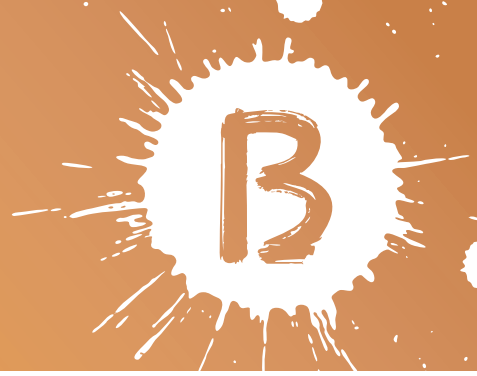


B Part of It – Website Q&A



About Meningococcal B

What is Meningococcal B?

Meningococcal disease is a life threatening illness caused by a bacterium called **Neisseria meningitidis**, often known as meningococcus.

There are six different types of meningococcus that cause infection in humans (Meningococcus A, B, C, W, X and Y), but most infections in Australia (80 per cent of cases) are caused by the Meningococcal B strain.

How does it differ from other strains of Meningococcal disease?

The types of meningococcus causing disease may change over time (e.g. the Meningococcus C strain was previously a common type like the B strain). Today, cases of the C strain are not often seen. This is because the Meningococcal C vaccine was introduced in a funded program in 2003. The vaccine was very effective, because it has a herd immunity effect – it not only protects those who were immunised, but also stopped the bacteria being transmitted between people.

Although the overall number of cases of meningococcal disease has decreased since the Meningococcal C vaccine was introduced, the numbers have started to rise again. It is difficult to predict which strains of the meningococcus bacteria may increase or decrease over time, however in South Australia, we have consistently had around 25-30 cases reported each year due to the B strain.

How do you contract it?

The meningococcus bacteria can be carried without causing harm in the nose and throat of around 10 per cent of the population – and up to 25 per cent in adolescents and young adults ('carriers'). The bacteria can spread when a person carrying it coughs or sneezes, sending small droplets containing the meningococcus into the air, which may be breathed in by those nearby. The meningococcus bacteria is also spread by close contact with nose or throat secretions, for example during kissing.

Even though it is hard to catch and is uncommon, meningococcal disease is a feared infection due to its severity, and is often featured in the media. Meningococcal disease can affect all age groups, but is most common in children under five years of age and in young adults (15-24 years).

Meningococcal disease can occur throughout the year, but is most common in winter and spring. Viral infections such as the flu can increase the risk of people developing meningococcal disease, which may explain why the infection is more common in winter and spring.

What symptoms should people look out for? If someone contracts Meningococcal B, what does it do to them?

People with meningococcal disease can become extremely unwell very quickly. The symptoms from meningococcal disease may be very non-specific, with a general feeling of being unwell. Usually, a fever is present, with other possible symptoms such as headache, neck stiffness, muscle aches, drowsiness, nausea and vomiting, convulsions and seizures, and a rash. An unusual symptom, which is highly suggestive of meningococcal disease, is the feeling of having cold feet and hands – usually in addition to the other symptoms.

The typical rash of meningococcal infection usually starts as small pinpricks, but as the disease progresses, deep purple blotches that do not fade under pressure can appear. Not all children or adolescents get this rash, so you should not wait for this before seeking help.

Anyone concerned that they or their child has symptoms suggestive of meningococcal disease should seek urgent medical attention.

Meningococcal septicaemia (infection of the blood) and meningitis (infection around the surface of the brain) can cause shock and death within hours of the onset of symptoms, or permanent disabilities such as brain injury and amputation of fingers, toes, arms or legs due to the lack of blood circulation to the limbs.

In Australia, 5-10 per cent of people with meningococcal disease die, despite rapid treatment.

How can you prevent yourself or others from contracting it?

A Meningococcal B vaccine (Bexsero®) is available and recommended in Australia for infants and adolescents/young adults, or for anybody wanting to be immunised against the disease. The vaccine is safe and licensed and is already used in Europe, the United States and Australia. More than 10 million doses of the vaccine will have been administered worldwide by 2017.

In Australia, at this point in time, the vaccine can only be purchased through the private market, costing approximately \$300 per adolescent/adult (two doses) and up to \$500 for infants. It is not available on the free National Immunisation Program.

Some behaviours, such as smoking, intimate kissing with multiple partners, and recent or current respiratory infection may increase an individual's risk of meningococcal infection.

About the Meningococcal B vaccination

At what age can people be vaccinated against Meningococcal B?

A Meningococcal B vaccine (Bexsero®) is available and recommended in Australia for infants and adolescents/young adults. This vaccine can be given to children as young as six weeks of age, and can be provided to children and adults.

The Meningococcal B vaccine is recommended for babies and young children, particularly those aged under two years and adolescents aged 15-19 years of age. It is particularly recommended for adolescents and young adults living in close quarters, such as students living in residential accommodation.

Some medical conditions, such as immune defects or deficiency, place individuals at higher risk of meningococcal disease.

Vaccines are also available at a cost to protect against serogroups A, C, W and Y, as serogroup W occurs more frequently in other states of Australia.

Aren't people already immunised? I thought the vaccines given to babies/infants were to protect them against Meningococcal B.

Currently, the meningococcal vaccine available for free for babies/infants as part of the National Immunisation Program provides protection only against the C strain.

You can be immunised by your GP against Meningococcal B with the vaccine Bexsero®. Infants from six weeks to five months of age require three doses given eight weeks apart and a booster vaccination at 12 months (four doses in total). Infants aged between six and 11 months of age require two doses given eight weeks apart and a booster at 12 months (three doses), and in infants and children one year of age and older, two doses are given approximately eight weeks apart. Adolescents and adults require two doses given approximately eight weeks apart.

Is the vaccine safe?

Yes. All vaccines used in Australia are extensively tested for safety. Before a vaccine or any medication can be used in this country it must be licensed by the Therapeutic Goods Administration (TGA), which extensively assesses each vaccine for safety and effectiveness. This assessment is based on scientific evidence from clinical trials in adults, adolescents, children and infants.

Information about immunisation and reactions can be confusing. If you would like further information, go to 'Immunisation Myths and Realities' at www.immunise.health.gov.au or visit the website for the National Centre for Immunisation Research and Surveillance (NCIRS) at www.ncirs.edu.au

What are the risks and/or side effects of the vaccine?

The Bexsero® vaccine is well tolerated, with more than six million doses already distributed worldwide. Like all vaccines, there is the possibility of common side effects (similar to some other vaccines), which are mild and may include a mild fever, soreness at the injection site, headache and generally feeling unwell for one to two days.

Like all vaccines, there is the possibility of rare, more serious reactions, such as an allergic/anaphylactic reaction to the vaccine.

Does the vaccine immunise you for life?

The evidence of long term protection against Meningococcal B disease is not yet available

Why isn't the vaccine free of charge or available at a reduced price through the Pharmaceutical Benefits Scheme (PBS)?

The vaccine has not been assessed as cost effective, and therefore has not been included in the funded National Immunisation Program. The Pharmaceutical Benefits Advisory Committee (PBAC) which assesses the cost effectiveness of vaccine programs has requested further information on effectiveness of a Meningococcal B vaccine program and information on any herd immunity effects of the vaccine to assist in further cost effective analyses.

The vaccine has been shown to be 83 per cent effective following introduction of the funded infant immunisation program in the United Kingdom and up to 94 per cent effective against strains causing disease that are closely related to the vaccine.

Is the vaccine free of charge or available at a reduced price through the Pharmaceutical Benefits Scheme (PBS) in other parts of Australia?

No the vaccine is only available for purchase in each state and territory in Australia.

If I/my child are/is given this vaccine, what do we need to do to protect ourselves against all the other strains of meningococcal disease?

Vaccines are also available at a cost to protect against serogroups A, C, W and Y, as serogroup W occurs more frequently in other states of Australia

All children are offered Meningococcal C vaccine at 12 months of age through the funded National Immunisation Program.

About the program

Why is this program being launched in South Australia? What does it involve?

South Australia has had the highest rate of meningococcal disease in Australia since 2012, with more cases in adolescents than infants. It is vital we learn more about the disease and the benefits of vaccinating against Meningococcal B.

At this point in time, a vaccine to immunise against Meningococcal B is not available for free through the National Immunisation Program, as more information is required to demonstrate it whether has a herd immunity effect (that immunisation prevents transmission to others) in addition to the individual protection it offers.

This study will examine if the Meningococcal B vaccine reduces the spread of meningococcal bacteria in teenagers through a herd immunity study. Only students enrolled in Years 10, 11 and 12 in 2017 and 2018 will be able to participate in the study.

The study will be rolled out across South Australia through a staged program running throughout 2017 and 2018. Participants will be involved in the study for 12 months. During that time, all participants will be vaccinated with Bexsero® (two doses given approximately eight weeks apart – and at least one month to less than three months) free of charge. In addition, two throat swabs will be collected from each participant across the 12 months of the study (2017-2018).

To receive the vaccines, participants must be at school on vaccination day. If they are not present, they may not be able to receive the vaccine.

How is the throat swab taken?

A swab is rubbed gently on the back of the throat for a few seconds. This may cause minor discomfort and, in some individuals, a gagging sensation may occur.

Participants will be provided with a \$20 iTunes voucher each time a throat swab is taken (they will receive two \$20 iTunes vouchers) to compensate them for the time taken to be involved in the study and to have the swabs taken.

What will happen to the throat swabs?

The throat swabs will be tested by SA Pathology and stored for future testing related to meningococcal bacteria and infection.

The samples may be sent to other laboratories nationally and internationally for further tests on the bacteria.

No human genetic testing will be done on swab samples. No individual results will be provided to participants or their families.

What is herd immunity?

Herd immunity is when a significant portion of a population is immunised against a disease, preventing the transmission of that disease from one person to another and protecting those who are not immune.

Herd immunity protects people who cannot be administered vaccinations because they are too young or have a medical condition that prevents it.

If enough people in the community are immunised and protected from a disease, it can no longer spread.

The more people immunised, the more that will be protected.

I've heard that this is a study. What does that mean? Is this vaccination new or experimental?

South Australia has had the highest rate of meningococcal disease in Australia since 2012, with more cases in adolescents than infants. It is vital we learn more about the disease and the benefits of vaccinating against Meningococcal B.

At this point in time, the licensed and recommended vaccine to immunise against Meningococcal B is not available for free through the National Immunisation Program, as more information is required to demonstrate it has a herd immunity effect (that immunisation prevents transmission to others) in addition to the individual protection it offers.

This study will examine if the licensed and recommended Meningococcal B vaccine reduces the spread of meningococcal bacteria in teenagers. Only students enrolled in Years 10, 11 and 12 in 2017 will be able to participate in the study.

All vaccines used in Australia are extensively tested for safety. Before a vaccine or any medication can be used in this country it must be licensed by the Therapeutic Goods Administration (TGA), which extensively assesses each vaccine for safety and effectiveness. This assessment is based on scientific evidence (clinical trials).

The Bexsero[®] vaccine is well tolerated, with more than 10 million doses administered by 2017.

Who has approved the research study?

This study has been approved by the Women's and Children's Health Network Human Research Ethics Committee.

When is the program taking place?

All South Australian school students enrolled in Years 10, 11 and 12 in 2017 will be eligible to participate in the study if their school signs up and their parents provide consent.

Who is funding this program?

This study is sponsored by the University of Adelaide. The vaccines and funding to conduct the study have been provided by GlaxoSmithKline (GSK), the company that manufactures the Meningococcal B vaccine. GSK has no other involvement in the study.

Which pharmaceutical company is involved?

The vaccines and funding to conduct the study have been provided by GlaxoSmithKline (GSK), the company that manufactures the vaccine. GSK has no other involvement in the study.

Who administers the vaccinations through this program?

Nurses employed through local health authorities and councils who conduct the Year 8 school immunisation program will work with schools that sign up to participate in the study to provide immunisations to eligible students.

Who is eligible to participate?

All South Australian school students enrolled in Years 10, 11 and 12 in 2017 will be eligible to participate in the study if their school signs up and their parents provide consent.

What do I have to do to make sure I/my child can participate?

All South Australian school students enrolled in Years 10, 11 and 12 in 2017 will be eligible to participate in the study if their school agrees for their local council immunisation provider to provide the Meningococcal B vaccines to students and collect the throat swabs and if their parents provide consent.

If I/my child is in Year 12 in 2017, what will be required of me/them when I/they have left school?

We will ensure that all Year 12 students enrolled in the study have the opportunity to be vaccinated in 2017 or 2018. Those receiving the Meningococcal B vaccine in 2018 after they have left school will receive information about where they can receive the free Meningococcal B vaccine.

How do I find out if my/my child's school has signed up?

All South Australian school students enrolled in Years 10, 11 and 12 in 2017 will be eligible to participate in the study if their school signs up and their parents provide consent.

To ensure you/your child are/is able to take part in the program, speak with your school to confirm it has agreed to participate.

What happens if my school/my child's school does not agree to participate in the program?

Unfortunately, only students from schools that agree to participate can receive the free immunisation and take part in the study.

The University of Adelaide is working closely with the Department of Education and Child Development, Catholic Education South Australia and the Association of Independent Schools of South Australia to support all schools in South Australia being involved.

If the school you/your child attends decides not to participate in the study, the Bexsero[®] vaccine can be purchased privately through your GP (the cost is approximately \$300 per adolescent/adult). See your GP for further information and medical advice.

What are my options in that case?

If you/your child is unable to access the Bexsero[®] vaccine through the study, it can be purchased privately through your doctor (the cost is approximately \$300 per adolescent/adult). See your GP for further information and medical advice.

What consents do you require from parents?

All schools that agree to participate in the study will require written parental consent for each student involved and assent or agreement from the adolescent to be involved. Both the parent and adolescent will need to sign the consent form to be eligible to participate in the study. All necessary forms will be provided to the school and they will provide those to parents.

Please make sure all relevant consent forms are signed and returned promptly.

What if consent has been given but the student is unwell or not at school on vaccination day?

If a participant in the study is unwell or not at school on swab/vaccination day, they may not be able to receive the free Meningococcal B vaccine. They must be present at school on the day to participate.

Why is this program only available to South Australian students enrolled in Years 10, 11 or 12 in 2017 and 2018?

South Australia has had the highest rate of meningococcal disease in Australia since 2012, with more cases in adolescents than infants. It is vital we learn more about the disease and the benefits of vaccinating against Meningococcal B.

At this point in time, a vaccine to immunise against Meningococcal B is not available for free through the National Immunisation Program, as more information is required to demonstrate it has a herd immunity effect (that immunisation prevents transmission to others) in addition to the individual protection it offers.

This study will examine if the Meningococcal B vaccine reduces the spread of meningococcal bacteria in teenagers. For this reason, only students enrolled in Years 10, 11 and 12 in 2017 will be able to participate in the study.

If I/my child am/is not in the catchment group for the program (all South Australian students enrolled in Years 10, 11 or 12 in 2017), what should we do to protect ourselves from contracting Meningococcal B?

The Bexsero[®] vaccine can be purchased privately through your doctor (the cost is approximately \$300 per adolescent/adult). See your GP for further information and medical advice.

What are the alternatives to participation in the study?

Participation in the study is not compulsory. Whichever decision individuals and families make will not affect any of the Centrelink family benefits paid to them.

The Bexsero[®] vaccine can be purchased privately through your doctor (the cost is approximately \$300 per adolescent/adult). See your GP for further information and medical advice.

What happens to personal information?

Personal information will be collected to verify and update each participant's vaccination records. In addition, telephone contact details will be collected for emergency and/or text message reminders of school visits.

Overall results of the study will be presented nationally and internationally to regulatory authorities (such as the Australian Government). All information will be de-identified to ensure participant privacy.

What is the cost of participating in the program?

There is no cost. Participants in the study will be administered two doses of the Bexsero[®] vaccine free of charge.

What if I/my child has already had one dose of the Meningococcal B vaccine? Can I/they still participate in the study?

Unfortunately, no. You will need to purchase the vaccine privately and complete the scheduled course. Supply of vaccines will be available in 2017.

If I elect to immunise myself/my children privately, how do I go about that and what are the costs involved?

The Bexsero[®] vaccine can be purchased privately through your doctor (the cost is approximately \$300 per adolescent/adult). See your GP for further information and medical advice.

What can South Australians do to support this program?

There is already strong commitment from the education and health sectors in South Australia to undertake this important, ground breaking study. Partners include SA Health, the Department of Education and Child Development, Catholic Education South Australia, the Association of Independent Schools of South Australia, local government, SA Pathology and the South Australian Health and Medical Research Institute (SAHMRI).

It is hoped that all Year 10, 11 and 12 students will be involved in the study to provide protection against Meningococcal B infection for themselves and, potentially, for others they come into contact with.

There will be many communication activities undertaken during the next 12 months to raise awareness about the study and the benefits it brings to South Australia.

How will the outcomes of the program be monitored and how will they be communicated publicly?

Overall results of the study will be presented nationally and internationally to regulatory authorities (such as the Australian Government). All information will be de-identified to ensure participant privacy. The results will be communicated to school students, parents, schools and local councils through newsletters and updates on the website.

References:

Australian Immunisation Handbook 2013, Commonwealth Government

<http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home-handbook10part4~handbook10-4-10>