Young Person Information Sheet

Study Title	**Q fever vaccine trial in Australian adolescents** **Safety and immunogenicity of Q fever vaccine (Q-VAX®) in children aged 10 to <15 years**
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1. Introduction

You are invited to participate in a research study titled **Q fever vaccine trial in Australian adolescents. Safety and immunogenicity of Q fever vaccine (Q-VAX®) in children aged 10 to <15 years**. This information sheet tells you about the study. It will help you choose if you want to join or not. You can ask your parents, carer, friend or doctor if you need. You do not have to join this study if you do not want to.

Before you think of joining this study, you should know why and how the research is being done. Please read this information sheet carefully.

2. What is the purpose of this study?

Q fever is a highly infectious disease caused by a bacteria called *Coxiella Burnetii*. Each year in Australia there are over 450 cases, which equates to approximately 8-10 cases per week. Most cases happen in adults but each year some children get infected.

Q fever is usually spread from animals to people by breathing in infectious droplets or dust. People thought to be most at risk of infection include farmers and abattoir workers, recreational shooters, shearers, livestock transporters and veterinarians.

In most cases Q fever infection is mild (such as an influenza like illness) and in some cases it is so mild that people will not even know they have had Q fever infection or thought it was the flu instead. However it can sometimes be more severe and lead to lung, liver, heart or bone infections.

There is an effective vaccine against Q fever, called QVax®, which is made in Australia. It is currently only recommended for those over 15 years old.

The main reason it is only given to those over 15 years old is not because there are safety concerns but because the initial studies did not include children under 15 years old and so we don't know about the safety and antibody responses of the Q fever vaccine.

We aim to study the safety and antibody (immune) responses of the Q fever vaccine in children aged 10 to < 15 years old.

The results of this study may result in a change to Q fever vaccine recommendations in Australia and potentially allow younger children who are at risk of Q fever to be vaccinated.

3. Why have I been invited to this study?

You are invited to take part in this study because you are healthy and aged 10 to <15 years (not yet turned 15 years old). We are keen to invite children who may be at risk of Q fever infection because of where they live, study or work to take part in this study. This study is taking place in NSW and Queensland.

4. Do I have to be in this study?

You do not have to participate in this study if you don't want to. The doctors and nurses will take the best care of you as they have in the past, regardless of whether you are in the study or not. If you choose to participate, you can stop being in it at any time. All you need to do is tell one of the researchers or your parents/carers that you don't want to take part anymore.

5. What will happen to me in this study?

If you choose to join the study, we will see you on five occasions over 12 months. All visits may be conducted by study staff at a medical facility.

You must not have had a Q fever vaccine previously or had Q fever disease. We will talk with you and your parents/guardians to check your medical history to see if you are allowed to take part in this study.

Before we can give you the Q fever vaccine we need to check if you may have already had Q fever infection but you did not know or were not tested for it. We do this by taking a blood test to look for Q fever antibodies and doing a skin test. During the skin test a trained doctor will inject a small amount of dilute Q fever vaccine in the skin of your forearm. This can be painful and itchy at the site for a few days only.

One week later at Visit 2 the study doctor will look at and feel the area on your arm where the dilute Q fever vaccine was injected. If the area is raised or red then it is considered to be positive.

If you have a positive skin test or we find positive antibodies to Q fever in the blood test then this tells us you have already had Q fever and recovered. It means you now have natural immunity and so do not need to have the Q fever vaccine. This same screening process is followed before we give adults the Q fever vaccine. We will give you a copy of your blood and skin test results for your medical records.

Only children who are both negative to the skin and serology test will be given the Q fever vaccine.

Pregnancy test: Females who have started their menstrual periods will be asked to take a urine pregnancy test at visit 2 prior to the vaccine being given to make sure they are not pregnant. As Q fever vaccination is not recommended during pregnancy we do not want to give the Q fever vaccine to anyone female who may be pregnant.

Diary card: We will give you either a paper or electronic diary card asking you to record any redness or swelling at the injection site and other symptoms you may have after vaccination. You will be given a thermometer to record your temperature each evening measured under the armpit.

Blood tests: Blood samples are taken by a qualified and experienced member of the study staff. We will need to take about 7mls of blood from a vein in your child's arm. This can be painful and bruising can occur. If you wish we can use a topical anaesthetic on your arm to reduce any discomfort associated with taking the blood sample.

We take the blood to measure the level of antibody to Q fever. You and your parent/carer will be given your individual results and their meaning.

The following table describes the five study visits.

Visit intervals and procedures

Visit Number (Timing)	**Study procedure**
Baseline **Visit 1** (Day 0) Around 1 hour visit	Explanation and discussion of the study Sign consent form Medical history, Q fever risk questions, and examination Blood sample collection (7ml) Perform QVAX® skin test
Visit 2 (7 days post visit 1) Around 1 hour visit	Measure skin test results Medical history and examination Check temperature Urine pregnancy test only for females who have commenced periods QVAX® vaccine administration in upper arm **(ONLY if serology and skin test negative)** Observed for ½ hour post vaccine
Possible telephone call Week following Visit 1	Our study team will review the electronic diary cards remotely. If a paper diary card was used we will email/text you to remind you to return it. If there are any concerns on review we will make contact with you and your parent/carer to check for any side effects after vaccination or other problems encountered
Visit 3 (28-42 days post visit 2) Around ½ hour visit	Check post-vaccination adverse events diary Medical history and examination Take blood sample (around 7mls)
Visit 4	Medical history and examination

(180-210 days post visit 2) Around ½ hour visit	Check adverse events Take blood sample (around 7mls)
Visit 5 (365-395 days after visit 2) Around ½ hour visit	Medical history and examination Check ongoing adverse events Take blood sample (around 7mls)

6. Can anything bad happen?

You may get some of the following side effects from the Q fever vaccine. These are usually mild and similar to side-effects seen following several routine other vaccines, like the COVID-19 vaccine you may have had.

Side effects can include feeling unwell within 48 hours of the injection, developing a fever or developing a small lump or some redness where you had the injection.

Injection site reactions are common (local pain (>50%) and redness (30-50%)). Sometimes adults who have had the Q fever vaccine report fever (up to 15%), headaches, muscle and joint pains (10-20%), chills and minor sweating, which can last several days. If you feel sick then let your parent/carer know and they can tell the study doctors. You can take paracetamol or other similar medicine if you have fever or aches.

Side effects you report to your study doctor may be reported to Seqirus, Australia (the manufacturer of the Q fever vaccine) and the Therapeutic Goods Administration (TGA) Australia, but the report will not contain any identifying details about you. This reporting allows continued monitoring of the benefit-risk balance of the vaccine.

7. Will there be any benefits for me in this study?

We cannot promise that you will receive any benefits from this research; however, possible benefits may include some protection against future Q fever infection. The results of this study may result in a change to Q fever vaccine recommendations in Australia and potentially allow younger children, like yourself, who are at risk of Q fever to be vaccinated.

8. How will my privacy be protected?

Your privacy and confidentiality will be protected at all times in this study. Unless you allow us, we will not tell anybody else you are or have been a part of this study. We will not release any information to anybody else that could be used to identify you, unless we are required to do so by law. For example, researchers are required to report if a participant is believed to be at risk of harm.

All information about you (including your email address and mobile phone number) will be stored securely with access restricted to authorised members of the research team from the University of Sydney and research teams at your study site.

In order to protect your privacy, the study team will remove any information that may be used to identify you from any study documents, and instead of your name appearing on them, you will be identified by a specific study code number that applies only to you. Only this code number will be used on any research-related information collected about you for this study, so that your identity as part of the study will be kept completely private. Only the study team at The Children's Hospital at Westmead

and the University of Sydney will have the ability to link this code number with your personal information, and the linking information will be kept with the study team at The Children's Hospital at Westmead.

Your data will be stored for a minimum of 15 years after the study finishes or until the youngest participant turns 25, whichever occurs later.

If you decide to leave the study, we will not collect any more information about you. We would like to keep the information we have already collected about you to help us ensure that the results of the research project can be measured properly. Please let us know if you do not want us to do this.

9. What will happen to the study results?

We would like to share the study results by publishing them in relevant journal articles and / or presenting them at different conferences. We will make sure that information is published /presented in such a way that you are not identifiable, unless you have given us permission to do so.

Your parent/carer can also tell us on the consent form if you want to receive a simple summary of the study findings for information.

10. Who should I contact if I have any questions?

If you have any questions or want more information about this study before or during participation, you can talk to Professor Nicholas Wood on 0429 849 440.

You can also ask your parents/carers to talk to us.

11. Who do I contact if I have concerns about the study?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study has been approved by the Sydney Children's Hospitals Network HREC **(approval number:** 2022/ETH00624**)**.

Please talk to your parents/carers if you are worried about being in this study, or you have a complaint. They can talk to Professor Nicholas Wood on 0429 849 440 or they can contact the Human Research Ethics Committee on (02) 7825 1253 or SCHN-Ethics@health.nsw.gov.au.