



NETSCC, HTA

24 November 2009

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 CSP Number: 27118

NIHR Portfolio Number: 7376

Substantial Amendment 1 (03NOV2009)

The Chief Investigator has submitted a Substantial Amendment for this study. REC approval was granted on 7 September 2009 (**ref 09/H0905/66**). The amendments only apply to the UKTIS primary care element of the study. The UKOSS secondary care element has not been amended. Each amendment is highlighted below, along with a document control table.

Protocol (v3 05NOV2009)

Vaccination of pregnant women has been identified as a priority in the UK and is thus likely to impact on the results of our current Influenza AH1N1v in pregnancy study. Furthermore, data on the safety of AH1N1v vaccination in pregnancy is limited. GlaxoSmithKline (GSK) and Baxter (manufacturers of the two swine flu vaccines available in the UK) are under obligation to the EMEA to collect data on AH1N1v vaccine exposure in pregnancy as part of the post-marketing surveillance for their respective swine flu vaccines, and have asked UKTIS to establish a registry of AH1N1v vaccination in pregnancy. We would therefore like to amend our current study protocol to include collection of information on the maternal and fetal outcome for women who are vaccinated against swine flu in pregnancy, and the additional vaccine data and neonatal follow up data as requested by GSK and Baxter. GSK and Baxter have agreed to provide funding to the Newcastle Hospitals NHS Foundation Trust to enable UKTIS to establish a registry of pregnant women vaccinated against swine flu in the UK if the amendments are agreed.

We would be grateful if the following changes to the Protocol are considered:

- 1) to include pregnant women offered vaccination against swine flu
- 2) to collect additional data on the swine flu vaccine administered (manufacturer, adverse effects)
- 3) to extend follow up of the neonate to six months

In light of the ongoing risk of postal strikes, we have also taken the opportunity of this amendment to request that information on participants is ideally notified to UKTIS by telephone or fax, with postal notification or return of information by post being used only where these first two options are not feasible.

The Protocol circulated as part of the Substantial Amendment has a tracked change function on highlighting the amended or additional sections.

Reporting Form for HCPs (v3 03NOV2009)

The form now contains additional data collection fields around swine flu vaccination and any suspected adverse events linked to the vaccine. The method of returning the data to UKTIS as outlined on Page 3 has been changed to:

“To submit this form:

- a) Telephone the Swine Flu Reporting Line on 0191 260 6197; *or*
- b) FAX to 0191 260 6193; *or*
- c) Post to: UK Teratology Information Service, Regional Drug & Therapeutics Centre, FREEPOST NEA1573, Newcastle upon Tyne, NE2 1BR

Note that the FREEPOST option should only be used as a last resort, where telephone or FAX is not available or appropriate

Four Week Update Form for HCPs (v2 03NOV2009)

The method of returning the data to UKTIS as outlined on Page 3 has been changed to:

“To submit this form:

- a) FAX to 0191 260 6193; *or*
- b) Post to: UK Teratology Information Service, Regional Drug & Therapeutics Centre, FREEPOST NEA1573, Newcastle upon Tyne, NE2 1BR

Note that the FREEPOST option should only be used as a last resort, where telephone or FAX is not available or appropriate”

Pregnancy Outcome Form for HCPs (v2 03NOV2009)

The form now contains additional data collection fields around swine flu vaccination and any suspected adverse events linked to the vaccine. The method of returning the data to UKTIS as outlined on Page 3 has been changed to:

“To submit this form:

- a) FAX to 0191 260 6193; *or*
- b) Post to: UK Teratology Information Service, Regional Drug & Therapeutics Centre, FREEPOST NEA1573, Newcastle upon Tyne, NE2 1BR

Note that the FREEPOST option should only be used as a last resort, where telephone or FAX is not available or appropriate”

Notice of Declined Consent for HCPs (v3 03NOV2009)

The form now contains additional data collection fields around swine flu vaccination and any suspected adverse events linked to the vaccine. The method of returning the data to UKTIS as outlined on Page 3 has been changed to:

“To submit this form:

- a) Telephone the Swine Flu Reporting Line on 0191 260 6197; *or*
- b) FAX to 0191 260 6193; *or*
- c) Post to: UK Teratology Information Service, Regional Drug & Therapeutics Centre, FREEPOST NEA1573, Newcastle upon Tyne, NE2 1BR

Note that the FREEPOST option should only be used as a last resort, where telephone or FAX is not available or appropriate”

GP Information Sheet (v1.0 03NOV2009)

Following advice, and queries from GPs a comprehensive information sheet has been devised. This is a new document and draws from the Patient Information Sheet, Protocol and queries received so far from primary care.

Primary Care Flowchart (v1.0 03NOV2009)

As with the GP Information Sheet, a flowchart has been produced detailing each step/stage in the UKTIS element of the study. The flowchart outlines at each stage what GPs, patients and the study team are to do. The flowchart clarifies how GPs are to submit information to UKTIS.

Incidence Reporting Form (v1.0 03NOV2009)

To aid the sentinel practices identified by PCRN, a reporting form on swine flu incidence has been devised. This form allows easy data capture of the information needed to gain incidence into swine flu and the associated treatments. For a definition of sentinel practices, refer to the document titled “Study Summary (v4.0 02NOV2009)”.

For queries or issues relating to this study, contact Mark Ryan-Daly (mark.ryan-daly@nuth.nhs.uk or 0191 241 8808) in the Lead CLRN.

Mark Ryan-Daly

Project Manager, Northumberland, Tyne and Wear CLRN

3 November

Documents submitted as part of the Substantial Amendment		
Document name	Version & date	Supersedes
Protocol	v3 05 NOV2009	V2 03 SEP 2009
GP Information Sheet	v1.0 04NOV2009	None – new document
Primary Care Flowchart	v1.0 03NOV2009	None – new document
Study Summary	vV4.0 02NOV2009	v3.0 04SEP2009
Incidence Reporting Form	v1.0 03NOV2009	None – new document
Reporting Form for HCPs	v3 03NOV2009	v2 03SEP2009
Reporting Form for Participants	v3 03NOV2009	v2 03SEP2009
Study Recruitment Poster/Advert	v4 03NOV2009	v3 01OCT2009
Four Week Update Form for HCPs	v2 03NOV2009	v1 25AUG2009
Pregnancy Outcome Form for HCPs	v3 03NOV2009	v2 02SEP2009
Pregnancy Outcome Form for Participants	v3 03NOV2009	v2 02SEP2009
Infant Outcome/Development Form for HCPs	v1 03NOV2009	None – new document
Infant Outcome/Development Form for Participants	v1 03NOV2009	None – new document
Notice of Declined Consent for HCPs	v3 03NOV2009	v2 03SEP2009
Covering letter for GPs	v4 03NOV2009	v3 01 OCT2009
Covering letter for Midwives	v4 03NOV2009	v3 01 OCT2009
Participant recruitment covering letter	v4 03NOV2009	v3 01 OCT2009
Participant Information Sheet	v4 03NOV2009	v3 01 OCT2009
Participant 4 week fu cov letter	v1 03NOV2009	None – new document
Participant pregnancy outcome fu cov letter	v1 03NOV2009	None – new document
Participant infant 6month cov letter	v1 03NOV2009	None – new document