

PARTICIPANT INFORMATION SHEET

Influenza A/H1N1v in pregnancy: An investigation of the characteristics and management of affected women and the relationship to pregnancy outcomes for mother and infant

We would like to invite you to take part in our research study. Before you decide, we would like you to read this information sheet so that you understand why the research is being done and what it would involve for you. This should take about 10 minutes. If it would help, a member of the research team would be happy to go through the information sheet with you over the telephone and answer any questions you have. Contact telephone numbers are given at the end of this information sheet. You may also wish to discuss the study with your general practitioner, midwife, family or friends.

What is the purpose of the study?

There has recently been an outbreak of a new strain of influenza, called A/H1N1 influenza or “swine ‘flu”. Many people, including women who are pregnant, are expected to catch the illness or come into contact with it. Experience from previous influenza epidemics indicates that most pregnant women who develop influenza make a full recovery, but a small number may be at a higher risk of certain complications, such as pneumonia. For this reason, it is currently recommended that pregnant women developing or coming into contact with swine ‘flu should be offered antiviral medication, Relenza® (zanamivir) or Tamiflu® (oseltamivir) to treat the illness or prevent it developing.

Because the “swine ‘flu” virus is new, we don’t know if it has different effects in pregnancy from influenza viruses that have circulated in the past. We also don’t have as much information as we would like on the effects of the antiviral drugs in pregnancy, although the scientific information available so far suggests that the benefits of these outweigh any risks, both for mother and baby.

We would therefore like to collect clinical information from pregnant women who develop influenza or who come in contact with it, whether or not antiviral medicines are used and from pregnant women who are offered vaccination against AH1N1v influenza. This information includes details of ‘flu symptoms experienced side effects of the medications / vaccine, the progress of their pregnancy and the health of their babies before and after birth. By collecting these data from as many pregnant women as we can, we will be able to provide much better information to women in the future about the effects of ‘flu and its treatments or prevention by vaccination during pregnancy.

If complications were to develop during your pregnancy or with your baby, it does not necessarily mean that these were caused by swine ‘flu, its treatment or the swine flu vaccine. Medical problems do sometimes affect women who have been healthy throughout pregnancy and have not needed any medicines or other treatments. This is why we need information from a large number of pregnancies so that we can compare the frequency of medical problems between women who have had swine ‘flu or received treatment with those of pregnant women who have not been affected.

Why have I been invited?

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The Newcastle upon Tyne Hospitals 
NHS Foundation Trust

You have been invited to take part because you may have had influenza or been in contact with it during your pregnancy or because you have been offered vaccination against swine flu. You have contacted us or your GP, midwife or another health professional has told us about this, with your permission.

Do I have to take part?

It is up to you to decide if you want to take part. If you agree to take part, we will ask you to sign the consent form which is also enclosed. You are free to withdraw from the study at any time, without giving a reason. This would not affect the standard of care you receive. A form is also enclosed to allow you to do that.

What will happen to me if I take part?

We want to collect information from you and from your GP or midwife about your health and that of your baby during and after your influenza illness, or after you have received prophylaxis ('flu preventative treatment) with antiviral drugs or vaccination against swine flu. We will ask for information on the health of your baby until he/she reaches about six months of age. You can provide this information by filling in and returning our questionnaires in the post or by fax, or by answering questions over the telephone.

The information we are asking for is as follows

Now: Your personal details, medical history and any symptoms of 'flu you have experienced so far. There is a questionnaire enclosed with this leaflet that we would like you to return along with your consent form if you agree to take part.

In about 4 weeks time: We will ask you to complete a further questionnaire about your symptoms of 'flu and how long you remained unwell. If you are still unwell then, we would like to send you a further questionnaire after 4 more weeks.

After you have given birth: We will ask you to complete a questionnaire soon after you deliver on how your pregnancy went and details about the health of you and your baby (or babies)

When your baby is about six months of age: We will ask you to complete a final questionnaire about your baby's (or babies') health at about six months of age.

We will also, with your permission, tell your GP that you have agreed to take part in the research and will ask your GP or midwife to provide information from your records that is of relevance to this research.

Some women will already have had swabs of the throat and/or nose to see if they have influenza as part of their usual NHS care. If you have any flu symptoms and have not had swabs done as part of your routine care, we have enclosed some nasal swabs in this pack for you to use to swab the inside of your nose so that we can test for the swine 'flu virus as part of our study. This is simple and painless and full instructions are provided with the swabs. When you have taken the swabs please return them directly to the laboratory in the envelope provided. ***It is important that this is done straight away.*** We will not need you to collect swabs if you do not have influenza symptoms.

Expenses and payments

You will not have any additional expenses from taking part in the study. We will provide you with stamped addressed envelopes for returning questionnaires and swabs in the post, and we can call you back to minimize cost to you if you need to talk to us on the telephone.

What will I have to do?

All you are asked to do is to provide the information we will request about yourself, your pregnancy and your baby. If you are unsure of the answers to any questions, or there are questions you prefer not to answer, it is fine to say that. We also need swabs of the inside of your nose straight away if you have not had this done already. Please contact a member of our research team if there is anything about the study that you would like to discuss further or that we can be of help with.

What are the alternatives for diagnosis or treatment?

If you agree to take part in this research it will not affect how you are treated. All pregnant women in the UK are being offered vaccination against Swine Flu. Some women will already have been given antiviral medicines, either a Relenza® (zanamivir) inhaler or Tamiflu® (oseltamivir) tablets, to treat or prevent influenza as part of their usual NHS care. The decision to provide these medicines or to have the vaccination rests with you and the health professionals looking after you. Taking part in the research makes no difference to this. However, as part of the research we would like to know about medicines that you receive and any effects that these have had.

What are the possible disadvantages and risks of taking part?

There are no physical risks to you or your baby from taking part in the research. You may be worried about the effects of the influenza or its treatment on you or your baby. We can provide you with further information about that if you need this.

If you do suffer problems with your pregnancy, we realize that it may be distressing to provide details about these problems to the research team. It is important that the details we collect are as complete and accurate as possible, but if you prefer not to provide any information we will understand.

We need to collect personal health information about you and your baby in order to perform the research. We will keep this in the strictest confidence and we will not share your personal information with anyone else.

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

There are no treatments being administered as part of this study, so there are no additional risks to you and your baby from taking part in the research.

What are the possible benefits of taking part?

Taking part in the study will not help you, but the information we get from this study may help improve the treatment of pregnant women with influenza in the future, and provide them with more information about the effects of influenza and its treatments or prevention by vaccination during pregnancy on women and their babies.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time. If you do this, with your permission we would like to stay in contact with your GP or midwife to collect further information without troubling you further. However, we will not do this unless you agree.

If you decide to withdraw, we will continue to use the information that you have provided up to the time you withdraw, but we can remove identifying details such as your name and contact details if you wish.

What happens when the research study stops?

Once we have obtained information about the outcome of your illness, the progress of your pregnancy and the health of your baby up until six months of age, we will not be in touch with you again to collect any more information. We will write a news sheet for participants about results of the research, once these have been analysed. We will send you a copy if you want this.

Will my taking part in this study be kept confidential?

Yes. We realise the importance of keeping personal information about you and your health in confidence. All information that you provide will be stored securely.

Paper records will be kept under lock and key when not in use. Information held on computers will only be stored on machines within the hospital Trust with password-controlled access. This information will only be accessible by the immediate research team. However, other authorised persons may also need access to allow them to monitor the quality of the research. No identifiable information will be kept on laptop computers,

memory sticks, or other portable devices. Identifiable information about you will not be transferred by email or portable devices.

We would like to keep details of your name and contact details so that we can get in touch about research projects in the future. We will ask you permission to do this. Any further studies we might approach you about would need to be approved by an ethics committee.

We would like to keep clinical information about you indefinitely. This information remains useful for monitoring the safety of medicines and can be combined with information that might be collected in other studies in the future.

Involvement of the General Practitioner/Family doctor (GP)

We would like to inform your general practitioner and midwife about your participation in the study. With your permission, we would also like to ask them to provide information about you and your pregnancy.

What will happen to any samples I give?

If a nose swab is required from you, a self swab kit will be included with this leaflet. Samples received from participants will be analysed in batches and the results provided to the research team in due course. We will not provide you or your GP with the results as a matter of routine, because these will not be ready in time to help in the management of your illness. Only virological material will be stored from your sample to enable the Health Protection Laboratories to carry out further tests in the future as part of their routine Public Health Surveillance program on influenza viruses.

Will any genetic tests be done?

No genetic tests are being done.

What will happen to the results of the research study?

A report of the research will be written and submitted for publication in a scientific medical journal once the research is completed. Reports will also be provided to the National Institute for Health Research. None of these reports will identify you by name.

Who is organising and funding the research?

The primary study to assess the effects of swine flu and its treatment with antivirals during pregnancy has been funded by the National Institute for Health Research, who will provide the necessary resources to Newcastle University for conducting the research.

Further funding has subsequently been provided by GlaxoSmithKline (GSK) and Baxter to The Newcastle Hospitals NHS Foundation Trust to enable additional information to be collected on swine flu vaccination during pregnancy as an extension of the original study.

No members of the research team will benefit financially from the study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. The original study has been reviewed and given favourable opinion by the County Durham and Tees Valley 1 Research Ethics Committee. The protocol amendment relating to AH1N1v vaccination in pregnancy has been submitted for ethical review.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Contact numbers are provided at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this via the Complaints Procedure of the Newcastle Hospitals NHS Foundation Trust. Details can be obtained from

Patient Relations Department

PIS, Consent forms. Influenza A/H1N1v in pregnancy - (Version 4 , 3 November 2009)

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In the event that something does go wrong and you are harmed during the research due to someone's negligence, then you may have grounds for a legal action for compensation against the Newcastle Hospitals NHS Foundation Trust, but you may have to pay your own legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Further information and contact details

Further information about the study can be obtained from

Dr Laura Yates, Dr Sally Stephens or Prof Simon Thomas
UK Teratology Information Service
Wolfson Unit of Clinical Pharmacology, Newcastle NE1 4LP
Tel 0191 2606197

Independent Contact:

Dr Ruben Thanacoody
Consultant Clinical Toxicologist
Regional Drugs and Therapeutics Centre
Tel 0191 260 6182