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Pandemic Influenza: Population susceptibility, severity and spread: Rapid Research using the Health Survey for England (HSE)

Submission date
19/09/2013

Recruitment status
No longer recruiting

Registration date
20/01/2014

Overall study status
Completed

Last Edited
02/02/2017

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The next influenza pandemic will arise suddenly and with little warning. Pandemic influenza can be severe with high death rates or, as was seen in the last pandemic, the strain may be relatively mild with low hospitalisation and death rates. Governments need information on the severity of influenza early in a pandemic to help them decide how much pandemic vaccine and antivirals to order. They need to regularly reassess the situation to decide how best to use these antivirals and vaccines throughout the pandemic. Measuring severity needs large studies to look for evidence of infection in blood samples and to ask people about their illnesses. Research on such a large scale usually takes many months to set up but in a pandemic results are needed much more quickly than this. This research study is designed to overcome this problem by working alongside a very large national survey which already takes place every year -The Health Survey for England. This survey is one of the most important ways we have of monitoring the health of the general public.

Who can participate?
Households across the UK who have a Health Survey of England interview between October 2012 and March 2013 can participate in this study.

What does the study involve?
It involves research nurses visiting households across the country throughout the year to collect detailed health data and to take blood samples (for tests such as cholesterol levels). We will add simple questions (about influenza-like illness and vaccination) and take an additional blood sample (to look for evidence of influenza infection) so that we can quickly measure the severity of a new strain of the influenza virus as soon as it starts to spread. Making this a routine part of a survey that is already running means that the additional cost per participant is minimal and that in a pandemic where time is of the essence, the delays needed to plan the study, get ethical and organisational approvals, and to train staff can be avoided.

What are the possible benefits and risks of participating?
The additional blood sample uses the same needle as the sample that is already being taken and therefore will result in minimal additional discomfort to the participants.

Where is the study run from?
The study is run from households across the UK.

When is study starting and how long is it expected to run for?
The study has two phases, each one lasting a year. Phase one starts in September 2013 and phase 2 (the pandemic phase) would only be initiated in the event of an influenza pandemic.
Who is funding the study?
The National Institute for Health Research (NIHR), UK.

Who is the main contact?
Dr Andrew Hayward
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Contact information

Type(s)
Scientific

Contact name
Dr Andrew Hayward

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NW3 2PF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NETSCC ID: 11/46/09

Study information

Scientific Title
Pandemic Influenza: Population susceptibility, severity and spread: a cross-sectional survey

Study objectives
The study aims to draw on our experience of large-scale community influenza studies, community surveys, surveillance and serological assays to establish an efficient system allowing real-time assessment of population susceptibility, spread of infection and clinical attack rates.

Objectives:
1. To develop the HSE as a tool for rapid population-based surveys of influenza infection and influenza-like illness rates.
2. To provide monthly measures of numbers of cases infected and weekly updates on numbers of influenza-like illnesses during the first two waves of a pandemic to act as denominators for national estimates of case fatality and hospitalisation rates.
3. To assess spread of the novel influenza strain geographically, by age, and through time.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford A Research Ethics Committee (REC), 10/H0604/56

Study design
Serial cross-sectional serological prevalence surveys with retrospective ascertainment of vaccination and respiratory illness history in conjunction with the National Health Survey for England (HSE).

Primary study design
Observational

Secondary study design
Cross-section survey

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

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

Interventions
This survey is one of the most important ways we have of monitoring the health of the general public. It involves research nurses visiting households across the country throughout the year to collect detailed health data and to take blood samples (for tests such as cholesterol levels). We will add simple questions (about influenza-like illness and vaccination) and take an additional blood sample (to look for evidence of influenza infection) so that we can rapidly measure the severity of a new strain of influenza as soon as it starts to spread.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Influenza antibody titres - haemagglutination inhibition assay (HIA test)
2. Influenza-like illness - questionnaire

Measured at baseline

Secondary outcome measures
None

Overall study start date
01/09/2013

Completion date
31/08/2014

Eligibility

Key inclusion criteria
All participants participating in the HSE who have a household interview date between 01/10/2012 and 31/03/2013.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3216

Key exclusion criteria
None

Date of first enrolment
01/09/2013

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UCL Centre for Infectious Disease Epidemiology
London
United Kingdom
NW3 2PF

Sponsor information

Organisation
University College London (UCL) (UK)

Sponsor details
Joint Research Office
1st Floor of Maple House
149 Tottenham Court Road
London
England
United Kingdom
W1T 7DN

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2015		Yes	No
HRA research summary			28/06/2023	No	No