

GP 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 (NIHR Portfolio No: 7376)

Thank you for agreeing to be a Participant Identification Centre for our research study. This information sheet outlines why this research is important, what your involvement will be and who to contact for support/help.

This document should be read alongside the Primary Care Flowchart.

What is the purpose of the study?

There has recently been an outbreak of a new strain of influenza, called 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. Vaccination against swine flu has now also been recommended for all pregnant women as a priority.

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 and the swine flu vaccines, 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 who are offered vaccination against swine flu. This information includes details of ‘flu symptoms experienced side effects of the medications, 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 during pregnancy.

If complications were to develop during a pregnancy or with a baby, it does not necessarily mean that these were caused by swine 'flu, the swine flu vaccine or its treatment. Medical problems do sometimes affect women who have been healthy throughout pregnancy and who 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.

Do patients have to take part?

It is up to a patient to decide if they want to take part. If they agree to take part, we will send them detailed information about the study (Participant Information Sheet) and ask them to sign the consent form if they decide to take part. A patient is free to withdraw from the study at any time, without giving a reason. This would not affect the standard of care they receive. Patients are sent the withdrawal of consent form along with the Patient Information Sheet during the first contact by UKTIS.

What is a GPs involvement if a pregnant woman wants to take part?

Refer to the Primary Care Flowchart for each stage in the study and GP involvement.

When a pregnant woman presents with suspected swine flu, is offered antiviral treatment e.g. as prophylaxis (even if she decides not to take these) or is offered vaccination against swine flu, we ask that you briefly explain the study to her and seek verbal consent to refer her details on to the study team. If she agrees please either:

1. Telephone details of patient through to UKTIS on our dedicated Swine Flu reporting line 0191 260 6197
OR
2. Complete a 'Reporting Form for HCPs' and send immediately by FAX to 0191 260 6193

We will then post full details of the study and consent forms to the woman directly. If she agrees to take part, we will send you a questionnaire

- ***In about 4 weeks time:*** We will ask you to complete a further questionnaire about the patient's symptoms of 'flu and how long they have remained unwell. If a patient is still unwell, we would like to send you a further questionnaire after 4 more weeks.
- ***After the patient has given birth:*** We will ask you to complete a questionnaire on how the pregnancy went and details about the patient's health and that of their baby (or babies).
- ***6 months after birth:*** We will ask you to complete a questionnaire on the infant's health and development.

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 a patient has any flu symptoms and has not had swabs as part of their routine care, we will send the patient a nasal swab pack so we can test for swine flu as part of the study. This will be sent direct to the patient, and returned direct to the study team for testing in a HPA laboratory.

Expenses and payments for participants

Patients consenting to the study will not have any additional expenses from taking part in the study. The study team will provide patients with stamped addressed envelopes for returning questionnaires and swabs in the post, and can call patients back to minimise the cost if telephone support is needed.

Reimbursement for GPs for taking part in the study

Any payment reimbursing GPs for referring patients in the study are covered by NHS Service Support Costs under Department of Health guidance. Payment of NHS Service Support Costs is from your local Primary Care Trust or Health Board. For queries on service support, contact Mark Ryan-Daly (contact details on page 6).

What will participants have to do?

Patients are asked to provide the information we will request about themselves, their pregnancy and their baby. If they are unsure of the answers to any questions, or there are questions they prefer not to answer, it is fine to say that. If a woman has flu-like symptoms and has not been tested for the Swine Flu Virus as part of her routine care, we will ask the woman to swab the inside of her nose using the swab kit we post to her with the information on the study. These swabs will only be tested at the end of the study, and there is therefore no guarantee that the result will be fed back to the woman or the health professional involved in her care.

Women are encouraged to contact a member of our research team if there is anything about the study that they would like to discuss further or that we can be of help with.

What are the alternatives for diagnosis or treatment?

If a woman agrees to take part in this research it will not affect how she is treated. 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 rests with the health professionals looking after her and taking part in the research makes no difference to this. However, as part of the research we would like to know about medicines that she receives and any effects that these have had.

What are the possible disadvantages and risks of taking part to patients?

There are no physical risks to a patient or her baby from taking part in the research. Pregnant women may be worried about the effects of the influenza or its treatment on themselves or their baby. We can provide both the GP and patient further information about that if needed.

If a patient does suffer problems with their pregnant, we realise 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 a patient prefers not to provide any information we will understand.

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

Are there any side effects of any treatment?

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

What are the possible benefits to patients for taking part?

Taking part in the study will not directly help any patient, 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 during pregnancy on women and their babies.

What will happen if a patient doesn't want to carry on with the study?

A patient can withdraw from the study at any time. If they do this, with their permission, we would like to stay in contact with their GP to collect further information without troubling them further. However, this will not be done unless the patient agrees.

If a patient decides to withdraw, we will continue to use the information you have provided up to the time they withdraw, but we can remove identifying details such as the patients name and contact details should they wish.

What happens when the research study stops?

Once we have obtained information about the outcome of a patient's illness and their pregnancy, we will not be in touch with you or the patient 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 a patient taking part in this study be kept confidential?

Yes. We realise the importance of keeping personal information about a patient and their 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 patients will not be transferred by email or portable devices.

We would like to keep details of patients' names and contact details so that we can get in touch about research projects in the future. We will ask a patient permission to do this. Any further studies we might approach a patient about would have been approved by an ethics committee and have the appropriate NHS R&D approval.

We would like to keep clinical information about patients in the study 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.

Are any samples taken?

Yes, for those patients not previously tested for swine flu. Any pregnant woman referred with suspected swine flu will be sent a virology (nose swab) testing kit in the post. This is then returned direct to the HPA Newcastle virology laboratory for analysis. Samples received from participants will be analysed in batches and the results provided to the research team in due course. We will not provide a GP or patient with the results as a matter of routine, because these will not be ready in time to help in the management of the illness. Only virological material will be stored from a sample to enable the Health Protection Laboratories to carry out further tests in the future as part of their routine Public Health Surveillance programme on influenza viruses.

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 a patient by name. Any GP involved in referring a patient to the study, can request a copy of the final report following publication.

Funding and Management

The study has been funded by the National Institute for Health Research, who will provide the necessary resources to Newcastle University for conducting the research. No members of the research team will benefit financially from the study.

Additional resources to collect additional information on swine flu vaccination in pregnancy have been provided by GlaxoSmithKline and Baxter to Newcastle upon Tyne Hospitals NHS Foundation Trust.

Management of the study is via Newcastle upon Tyne Hospitals NHS Foundation Trust as the Sponsor.

Ethical approval

This study has been reviewed and given favourable opinion by the County Durham and Tees Valley 1 Research Ethics Committee.

Sponsorship

The study is Sponsored by The Newcastle upon Tyne Hospitals NHS Foundation Trust. Any queries regarding the study should first be directed to the study team. However, any complaints or issues over insurance/indemnity should be sent to the Amanda Tortice (amanda.tortice@newcastle.ac.uk) as the Sponsors representative.

Recruitment (accrual)

Any recruitment will be mapped to the referring GP Practice and relevant PCT/Health Board. Any queries should be directed to Mark Ryan-Daly (mark.ryan-daly@nuth.nhs.uk) in the Northumberland, Tyne and Wear CLRN who is managing this process. Accrual will also be used by the Primary Care Research Network to ensure that NHS Service Support Costs are paid to the correct GP Practices.

Welsh Language Act

To comply with the Welsh Language Act 1993, any study documents will be translated upon request.

Problems

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 by contacting Amanda Tortice (amanda.tortice@newcastle.ac.uk) as the Sponsors representative.

If any patients have a complaint, they can raise an issue via the Complaints Procedure of the Newcastle Hospitals NHS Foundation Trust. Details can be obtained from:

Patient Relations Department
Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
High Heaton
Newcastle upon Tyne
NE7 7DN

Tel: 0191 233 6161

Email: patient.relations@nuth.nhs.uk

Web: <http://www.newcastle-hospitals.org.uk/patient-guides/have-say.aspx>

In the event that something does go wrong and a patient is harmed during the research due to someone's negligence, then a patient may have grounds for a legal action for compensation against the Newcastle upon Tyne Hospitals NHS Foundation Trust, but a patient may have to pay their own legal costs. The normal National Health Service complaints mechanisms will still be available to any patient under such circumstances. Any queries regarding suspected negligence should be directed to Patient Relations (contact details above).

Further information and contact details

All study documents can be downloaded from our website at www.uktis.org

Further information about the study can be obtained from:

Dr Laura Yates, Dr Sally Stephens or Professor Simon Thomas
UK Teratology Information Service
Wolfson Unit of Clinical Pharmacology, Newcastle, NE2 4HH
Tel: 0191 260 6197
Email: UKTISH1N1Study@nuth.nhs.uk

Independent Contact:

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

Further information on R&D, accrual (recruitment), NHS Service Support can be obtained from:

Mark Ryan-Daly
Project Manager
Northumberland, Tyne and Wear CLRN
Tel: 0191 241 8809
Email: mark.ryan-daly@nuth.nhs.uk