Public Health England

INFORMATION LEAFLET

for parents/guardians

Nasal flu vaccine study (LAIV Immuno)

Full(technical) title: A phase III/IV open-label study of the immunogenicity and safety of a single dose of a Live Attenuated Influenza Vaccine (LAIV) (Fluenz™) for each of three successive years in children naïve to, or in previous receipt of, AS03B adjuvanted H1N1 (2009) pandemic influenza vaccine (Pandemrix™).

Public Health England (PHE) is conducting a study at various GP surgeries, including yours, of nasal influenza (flu) vaccine. Before you decide if you would like your child to join this study, you need to understand the reasons why the research is being done and what it would involve. Please take the time to read the following information carefully and talk to others about the study if you wish.
Part 1 tells you the purpose of the study and what it would involve.
Part 2 gives you more detailed information about the conduct of the study.

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PART 1

What is the purpose of the study?

The Department of Health has recommended flu vaccine, which is given as a spray into the nose, to be given each year to all children under 18 years of age. In 2014-2015 this programme will include children aged 2-7 years, mainly because of supply of the vaccine and logistical issues of giving it to millions of children across the UK.
In this study, we will be giving the nasal flu vaccine, which is marketed under the name “Fluenz” to children aged 5-10 years old, this year and next year, so by taking part in the study your child may get the vaccine a year earlier than they would do from the GP. We will do some blood tests and collect some saliva to measure antibody levels that will help us to understand how the vaccines work when given each year, including to children who had the pandemic flu vaccine in 2009-2010.

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Why has my child been invited to take part?

We would like to invite your child to join the study as they are aged between 5-10 years old, which is the age group we are including.

Does my child have to take part?

No, participation in the study is entirely voluntary. If you wish to enrol them after discussion with your PHE Vaccine Research Nurse, you will be asked to sign a consent form and they will be asked to sign an assent form. Both the consent and assent forms will need to be signed in order to enrol your child in the study. At the end of the study, we will inform you of the overall results. You would be free to withdraw your child at any time without giving a reason and this will not affect their routine care. If you withdraw your child during the study, your PHE Vaccine Research Nurse will be happy to discuss any further routine vaccinations that should be given by your General Practice surgery, though it is not yet known when your child would receive this vaccine if they do not take part in the study.

Will you do any safety checks before my child takes part?

Yes, so that we can be sure we include children appropriately both for their safety and for the study, we will check certain criteria. These include things like whether they have allergies to components in the vaccine. So, the study nurse will ask you some questions and, with your consent, may need to check your child's GP record for things like allergies to be sure they are eligible.

What will happen to my child if they take part?

Your child will be involved with the study for two years. We will give them a dose of the nasal flu vaccine each year, during which time they should not have any other flu vaccines. We will do a blood test and collect some saliva before and about three weeks later. We will also phone you about a week after they have the flu vaccine to see how they have been. Each year the schedule will be:

Visit 1	☎ Telephone call, about 8 days later	**Visit 2, about 3 weeks later**	**Ad hoc swab during flu season**
• Complete consent form (year 1 only) • Blood test and saliva sample • Give a dose of nasal flu vaccine • Give the health diary (daily recordings for a week)	• Phonecall to see how your child has been	• Blood test and saliva sample • Review of health diary	• Nasal swab if your child has a flu like illness

The study visits will be conducted by your child's study nurse, and will take place at your child's GP surgery. It may be possible to arrange the blood test and saliva sample at your home if it is more suitable for everyone. The first visit will take about

half an hour and the second about 20 minutes, completing the health diary should take a couple of minutes each day. No payments will be made to families for taking part in the study.

An essential part of the study is checking whether the vaccines are able to stimulate natural body defences against flu. This can only be done by collecting blood and saliva samples. Your child will be offered some anaesthetic cream to numb the skin before the nurse takes a small blood sample (about 10ml, which is about two teaspoons). Saliva is collected by passing a foam swab across the teeth and gums for about a minute, in an action similar to brushing teeth, which you or the study nurse can help your child with. Samples will be done before vaccination and about 3 weeks later, each year.

Each time your child or any other children in the house have a flu like illness, where they have a cough/ cold/ runny nose, and maybe a temperature, during the flu seasons whilst they are in the study we will ask you to take one nasal swab within the first few days of being ill. This will help us understand which viruses, that can cause flu and other respiratory illnesses, are in their nose. This involves passing a swab, which looks like a cotton bud, around their nostril for under a minute. We will let you know when the flu season starts and ends, i.e. time to take the swabs, by sending you a postcard. We ask you to take one swab during each period your child(ren) is ill, ideally at the beginning of when they are unwell. Your nurse will explain and show you how to do this and we will give you written instructions to keep, and a prepaid envelope to post the swab to us. We will write to you, and your child's GP, if we find the flu virus on the swabs.

At the end of this study, once we have completed the tests, any samples left over may be valuable in other studies to help improve our understanding of vaccines and how they work. You will be asked to consent to any samples left over from this study being kept for use in this way. If you consent to this, then at the end of your child's blood test, your nurse will touch the tip of the needle on filter paper after the blood test to make a dry blood spot which is a new way of testing that we are developing. Your child can still take part in this study if you do not wish any leftover samples from them to be kept for this use.

On each evening for seven days after the vaccination we will ask you to fill in a "Health Diary". This involves answering some simple questions about how your child has been.

If your child takes part in the study, with your consent, we will inform your child's General Practitioner (GP). If your child has an illness and sees the GP or a hospital doctor or nurse, please inform them that your child is taking part in this study. If possible and at your convenience, please then let us know by telephoning your child's Vaccine Research Nurse, that they have been unwell, even if this seems unrelated to vaccination. We may then contact your child's doctor for further information.

For children aged 9 years old and over, there is an optional extra step in the study. This involves a further 5ml of blood being taken when the other samples are collected, so no extra needles. This sample will allow us to look at how the cells in the immune system work so we understand better how we could design vaccines to

fight infection more effectively in the future. This is optional, and doesn't affect your child taking part in the main study, so you can either sign to give permission or strike this through on the consent form. This is being done just in Hertfordshire because the laboratory where the samples go for this work is in London and they can arrive there quickly enough.

Which vaccine is being given in the study?
There is one vaccine, called "Fluenz, which is licensed for use in the UK. Your child will receive one dose of Fluenz each year for the two years of the study. After that the annual doses will be given by your GP surgery**.**

Will this change my child's normal routine vaccination in any way?
Yes, we will be giving your child the nasal flu vaccine this year, it is not yet known when they would receive it in the national schedule. They will not need to have the flu vaccine with the practice nurse.

What are the possible disadvantages and risks as well as benefits of taking part?

Risks:

There are some possible side effects to any vaccination, for Fluenz these include getting a blocked nose, a headache and some muscle aches. Children may lose their appetite and feel generally unwell for a day or two. These symptoms usually subside by themselves without treatment or affecting normal activities. Allergic reactions can occur with any vaccine but these are very rare, and the usual safety precautions as for any vaccination will be taken during this study.
To date, there has been no indication of any particular side effects with any of the study vaccines, other than those listed above and associated with any vaccine.
The blood sampling may cause slight discomfort and there may be some pain or bruising at the site where the blood is taken, though an anaesthetic cream will be offered to minimise this. There should be no discomfort from the nasal or saliva swabs.

Benefits:

Your child will receive the flu vaccine earlier than scheduled by the Department of Health.

What are the side effects of any treatment when taking part?

The section on "risks" (above) describes some side effects to vaccination. Severe allergic reactions can occur with any vaccine but these are very rare, all our

research nurses are trained for this and the usual safety precautions for any vaccination will be taken.

What if there is a problem?

The section on "risks" (above) describes some side effects to vaccination. Severe allergic reactions can occur with any vaccine but these are very rare, all our research nurses are trained for this and the usual safety precautions for any vaccination will be taken.

What if there is a problem?

Any complaint about your child's participation in the study or any possible harm your child might suffer will be addressed. The detailed information on this is given in part 2.

Will my child's participation in the study be kept confidential?

Yes, we will follow ethical and legal practice and all information will be handled in confidence. The details are included in part 2.

This completes part 1.

In summary:

- **Children will receive a dose of Fluenz each year for the three years of the study**
- **During the study**, six blood (including blood spot if you agree) and saliva samples will be taken; before and three weeks after each vaccination and we ask you to take a nasal swab if they have a flu like illness

If the information in part 1 has interested you and you are considering participation please read the additional information in part 2 before making any decision.

PART 2

What if relevant new information becomes available?

Sometimes we get new information about vaccines which could include the one we are using here. If this happens, we will let you know and discuss whether your child should continue in the study. In some circumstances the study doctors may advise it best for your child to withdraw from the study. If you and your child decide to continue in light of the new information we may ask you to sign an updated consent form.

The study may be stopped at any time, including by the Department of Health which is funding this work. If the study is stopped for any reason we will let you know, as well as give your child's GP information about your child's continuing care.

What will happen if we do not want to carry on in the study?

You can remove your child from the study at any time without having to give a reason. You would need to decide if you want samples collected from your child (if any have already been collected) to be destroyed. If you would like them to be destroyed, you would need to inform us in writing. We would retain any information collected to that point in case we needed to reach you at some time in the future, for instance in relation to the vaccines given.

What if there is a problem?

Complaints

If you have any concerns about any aspect of this study, you and your child can contact the Vaccine Research Nurse or the study organisers (see details below), who will do their best to answer your questions. If you remain unhappy and wish to complain formally then you can do this through the National Health Service Complaints Procedure, details of which can be obtained at www.nhs.uk or by phoning 0845 601 3012.

Harm

In the event that something does go wrong and your child is harmed during the research and this is due to someone's negligence then you will have grounds for legal action for compensation against Public Health England but you may have to pay your legal costs. The National Health Service complaints mechanism will still be available to you and your child. Where justified, an ex gratia payment for any non-negligent harm may be made.

What data and confidentiality safeguards are in place?

Under the data protection laws, you have a right know how your child's personal data from this trial will be used, so that you understand exactly what information will be collected and who will have access to it. Personal data may include your child's name and address as well as results of the blood tests, and medical records so that we are able to analyse information and answer the study objectives. The only people with access to this information will be employees or agents of Public Health England or regulatory authorities who may wish to check the study is being properly carried out within the appropriate guidelines.

The data will only be used for the purposes of this study and any data released outside the above group will be anonymised. Data will be stored in secure Public Health England facilities and will be disposed of within clinical trial guidelines after the appropriate time period which may be a number of years. You have the right to obtain access to data relating to your child. If you wish to obtain any information, please contact us on the numbers listed in this leaflet.

Involvement of my child's GP

We will let your child's General Practitioner know that your child is taking part in the study by writing them a letter. We will also give them a copy of the letter that we send to you with the results of the study for their records.

What will happen to any samples from my child?

The samples we take for this study would not be part of your child's routine medical care. The samples will be labelled with your child's study number but not their name. The samples will be tested in collaborating laboratories and results will be sent to Public Health England where they will be linked with information about your

child so that we can see whether things such as age or gender affect responses to vaccination.

Once we have completed these tests any samples left over from this trial may be used to help develop and refine the tests we have for measuring responses to vaccines. Any samples shared with other laboratories will be anonymised and will not be traceable to the person who gave them. You will be asked to consent to any blood left over from this study being used in this way (this is optional and includes the blood spot). Your child may still take part in the study if you do not wish to consent to this.

Will any genetic tests be done?

No genetic tests will be carried out on your child's samples.

What will happen to the results of the research study?

We will send all families who take part a summary of what the study finds. We plan to publish the results in a medical journal which will be accessible to the public (an access fee may apply with some journals). The results of the study will also be reported to the Department of Health to help planning national vaccination programmes in the future. In any report or publication arising from this study, readers will not be able to identify any individual participant.

Who is organising and funding the research?

The study is funded by the Department of Health and is being organised by the Immunisation Department of Public Health England (PHE).

Who reviewed the study?

All research in the National Health Service is looked at by an independent group of people, called a Research Ethics Committee to protect the safety, rights, well-being and dignity of individuals This study has been reviewed and given favourable approval by The West London Ethics Committee - Reference 14/LO/0227

Further information and contact details.

Further information about our trials programme including links to the organisations reviewing research and the guidance we follow can be found at http://www.phe.gov.uk and typing *clinical trials* into the search bar.

Your child's contribution would be an important step towards the continual improvement of vaccine policy in the United Kingdom. Your child may be invited to take part in future studies with us by virtue of the surgery you attend. We reassure you that invitations for future studies will not be because of anything to be concerned about from results of this study.

If you have any further questions please ask your vaccine Research Nurse, or contact the organiser Professor Elizabeth Miller on 020 8327 7430.

You can also email your question to the Clinical Trials Team at clinical.trials@phe.gov.uk

Thank you for your time.

Vaccine Research Nurse

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