the children's hospital at Westmead

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Parent Information Sheet

Immunogenicity and safety of acellular pertussis vaccine at birth with follow-up to 4 years of age

Investigators
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Local investigators

We would like you to consider allowing your child to participate in the third phase of a research study that will be conducted with the National Centre for Immunisation Research and Surveillance. This study is being conducted in Sydney, Adelaide, Melbourne and Perth.

What is the study about?
Australia is currently in the midst of a pertussis epidemic, with children between 3-9 years old particularly affected. Some factors thought to contribute to this problem include decreasing levels of immune protection with time after the primary vaccination course, no booster vaccination at the age of 18 months, more sensitive testing of pertussis, and possibly whether the type (called strain) of pertussis has changed. This highlights the importance of optimal whooping cough vaccine schedules in early childhood, and led to the original (first phase) trial, *Pertussis Vaccine at Birth* study, that your child participated in.

The aim of the first phase study was to see if giving babies the pertussis vaccine (Pa vaccine) in the first few days of life, *in addition* to the regular vaccines on the Australian Immunisation Schedule meant that they were protected earlier. Some children in the first phase study then participated in a second phase study. This study aimed to compare the levels of immune protection following a booster dose of diphtheria (D), tetanus (T) and pertussis (Pa) vaccine, called the DTPa vaccine. This was either standard dose DTPa vaccine or a reduced dose dTpa vaccine. This second phase study was called "*Persistence of immunity and response to a booster dose of DTPa or dTpa vaccine at 18 months old following acellular pertussis vaccine given at birth in healthy infants"*

Your child is now reaching the age at which the routine pre-school (4 year old) DTPa and polio booster vaccine (called DTPa-IPV) is due. It is important that we follow up how long vaccine immunity lasts and measure booster responses at 4 years old in children who received the Pa vaccine at birth. We aim to assess whether their booster responses are any different (lower or higher) to children who did not receive a Pa vaccine at birth. Therefore this third phase study aims to compare levels of immune protection to diphtheria, tetanus and pertussis and their response to a booster dose of DTPa vaccine in children who did and did not receive Pa vaccine at birth. vaccine.
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Who can participate in the study?

Healthy children who are between 4 years and 4 years 364 days old, who completed the first phase of the Pertussis Vaccine at Birth Study. The children must not have any contraindications to vaccination and not received their 4 year booster diphtheria-tetanus-pertussis-polio (DTPa-IPV) vaccine. There must be a period of 30 days after a live vaccination (for example, chicken pox vaccine) and a period of 14 days after an inactivated vaccination (for example, influenza vaccine), before your child can receive the DTPa-IPV vaccine used in this study.

What will the study involve?

If you agree to your child participating in this study, we will see your child on two occasions one month apart. On the first occasion we will ask about your child's health and medical conditions, collect a blood sample and give the DTPa-IPV booster vaccine. This will take a little over an hour. You will complete a diary of your child's symptoms after vaccination. At the second visit we will review your child's health since the first visit and we will collect a blood sample. This will take a little over half an hour.

If your child participated in the second phase study at 18 months old, the booster vaccine that will be given at 4 years old will be at the same dose. That is, if your child received the standard dose DTPa vaccine at 18 months, they will receive a DTPa-IPV vaccine containing the same dose of DTPa as was given at 18 months old. If your child received the reduced dose dTpa vaccine at 18 months, they will receive a booster vaccine containing the same dose of dTpa plus polio at 4 years old. If your child participated in the first phase study but did not participate in the second phase study at 18 months, they will be given the standard dose (DTPa booster vaccine plus polio that is recommended for all children in Australia.

We may also need to contact you at a later time in order to ask additional questions related to the study.

Outlined below is a schedule for this study:

Schedule	Approximate time (minutes)	Description
Visit 1 Age 4 years to 4 years and 364 days	90	Explanation and discussion of the study Sign consent form Medical history and examination Check temperature Measure mid upper arm circumference of the arm to be vaccinated Take blood (around 7 ml) Vaccination with diphtheria-tetanus-pertussis-polio vaccine Observation for 15 minutes
Telephone call Week following Visit 1	5	Conversation with parent to check for any side effects after vaccination or other problems encountered
Visit 2 4 weeks (28-42 days) after Visit 1	30	Check post-vaccination adverse events diary Medical history and examination Take blood (around 7 ml)

Diary card
We will give you a diary card asking you to record any redness or swelling at the injection site and other symptoms your child may have after vaccination. You will be given a thermometer to record your child's temperature.

Blood tests
The blood samples are taken by an experienced nurse immunisation specialist or paediatrician. We will need to take about 7 mls 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 child's arm to reduce any discomfort associated with taking the blood sample.

We take the blood to measure the level of antibody to pertussis, diphtheria and tetanus, other components of the vaccine and other aspects of the immune response to the vaccine.

Are there any benefits for my child participating in this study?
There are no known benefits for your child participating in this study.

Are there any side effects and risks associated with this study?

Side-effects of immunisation
Your child may get some of the following side effects from the diphtheria-tetanus-pertussis vaccine. These are usually mild and similar to side-effects seen following several routine childhood vaccines. Side effects can include feeling unwell within 48 hours of the injection, developing a fever or developing a small lump or some redness where your child had the injection. Lumps can last for a few weeks. There is a very small chance of an allergic reaction occurring after vaccination or of having a convulsion with fever.

There may be other side effects that are not known at this time. You will be made aware of any significant new findings that may affect your decision for your child to remain in this study.

Other information
There are four study sites around Australia: Sydney, Melbourne, Adelaide, and Perth.

We do not anticipate that you will incur expenses during your participation, however you will be reimbursed for any travel related costs.. You will not receive any payments for your participation in the study.

Your personal information will be kept confidential, and only study staff will have access to your data.

What is the involvement of GSK Biologicals?
This study is an investigator-initiated study, funded by a study grant from GlaxoSmithKline Biologicals, a pharmaceutical company. GSK Biologicals will supply both types of the diphtheria-tetanus-pertussis vaccines used in this study. Your child's blood sample will be sent to a Centres for Disease Control (CDC), in Atlanta, USAs laboratory that will be analyzing the de-identified blood samples to check your child's protection levels. The analysis and interpretation of results will be performed by study investigators. The CDC laboratory will not be given any identifying information about your child.

What will happen to the data?
All data collected will be held in strict confidence to protect your child's privacy. No material which could personally identify you or your child will be used in any reports on this study. Results from the analysis will be stored in computer files and in written form for a period of up to 15 years in locked cabinets at the local research site and in the National Centre for Immunisation Research and Surveillance at The Children's Hospital at Westmead, after which time the information will be destroyed securely. You may ask to see or correct your child's data. We will give you a written copy and explanation of your child's immune responses once they have been tested. The data obtained from this study may be used in future related or unrelated research by principal investigators.

What if you decide not to participate in the study?
Participation in this study is voluntary. If you decide that your child will not to take part or, if you decide to withdraw your child from the study at any time this will not otherwise affect your child's care at the hospital. Participation in this study will be stopped if any harmful effects appear or if the study doctor feels it is not in your child's best interest to continue.

What happens if my child suffers an injury or complications as a result of the study?
If your child suffers any injuries or complications as a result of this study, you should contact the study doctor as soon as possible who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if the injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in this study (for example, the researcher, the hospital or the treating doctor). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

If you are not eligible for compensation for the injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for the injury or complication free of charge as a public patient in any Australian public hospital.

What if you have any questions or concerns about the study?
You have the right to ask questions at any time about this study or the potential risks associated with it. You will be informed of any significant new information pertaining to your child's safety.

If you have any concerns about the conduct of the study, please do not hesitate to discuss them with Professor Peter McIntyre (phone: 02-9845 1434) Principal Investigator, Dr Nicholas Wood (phone: 02-9845 1434),

This project has been approved by the Sydney Children's Hospitals Network Human Research and Ethics Committee.

The conduct of this study has been also authorised byThe Sydney Childrens Hospital Network Human Research Ethics Committee. **If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact: the Secretary of the Ethics Committee(phone 02 9845 3017) and quote reference HREC/14/SCHN/198**

This information sheet is for you to keep. We will also give you a copy of the signed consent form.

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I have read and understand the Information Sheet and give my consent for my child to participate in this research study and related follow-up, which has been explained to me by

_____

I understand that I am free to withdraw my child from the study at any time and this decision will not otherwise affect my child's treatment at the Hospital.

I consent to being contacted about future, as yet unplanned research studies.
☐ Yes
☐ No

NAME OF CHILD: _____ (Please print)

NAME OF PARENT OR GUARDIAN: _____ (Please print)

SIGNATURE OF PARENT OR GUARDIAN: _____ Date: _____

NAME OF WITNESS: _____ (Please print)

SIGNATURE OF WITNESS: _____ Date: _____

NAME OF INTERPRETER: _____ (Please print)

SIGNATURE OF INTERPRETER: _____ Date: _____