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Study Information & Authorization Form

Research Title: PCIRN Evaluation of Seasonal Trivalent Influenza Vaccine for 2010-2011 in Young Children in the First Year After the H1N1₂₀₀₉ Pandemic

Short Title: PCIRN Study of Seasonal Influenza Vaccine for 2010-2011

Researchers:

Principal Investigator: Dr. Joanne Langley, MD, Pediatric Infectious Disease Specialist, IWK Health Centre

Co-Investigators: Dr. Scott Halperin, MD, Pediatric Infectious Disease Specialist, IWK Health Centre

Dr. Shelly McNeil, MD, Infectious Disease Specialist, QEII Health Sciences Centre

Study Sponsor: Public Health Agency of Canada / Canadian Institutes of Health Research Influenza Research Network (PCIRN)

Funding: GlaxoSmithKline

Introduction

Your child is being invited to take part in the research study (clinical trial) named above. A clinical trial is a research study to answer specific questions about the vaccines or medications. It is important that you understand the purpose of the study, how it may affect your child, the risks and benefits of taking part and what you and your child will be asked to do before you decide if you want your child to take part. This form provides information about the study to help you decide if it is in your child's best interest to take part. Your child does not have to take part in the study. Taking part is entirely voluntary. If you have any questions that this form does not answer, the research nurse or study doctor will be happy to give you more information.

We refer to the process of giving you information about the study as "informed consent". This process starts with the first contact about the study and continues until the end of the study. You may decide today you want your child to take part in the study and change your mind later. You have the right to stop taking part at any time during the study. This will not affect the care you or your family members will receive from the IWK Health Centre in any way.

Why are the researchers doing the study?

Influenza or 'flu' is an infection of your breathing pipes and lungs. It is caused by a virus (a germ) and spread by nasal droplets. Symptoms include sudden fever, headache, chills, muscle ache and cough. Vaccination with a flu vaccine is the best way to prevent influenza and avoid complications. The viruses that cause flu usually change a little bit each year. This is why getting a new vaccination is recommended each year.

The seasonal flu vaccine is recommended for all children 6 to 23 months of age as they are at increased risk of being admitted to the hospital because of complications from the flu. Healthy children 2 and older were also encouraged to receive the flu vaccine even if they are not in the priority group. This year in Nova Scotia the flu vaccine is being publically funded for all persons over six months of age.

Every once in a while a new kind of flu virus that is much different from the regular flu (also called seasonal flu) appears and causes a world-wide flu outbreak called a pandemic. A new flu virus called swine flu (H1N1) caused a pandemic last year. This year the seasonal flu vaccine will contain the H1N1 strain in addition to other flu strains that are circulating.

This study is being done to compare the immune response (protection level) and adverse events (side effects) of children who received one or two doses of the H1N1 vaccine last year and are now receiving the seasonal flu vaccine this year. We will also look at whether or not your child received the seasonal flu vaccine last year too.

The purpose of this research study is to see if there are different rates of side effects in children who received the H1N1 and/or seasonal flu vaccine last year and are now receiving the seasonal flu vaccine this year.

We are conducting this study before you are able to receive the vaccine from your family doctor so we are able to obtain information quickly and make recommendations. Knowing this will help to better shape the vaccine recommendations for other children.

How will the researchers do the study?

This study will include about 200 children ages 12 to 59 months with about 50 children being enrolled in Halifax. This study will be carried out in Halifax, Montreal, Calgary and Vancouver.

The study involves 2-3 visits and 2-4 phone calls (depending on whether or not your child received a previous dose of the seasonal flu vaccine before) over an approximately 3-4 week period; plus a 6 month follow-up phone call. Children will:

- Have blood collected 2 or 3 times on Day 0, Day 21 (and Day 42)
- Receive 1 needle Day 0 (and Day 21 if they have not received a previous dose of seasonal flu vaccine).

All children in the study will receive the licensed seasonal flu vaccine using the recommended dosage depending on their age and vaccination history (whether or not they received the flu vaccine last year). This is the same vaccine that your child would receive from your family doctor; however you will be receiving the vaccine before the routine flu vaccine program starts in October.

For children less than nine years of age who have not previously received any dose of seasonal flu vaccine, regardless of whether or not they received the H1N1 pandemic vaccine, it is recommended that they receive 2 doses of the seasonal flu vaccine

What will my child be asked to do?

This study involves 2 visits and 2 phone calls for children receiving one dose of seasonal flu vaccine. For children requiring 2 doses there are 3 visits and 4 phone calls. All children will receive a 6 month follow-up phone call after the final visit. Here is a list of what happens at each study visit.

Study Day	What will happen at this visit
Visit 1 - Study Day 0 (1 hour)	<ul style="list-style-type: none"> • The study staff will explain the study and if you agree for your child to join, you will sign the consent form. • You will answer health questions to see if your child can join the study and we will measure their height, weight and temperature. • A blood sample will be taken (about 3-5 mLs or ½-1 teaspoons of blood). • Your child will receive the Vaccination (one needle). • Your child must wait for 30 minutes in the study office to make sure that there are no rare allergic reactions. • You will be given a card (called a memory aid) to write down safety information until the next visit.
Phone Call - Study Day 1 and Day 7 (15 minutes per call)	<ul style="list-style-type: none"> • A phone call to review and collect your child’s memory aid information.
Visit 2 - Study Day 21-28 (30-60 minutes)	<ul style="list-style-type: none"> • You will be asked to confirm if you want your child to continue in the study. • You will answer health questions and the memory aid will be reviewed. • A blood sample will be taken (about 3-5 mLs or ½ -1 teaspoon of blood). • <u>* If your child requires a second dose:</u> • Your child will receive the Vaccination (one needle). • Your child must wait for 30 minutes in the study office to make sure that there are no rare allergic reactions. • You will be given a card (called a memory aid) to write down safety information.
Phone Call - Study Day 1 and Day 7 (15 minutes per call)	<ul style="list-style-type: none"> • <u>* If your child requires a second dose:</u> • A phone call to review and collect your child’s memory aid information.

Visit 3 – Study Day 42-49 (30 minutes)	<ul style="list-style-type: none"> • * If your child requires a second dose: • You will be asked to confirm if you want your child to continue in the study. • You will answer health questions and the memory aid will be reviewed. • A blood sample will be taken (about 3-5 mLs or ½ -1 teaspoon of blood).
Phone Call - Study Day 180 (Day 200 if child received 2 doses of the vaccine) (15 minutes)	<ul style="list-style-type: none"> • You will answer health questions.

Recording in the Memory Aid

The study nurse will provide you with a memory aid and a thermometer, and instructions on how to use them. You will be asked to record information on local symptoms (such as pain, redness, lump, and swelling at the injection site) as well as general symptoms (such as irritability, drowsiness, decreased appetite, sweating, shivering and sleep disturbance) your child may have experienced during the evening following each vaccination and the next 6 days. You will also be asked to record any new medications your child takes, any new illnesses that your child may experience and any doctor visits between the study visits.

During the study, you should contact the study staff immediately should your child have any signs or symptoms that you see as serious. The study doctor and the study nurses will be available for the entire study period and will monitor all the side effects that your child may experience.

If you agree to your child taking part in the study your responsibilities will be:

- to follow the instructions given by the study staff
- to return to the clinic at scheduled visits
- to complete the information requested on the memory aids which includes taking your child's temperature and measuring any reactions to the vaccinations
- to **promptly call/report** to the study staff any **unexpected or serious events** your child may experience

What are the burdens, harms and potential harms?

The vaccine being used in the study cannot cause influenza because it is made with a killed virus, it is not a live vaccine. It is a licensed vaccine called Fluviral[®].

Based on studies to date of Fluviral[®], the following side effects are likely to occur in 1 in 10 people who receive the vaccine:

- Reactions at the site of injection such as pain, redness, swelling, hardness of the skin.
- Headache, feeling tired, muscle pain.

The following side effects may occur less commonly (1% - 10%) meaning these side effects may happen in 1 in 100 people but less than 1 in 10 people

- Generally feeling unwell, chest tightness, red eyes, sore throat, cough, sweating, or shivering.

Most of these reactions are mild and disappear within 1 to 4 days: treatment with medicines like Advil or Tylenol may be needed.

Uncommon side effects (occurring in less than 1 in 100 subjects) may include upper respiratory tract infections, nausea and facial swelling.

Rare side effects (occurring in less than 1 in 1000 subjects) may be nerve pain, sensation of “pins and needles”, convulsions (seizures), and temporary decrease in blood clotting cells (platelets). Allergic reactions, in rare cases leading to shock, have been reported. Guillain-Barre syndrome (GBS), which causes temporary paralysis has been reported in the six weeks after receipt of influenza vaccine in about one in one million persons. It is extremely rare for the symptoms of GBS to be permanent.

The study vaccines contain small amounts of egg proteins and the mercury-containing preservative thimerosal. These components are not unusual and are found in other vaccines, but you should tell the study staff if you believe your child is allergic to any of these materials, as your child will not be able to take part in this study.

As with any vaccine or drug, unexpected serious reactions, including severe allergic reactions may occur. All the medical equipment to treat any serious reactions to the vaccine will be available at the time of your child’s vaccination. If this should happen, Dr. Langley or another doctor will see your child and you will be given advice about any necessary treatment. Dr. Langley and the study staff will notify you if there is any new information about this study you should know about while your child is taking part in the study.

The blood tests that will be done can cause momentary pain and sometimes a small bruise. A cream called EMLA[®] can be applied over the vein where the blood will be taken to numb the skin and decrease the pain.

The MMR (measles, mumps, rubella) and Varicella (chicken pox) vaccinations should not be given while subjects are participating in the study (between the study visits) as it could interfere with responses to the study vaccines. This could potentially delay your routine 12 month vaccines by 42 days. There is minimal risk to delaying these vaccines. We can give any routine vaccines that are recommended during this time at the final visit if you wish. This is not considered part of the study and is being done as a courtesy.

What are the potential benefits?

Taking part in this study may be of no help to your child personally as your child will receive the same seasonal flu vaccine that is recommended for all children in this age group and available from your family doctor. The blood samples taken from your child will measure their protection levels and this will be reported to you. Blood testing is not usually done with vaccinations and protection levels are not routinely reported. The information collected during the study may increase knowledge about flu vaccines in children.

What are the alternatives to participation?

Your child does not have to participate in this study. If you decide to not participate this will not affect your care by your family doctor or the IWK Health Centre. The seasonal vaccine is available from your doctor. There are antivirals to treat and reduce the symptoms of flu infections but these are not routinely administered for mild to moderate cases.

Can I withdraw my child from the study?

Taking part in this study is entirely your choice. You may decide not to enroll your child and you may withdraw your child from the study at any time. This will not affect your child's care or your family's care at the IWK Health Centre in any way. If you decide to withdraw at any time during the study, the data collected up until that time will not be removed. Your child's participation may also be ended if in the opinion of the study staff it is not safe or reasonable to continue. Dr. Langley also has the right to end the study at any time. If the study is changed in any way that would affect your decision to continue to allow your child to participate, you will be told about the changes and you may be asked to sign a new consent form.

Will the study cost me anything and if so, how will I be reimbursed?

There will be no costs to take part in this study. In recognition of your time commitment to this study you will receive \$25/visit (2-3 visits). This will be paid out by cheque 4-6 weeks after your final study visit. Your parking will be paid at each study visit with a pre-paid exit pass. The thermometer is provided free of charge and is yours to keep at the end of the study.

Are there any conflicts of interest?

There are no known conflicts of interest on the part of researchers and/or IWK. GlaxoSmithKline will cover the costs of conducting the study at the IWK Health Centre and the study nurses and research assistants will be compensated for the time, effort and expenses to conduct the study.

What about possible profit from commercialization of the study results?

Neither you nor the investigators or study staff will receive any financial benefits from commercialization of the study results.

How will I be informed of study results?

The general study results and your child's individual results can be made available to you once the study is completed and reported. The summary of the results will be mailed to you if you want to receive them. You will be asked to initial the last page of this form indicating if you wish to receive the results. It will be important that you notify us if there is any change in your address, so we are able to contact you with study results.

How will my child's privacy be protected?

Any information that is learned about your child will be kept as confidential as possible within the limits of the law. With your permission, we will let your child's regular doctor know about the study participation. Study information sent to co-investigators in Canada will not include information that directly identifies your child; instead, a code number is assigned to the study information. This coded information will be reported to the funder GlaxoSmithKline (or the funder's representatives), its partners, and its agents, the Canadian Health Products and Food Branch (HPFB), and Health Canada.

Study staff will have access to your child's study record that contains information that directly identifies your child. In addition, these records may be shown to the regulatory authorities in Canada and the IWK Research Ethics Board as part of an audit. In addition, if you were to

report an illness or injury or hospitalization, we may need access to your child's health record (IWK hospital chart) to collect information about the illness or injury.

If the results of the study are published in the medical literature, the publication will not contain any information that would identify your child. Study records will be stored in a locked area at the Clinical Trials Research Center during the study and will be kept for 30 years in off site long-term storage, which meets or exceeds the requirements of the IWK Research Ethics Board, Health Canada and the study sponsor.

What if I have study questions or problems?

If you have any questions, please call the study nurse _____ at _____ You may also call the study coordinator, (*Name to be inserted*) at (*Number to be inserted*), Monday to Friday between the hours of 9 am and 5 pm. If you are calling after 5pm or on the weekend/holiday, please call **476-8837** to reach the on-call study nurse. You may also reach Dr. Langley by calling the IWK at 470-8888 and asking for her to be paged. In the event that participation in this study has led to any reactions or serious events please contact your study nurse or coordinator as soon as possible. The matter will be reviewed with you and Dr. Langley who will assist your child in obtaining appropriate medical care.

What are my child's research rights?

You are free to withdraw from the study at anytime without jeopardizing their health care your child is entitled to receive. If your child become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your child's participation in the study and agree to allow your child to participate as a subject. In no way does this waive your legal rights nor release the investigator, the research doctor, the study sponsor or involved institutions from their legal and professional responsibilities.

If you have any questions at any time during or after the study about research in general, you may contact the Research Office of the IWK Health Center at 470-8520, Monday to Friday between 9am and 5pm.

Contact for future studies

You will be asked if you are willing to be contacted for future studies. If you do wish to be included, we will collect information needed to contact you in the future. This information would include name, address, phone number and date of birth, which we would store in a secure area at the Clinical Trials Research Center. If you wish to be contacted, we will ask you to initial the signature page of this form to indicate this. We will not collect this information until the final study visit, when we will reconfirm you still wish to do this. If you indicate you agree today and change your mind later, it is not a problem and will not impact your care in any way.



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Parental/Guardian Authorization – I understand the nature of the study and understand the potential risk of reactions. I have read or had read to me this information and authorization form and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I understand that I have the right to withdraw my child from the study at any time without affecting my family’s care in any way. I have received a copy of the Information and Authorization Form for future reference. I freely agree to my child participating in this research study.

Name of Participant (Print)

Name of Parent/Guardian (Print)

Signature of Parent/Guardian

Date: _____ Time: _____

I would like to receive my child’s individual study results. (Please circle)
YES / NO Initials _____

I would like the study staff to inform my doctor of my child’s participation in the study (Please circle)
YES / NO Initials _____

I agree to be contacted and given information about future vaccine studies. (Please circle)
YES / NO Initials _____

STATEMENT BY PERSON PROVIDING INFORMATION ON STUDY

I have explained the nature and demands of the research study and judge that the participant named above understands the nature and demands of the study.

Name (Print): _____ Position: _____

Signature: _____ Date: : _____ Time: _____

STATEMENT BY PERSON OBTAINING CONSENT

I have explained the nature of the consent process to the participant and judge that they understand that participation is voluntary and that they may withdraw your child at any time from participating.

Name: _____ Position: _____

Signature: _____ Date: _____ Time: _____