



Dear Parent/Legal Guardian/Student,

Meningococcal B Vaccine Study called 'B Part of It NT'

The University of Adelaide and the Northern Territory (NT) Government are conducting a large study of the Meningococcal B vaccine in young people who are 14 –19 year old. We will look at whether this vaccine can protect against Meningococcal B and also Gonorrhoea, which is caused by a closely related bacteria.

Health Promoting School Nurses (HPSNs) will visit schools across Northern Territory in 2021 to offer free Meningococcal B vaccination to participating students in years 10, 11 and 12. The vaccine will also be available for 14-19 year olds through participating government clinics and Aboriginal Health Services.

This pack contains:

- Participant Information Sheet for the B Part of It NT study
- Consent Form to participate in the study

*** ONLY STUDENTS/YOUNG PEOPLE WITH
A COMPLETED AND SIGNED CONSENT FORM CAN
PARTICIPATE IN THE STUDY ***

Privacy

The information you provide on the Consent Form will be held by the Immunisation service provider (community health or clinic or NT Immunisation Unit). The data will be uploaded to an electronic study database and kept as a medical record. Information regarding your participation will also be disclosed to the study team (NT Government and University of Adelaide).



B Part of It NT

Participant Information Sheet

This information is for you to keep

Meningococcal disease and gonorrhoea are infections which affect young people in the Northern Territory (NT). The two diseases are caused by bacteria that are closely related, but cause different diseases that are spread in different ways. Recent findings suggest that the licensed Meningococcal B vaccine (Bexsero®) which protects against meningococcal B disease may also be effective against gonorrhoea. The Meningococcal B vaccine is not on the NT Immunisation Schedule for adolescents meaning that normally it is not free for this age group. Please note that this is not the same vaccine as the meningococcal ACWY vaccine which you/your child may have had previously.

The aim of this research study is to undertake an immunisation study in the NT to see how effective the Meningococcal B vaccine is against meningococcal disease, the carriage of meningococcal bacteria found in the throat (not causing disease but able to be transmitted) and gonorrhoea.

All young people aged 14 – 19 years in the NT are eligible to be part of the study.

What does the study involve?

Over a 12 month period each participant will:

- **Receive 2 free doses of Meningococcal B vaccine**
- **Complete a one page questionnaire (at first and 12 month follow up visit)**
- **Have 2 throat swabs taken to test if the meningococcus bacteria are in their throat**
- **Be given a \$20 voucher after each throat swab is taken.**

What do I need to do to participate?

You or your parent/carer or guardian will need to fill out the details requested on the Consent Form. If you received this form from your school, then your parent/carer or guardian must sign the consent form. If you are attending a health clinic and are 16 years of age or older you may sign the consent form for yourself. If you attend a health clinic and are 14-15 years old your parent/carer or guardian must sign the consent form.

More information about the study is on the next page. Please read the following information before filling out the Consent Form and then return it to the school or the health clinic.



What is meningococcal disease?

Meningococcal disease is a very serious illness caused by a bug called *Neisseria meningitidis*, often known as meningococcus. There are six different types of meningococcus strains that cause disease in humans, but in Australia most cases are due to the meningococcal B strain.

What is meningococcal disease and how is it spread?

The meningococcus bacteria can be found in the nose and throat of up to 20% of young people without causing harm. The bugs are spread when a person coughs or sneezes and small droplets containing the meningococcus bug are breathed in by those around them. The meningococcus is also spread by close contact for example during kissing. Even though it is hard to catch and is uncommon, meningococcal disease is a life-threatening infection. Meningococcal disease affects all age groups, but is most common in children under 5 years of age and in young people (15 to 24 years of age). People with meningococcal disease can become extremely sick very quickly. Severe meningococcal disease can cause death or permanent disabilities such as brain injury and loss of fingers, toes, arms or legs.

What is gonorrhoea and how is it spread?

Gonorrhoea is a sexually transmitted infection that can infect both men and women. It is very common, especially among young people aged 15-24 years. Gonorrhoea is spread from one person to another during all types of sexual activity if one of the two people has gonorrhoea. A woman can become infertile (unable to have a baby) after having gonorrhoea. A pregnant woman with gonorrhoea can give the infection to her baby during childbirth.

Prevention/Immunisation

Meningococcal B vaccine (Bexsero®) is a licensed vaccine that is recommended in Australia for infants and adolescents. The vaccine is not free for young people and has to be purchased on prescription. The course of 2 vaccines cost about \$300.00 per person. It is now available on the free National Immunisation Program in Australia for Aboriginal babies up to 2 years of age.

Why are we doing this study?

This study will test to see whether the Meningococcal B vaccine can reduce meningococcal disease in the NT. In addition, it will test if it can protect against gonorrhoea. The study is being conducted across the NT and is sponsored by the University of Adelaide and led by university researchers in partnership with NT Health, Australian Department of Health, SA Health and AMSANT. The vaccines given in the study have been provided by GlaxoSmithKline and funding is being provided by the National Health and Medical Research Council (NHMRC).

What does the study involve?

Young people aged 14 – 19 years old will be able to participate in this study. Participants will be involved in the study for 12 months. During the 12 months, all young people in the study will be immunised with the licensed Meningococcal B vaccine Bexsero® (2 doses given 2 months apart) free of charge and 2 throat swabs will be collected from all participants. Participants will also be asked to complete a one-page questionnaire when they have their throat swabs taken. It will ask questions about lifestyle such as antibiotic usage, smoking habits, kissing, and household size as well as current illnesses. This is because these factors may be related to carrying the meningococcal bug. No names will be placed on the questionnaires (de-identified) and the answers will not be shown to teachers or parents/legal guardians. The questionnaires and swabs are taken for research purposes. The throat swab specimens will be stored and may be used for research in the future for this project and for other research about the types of bugs that live at the back of the throat. Any future research would have to be approved by the relevant Human Research Ethics Committee. Your contact phone number will be forwarded to the study team for the purpose of SMS text reminders for the second and third visits. A \$20.00 voucher will be given to all participants for each swab taken, to reimburse you for your time and commitment to the study.

The NT government routinely counts the number of cases of meningococcal disease and gonorrhoea in the NT. We will look at the number of cases after the study and see whether the meningococcal B vaccine leads to less cases of these infections.

How is the throat swab taken?

A cotton tipped swab is rubbed gently on the back of the throat for 1-2 seconds. This is very safe but may cause minor discomfort; and in some people a gagging sensation. No side effects were reported from any of the 35,000 students who had swabs taken in the study in South Australia.

Common risks of Meningococcal Bexsero® vaccine

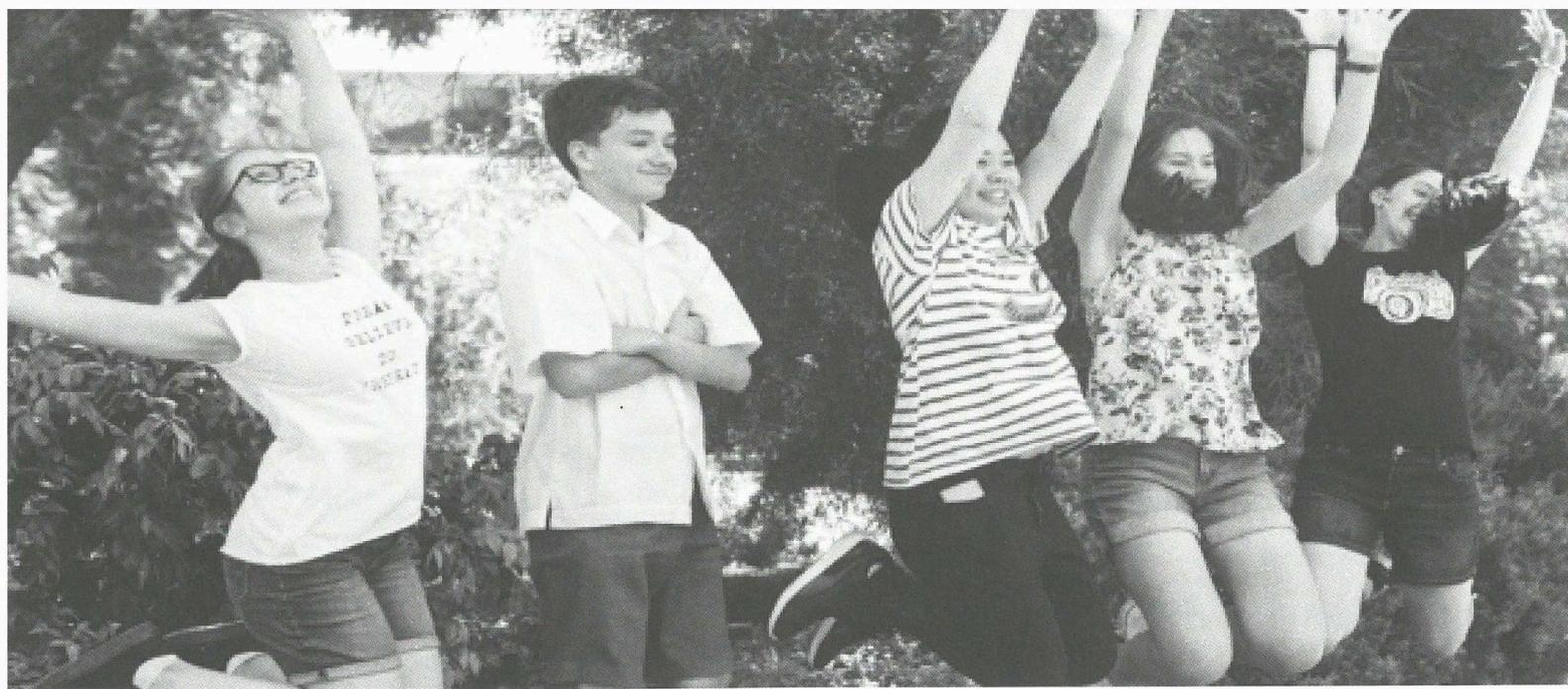
The Meningococcal B vaccine is safe and is well tolerated, with over 17 million doses already given worldwide. There is the chance of common side effects that are mild and may include a mild fever, soreness at the injection site, headache and generally feeling unwell for 1-2 days. As with all vaccines there is the chance of rare and more serious reactions such as an allergic/ anaphylactic reaction to the vaccine.

If you need further information on the safety of vaccines, please contact your school's immunisation provider or the NT Immunisation Register (NTIR) (08 8922 8315).

What are the alternatives to participation?

You do not have to take part in the study if you do not want to; it will not affect any of your Centrelink family benefits. You can purchase the Meningococcal B vaccine privately through your GP instead, if you prefer. If you have already had the Meningococcal B vaccine, you do not need to receive the study vaccine.





Ethics Committee Clearance

This project has been approved by the Human Research Ethics Committee of the NT Department of Health and Menzies School of Health Research, the Central Australian Human Research Ethics Committee and the Western Australian Aboriginal Health Ethics Committee.

Concerns and Complaints

If you have any concerns or complaints about the study, you are invited to contact:

Dr Rosalind Webby: rosalind.webby@nt.gov.au or

Dr Belinda Greenwood-Smith: Belinda.greenwoodsmith@nt.gov.au

For concerns regarding the ethical conduct of study contact Ethics Administration of the following institutions.

Top End: Human Research Ethics Committee of the NT Department of Health and Menzies School of Health Research on 08 8946 8600 or email ethics@menzies.edu.au

Central Australia: Central Australian Human Research Ethics Committee on 08 8951 4700 or email cahrec@flinders.edu.au

Western Australia: Western Australian Aboriginal Health Ethics Committee (WAAHEC) on 08 9227 1631 or email ethics@ahcwa.org

All further requests for information or queries regarding the study should be directed to the NT Immunisation Register (NTIR) 08 8922 8315 or the study website: www.bpartofitnt.com.au

Alice Springs: 08 9851 7549
Tennant Creek: 08 8962 4259
Darwin: 08 8922 8315

Katherine: 08 8973 9049
Nhulunbuy: 08 8987 0357





B Part of It NT Study School Consent Form

PLACE CONSENT FORM
STUDY ID LABEL HERE

Consent for immunisation, throat swabs and questionnaires For Parent / Guardian to complete

I have read and understood the B Part of It NT study Participant Information sheet and I consent for my child to receive the Meningococcal B (Bexsero®) vaccine, two throat swabs and complete two questionnaires.

Tick one box only. YES NO

Parent / Guardian Name: _____

Daytime phone contact: _____ Email: _____

Address: _____

Parent / Guardian Signature: _____ Date: _____

Privacy Information

The information on this form will be recorded on the NT Immunisation Register (NTIR) and later transferred to the Australian Immunisation Register (AIR). Inclusion on these registers is voluntary. All personal information collected by the NT Department of Health will be handled in accordance with the Information Act and the Department's Privacy Policy. Personal information.

Office use only

Swab 1 Date: ___/___/___ Time: _____ Voucher provided <input type="checkbox"/>	Swab 2 Date: ___/___/___ Time: _____ Voucher provided <input type="checkbox"/>
Meningococcal B (Bexsero®) (dose 1) Date: ___/___/___ Time: _____ Batch Number : _____ <input type="checkbox"/> Left arm <input type="checkbox"/> Right arm Signature of provider: _____	Meningococcal B (Bexsero®) (dose 2) Date: ___/___/___ Time: _____ Batch Number : _____ <input type="checkbox"/> Left arm <input type="checkbox"/> Right arm Signature of provider: _____

For further information please contact: Darwin 8922 8315 or Regional Centres: Katherine 8973 9049; Alice Springs 8951 7549; Nhulunbuy 8987 0357; Tennant Creek 8962 4259

