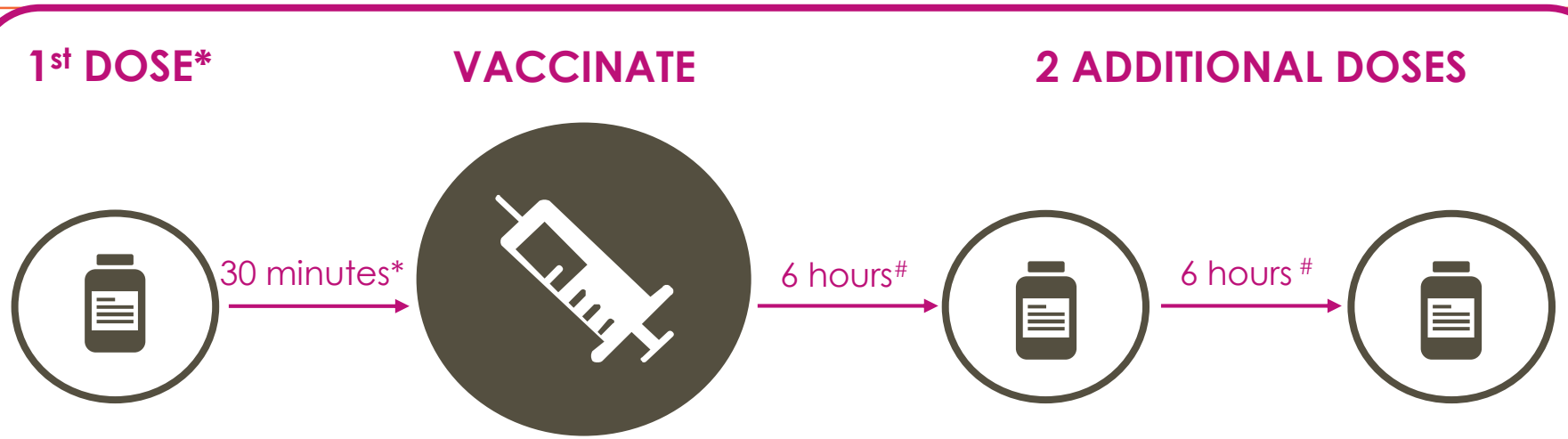
#Bexsero alone, N=626: infants vaccinated with BEXSERO at 2, 4 and 6 months separately from routine vaccines which were administered at 3, 5, and 7 months. Data shown are from the Bexsero time point only;
^Routine alone: N=310. Routine vaccines: PCV7 and DTaP-HBV-IPV/Hib. Infants vaccinated at 2, 3 and 4 months
†Pain was categorised as severe if subject cried when injected limb was moved or did not move injected limb. Erythema, induration and swelling were categorized as severe if local reaction was >100 mm.[1]

- There was **no increase** in the incidence or severity of the adverse reactions with subsequent doses of the vaccination series[1]


1. Gossger N, et al. *JAMA* 2012;**307**:573-82 [including supplementary online content]

# Recommendations: Prophylactic Paracetamol (< 2 years)

*New Zealand Immunisation Advisory Centre (IMAC)*[1]




15mg/kg paracetamol 30 minutes prior to vaccination, with all Bexsero doses administered to < 2 year olds.[1]
*If the first paracetamol dose has not been given before the child is vaccinated, administer the dose at the time of vaccination. # 2 further doses should be administered 6 hours apart, regardless of the presence of fever

- Prophylactic use of paracetamol reduces the incidence and severity of fever without affecting the immunogenicity of either Bexsero or routine vaccines (PCV-7 and DTP-IPV-HBV/Hib)[2]
- The effect of antipyretics other than paracetamol in the immune response has not been studied[2]

- There was **no increase** in the incidence or severity of the adverse reactions with subsequent doses of the vaccination series[1]


1. NZ Immunisation Advisory Centre (IMAC) Fact Sheet Sept 2018 Available at http://www.immune.org.nz/sites/default/files/resources/Written%20Resources/AdministrationParacetamolBexsero20180912V01Final.pdf
2. GSK New Zealand. Bexsero Data Sheet, July 2018. Available at http://www.medsafe.govt.nz/profs/Datasheet/datasheet.htm
3. Gossger N, et al. JAMA 2012;**307**:573-82 [including supplementary online content]

# Summary

- Invasive meningococcal disease is a rare, but potentially fatal disease
- **Serogroup B and W cause the majority of IMD in New Zealand**
- To date, in 2019, 58.3% of meningococcal cases that could be typed are group B, 28.3% are group W[1]
- Meningococcal B can strike any age, **but is most frequent in children <5 years of age, and adolescents**[1]
- Bexsero has new dosing indication for 2 +1 doses in infants[2]
- Use of **prophylactic paracetamol** is recommended by IMAC when meningococcal B vaccine is administered to infants and children **<2 years of age,** regardless of the presence of fever[3]
- Prophylactic paracetamol reduces reactogenicity and does not interfere with the immunogenicity of Bexsero or the co-administered vaccines[3]

1. The Institute of Environmental Science and Research. Invasive Meningococcal Disease Report Q2 2019 access July 2019 available at: https://surv.esr.cri.nz/surveillance/Meningococcal_disease.php 2. GSK New Zealand. Bexsero Data Sheet, 2018. Available at http://www.medsafe.govt.nz/profs/Datasheet/datasheet.htm 3. NZ Immunisation Advisory Centre (IMAC) Fact Sheet Sept 2018 Available at http://www.immune.org.nz/sites/default/files/resources/Written%20Resources/AdministrationParacetamolBexsero20180912V01Final.pdf

# Bexsero Prescribing Information

*Bexsero*® (Multicomponent Meningococcal group B Vaccine) is available as a private-purchase prescription medicine for active immunisation against invasive disease caused by *N. meningitidis* group B from 2 months of age. The use of *Bexsero* should be in accordance with official recommendations. A prescription charge will apply. A trained pharmacist can also administer *Bexsero* to a person aged 16 years and older. A single 0.5mL dose contains 50mcg of *Neisseria meningitidis* Group B Neisseria Heparin Binding Antigen fusion protein, 50mcg of *Neisseria meningitidis* Group B Neisseria Adhesin A protein, 50mcg of *Neisseria meningitidis* Group B Factor H Binding Protein fusion protein, 25 mcg of Outer membrane vesicles (OMV) from *Neisseria meningitidis* group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4. **Dosage and Administration: Administered by deep intramuscular injection**. 0.5ml dose in a pre-filled syringe. Infants (2-5 months): 2 doses (≥2 month interval), booster dose at 12-23 months (≥6 month interval between primary series and booster). Unvaccinated infants (6-11 months): 2 doses (≥2 month interval), booster dose at 12-23 months (≥2 month interval between primary series and booster). Unvaccinated toddlers (12-23 months): 2 doses (≥2 month interval), need for booster not established. Children 2 years - adults 50 years: 2 doses (≥1 month interval), need for booster not established. **Contraindications:** Hypersensitivity to any vaccine component. **Precautions: *Bexsero* should never be administered intravenously, subcutaneously or intradermally.** Postpone vaccination during acute severe febrile illness. Anticipate psychogenic response (syncope, hyperventilation). Manage fever (prophylactic antipyretics). Individuals with impaired immune responsiveness. No data for use in subjects aged ≥50 years or patients with chronic medical conditions. Apnoea in very premature infants. Kanamycin-sensitive individuals. Pregnancy (category B1). Lactation. May contain latex. As with any vaccine, vaccination with *Bexsero* may not protect all vaccine recipients. *Bexsero* is not expected to provide protection against all circulating meningococcal group B strains. **Bexsero should be administered at separate injection sites. Adverse reactions:** Infants & Toddlers: eating disorders, sleepiness, unusual crying, diarrhoea, vomiting, rash, fever (≥39.5°C), injection site reactions, irritability, arthralgia. Adolescents & Adults: headache, nausea, injection site reactions, malaise, myalagia, arthralgia. This is not a full list. **Before prescribing *Bexsero*, please review the full Data Sheet at** www.medsafe.govt.nz. ***Bexsero* is a registered trade mark of the GlaxoSmithKline group of companies. Marketed by GlaxoSmithKline NZ Ltd, Auckland. Adverse events involving GlaxoSmithKline products should be reported to GSK Medical Information on 0800 808 500. TAPS DA1921MB/PM-NZ-BEX-PPT-190002**

**Kia Ora**
**Mā te wā**

**Thank you**
**See you later**

Please review the Bexsero Data Sheet before prescribing
New Zealand Data Sheet is available at
http://www.medsafe.govt.nz/profs/Datasheet/datasheet.htm