

# Maternal and perinatal outcomes of pandemic influenza in pregnancy

<b>Submission date</b> 21/01/2013	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 24/01/2013	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/01/2023	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Evidence from the last influenza pandemic in 2009 showed that pregnant women were particularly vulnerable to severe infection. The aims of this study are, in a future influenza pandemic, to estimate the incidence of hospitalisation with pandemic-type influenza in pregnancy, and to describe the outcomes of pregnancy particularly in relation to specific treatments and according to whether women have received influenza immunisation.

### Who can participate?

Women with influenza in pregnancy in a future pandemic

### What does the study involve?

This study collects anonymous data only. The cohort of pregnant women infected with influenza are identified through the UK Obstetric Surveillance System (UKOSS) network of nominated reporting clinicians in each consultant maternity unit in the UK. Doctors and midwives are asked to report anonymous details of pregnant women with confirmed pandemic influenza admitted to their unit. Each month throughout the study, the information collected is analysed to describe the pregnancy and other outcomes for women and their babies and to describe their treatment. These data are compared with previously collected information about women who do not have influenza in pregnancy. These analyses are used to develop guidance for prevention and treatment during the pandemic.

### What are the possible benefits and risks of participating?

There is no benefit to individual women of inclusion of their anonymous data in the study. However, the information is used to improve care for women and babies in the future. This study collects anonymous data only, after women have been admitted to hospital and treated. There are thus no risks to participants.

### Where is the study run from?

University of Oxford (UK)

When is the study starting and how long is it expected to run for?  
The study was funded in 2012, but will only be activated in the event that there is a new influenza pandemic

Who is funding the study?  
National Institute for Health Research Health Technology Assessment (UK)

Who is the main contact?  
Prof. Marian Knight  
marian.knight@npeu.ox.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Marian Knight

**Contact details**  
National Perinatal Epidemiology Unit  
University of Oxford  
Old Road Campus  
Oxford  
United Kingdom  
OX3 7LF

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
HTA 11/46/12, Version 3 12/09/12

## Study information

**Scientific Title**  
Maternal and perinatal outcomes of pandemic influenza in pregnancy: a cohort study

**Study objectives**  
The hypothesis of this study is that in a future influenza pandemic, pregnant women will be at increased risk of poor maternal and pregnancy outcomes, and a rapid study of this susceptible group will be important to inform both ongoing preventive and management policies.

Further details of the UK-wide Obstetric Surveillance System (UKOSS) which will be used to collect these data can be found on [www.npeu.ox.ac.uk/ukoss](http://www.npeu.ox.ac.uk/ukoss)

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee East Midlands - Nottingham, 11/09/2012, ref: 12/EM/0365

**Study design**

Cohort study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**Participant information sheet**

There is no participant information sheet for this study as it uses anonymous data only

**Health condition(s) or problem(s) studied**

Pandemic influenza in pregnancy

**Interventions**

Observational study of pregnancy outcomes in women hospitalised with the pandemic influenza. Outcomes following extra corporeal membrane oxygenation (ECMO) and influenza immunisation will be described.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Incidence of hospitalisation with pandemic influenza in pregnancy

**Secondary outcome measures**

1. Maternal death
2. Level 3 critical care unit admission
3. Other major complication
4. Preterm birth
5. Congenital anomaly
6. Stillbirth
7. Early neonatal death
8. Perinatal death

**Overall study start date**

01/06/2012

**Completion date**

31/12/2020

**Reason abandoned (if study stopped)**

Study redesigned and relaunched for COVID pandemic (see ISRCTN40092247)

## Eligibility

**Key inclusion criteria**

All pregnant women in the UK admitted to hospital with confirmed pandemic influenza

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

500

**Key exclusion criteria**

Women not meeting the inclusion criteria

**Date of first enrolment**

01/06/2012

**Date of final enrolment**

31/05/2015

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

University of Oxford

Oxford

United Kingdom

OX3 7LF

# Sponsor information

## Organisation

University of Oxford (UK)

## Sponsor details

Joint Research Office  
Block 60  
Churchill Hospital  
Old Road  
Oxford  
England  
United Kingdom  
OX3 7LE

## Sponsor type

University/education

## Website

<http://www.ox.ac.uk/>

## ROR

<https://ror.org/052gg0110>

# Funder(s)

## Funder type

Government

## Funder Name

Health Technology Assessment Programme

## Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

**Publication and dissemination plan**  
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**  
Not provided at time of registration

**IPD sharing plan summary**  
Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	01/03/2015		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No