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Early estimation of pandemic influenza Antiviral and Vaccine Effectiveness (EAVE) - use of a unique community and laboratory national linked dataset

Submission date
15/01/2013

Recruitment status
Recruiting

Registration date
08/02/2013

Overall study status
Ongoing

Last Edited
13/06/2016

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
In the last century there were three pandemics (global epidemics) of influenza (1918-1919, 1957-58, 1968-1969) producing very large numbers of clinical cases and large numbers of deaths (an estimated 20-40 million, 1 million and 1 million deaths respectively) as the population had little immunity to the novel influenza viruses involved (H1N1, H2N2, H3N2 respectively).
Immunisation programmes delivered in primary healthcare settings have been shown to be acceptable (as evidenced by previous high uptake rates) and effective, and this will therefore be the mainstay of disease prevention in any new influenza pandemic.
Any new influenza vaccination will likely be targeted at those who are at increased risk of serious illness or death from influenza like illness. Observational studies can be used to estimate the effectiveness of healthcare interventions in situations where it is
unethical and/or not feasible to mount more rigorous experimental studies; such is the case with the introduction of a new pandemic influenza vaccine. Observational studies can also assess the effects of healthcare interventions without influencing the care that is provided or the patients who receive it. Results from these studies are generalisable in that they can be used by other countries or regions to help guide public health policy. The potential novelty of a new pandemic virus requires that a high degree of vigilance at both the epidemiological and microbiological levels accompanies the implementation of a vaccine programme for the whole population.
Policymakers will be reassured if:
1) Early evidence can be gathered that the new pandemic vaccine is widely acceptable as evidenced by high uptake rates and is being distributed by primary care as a priority to those at most risk of adverse effects of the virus especially if some groups are more susceptible than others e.g. children, the elderly, the most socioeconomically deprived or pregnant women and those deemed to be at-risk on the basis of existing illnesses and
2) if the vaccine is known, at an early stage, to be effective in preventing influenza like illness and death.
By extracting the relevant de- identified electronic patient information from general practice, which includes age, sex, illness data, vaccination and prescribing information and linking this

with laboratory data of patients with suspected new pandemic influenza and information on previous exposures to past pandemic A/H1N1 influenza and/or seasonal influenza and also information on death from the General Register for Scotland dataset; from this compiled dataset, we will be able to determine the:
1) Uptake of the new pandemic vaccine by the relevant at risk populations
2) The identification of susceptible groups in the population to help target the vaccination
3) Reduction in the expected incidence of influenza related serious morbidity and mortality in the most susceptible risk groups, since this is the major rationale behind the immunisation policy; and
4) Effectiveness of the pandemic vaccine/antivirals in the whole population.

Who can participate?
The setting for this project will be general practices based throughout Scotland. These practices have about 300,000 people registered with them and will be included in the project.

What does the study involve?
In the event of an influenza pandemic, the general practices enrolled will provide sufficient data to allow linkage to serology, virology and clinical outcome data to establish an anonymised dataset which can allow estimates of attack rate and vaccine/ antiviral effectiveness.

What are the possible benefits and risks of participating?
The will be no risks and no direct benefit to patients, rather this project will help inform policy makers and any vaccination or antiviral programme in the event of a new pandemic.

Where is the study run from?
The project is being jointly led by Health Protection Scotland and the Universities of Aberdeen, Edinburgh and Strathclyde.

When is the study starting and how long is it expected to run for?
The project will start in 2013. If there is no pandemic the project will be placed into hibernation from 2014.

Who is funding the study?
The project is being funded by the NIHR Health Technology Assessment programme.

Who is the main contact?
Dr Colin Simpson
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 11/46/23

Study information

Scientific Title
Early estimation of pandemic influenza Antiviral and Vaccine Effectiveness (EAVE) - use of a unique community and laboratory national linked dataset: an observational longitudinal cohort study with nested-case control study

Acronym
EAVE

Study objectives
Once the study commences, during a twenty-three month preparatory period, we will instigate a data and serology collection linkage system whereby, once a new pandemic occurs, we will be able to undertake a timely analysis of a large national retrospective observational cohort of patients using a unique community, hospital and laboratory linked dataset.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/114623
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0009/81774/PRO-11-46-23.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Research Ethics Committee 02, 15/11/2012, ref: 12\ss\0201

Study design
Observational longitudinal cohort study with nested-case control study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Pandemic influenza

Interventions
No intervention will be given to patients. Any pandemic influenza vaccine programmes implemented in Scotland will be assessed for effectiveness.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Primary outcome(s)
The vaccination uptake in the relevant at risk populations (patients <65 with at-risk co-morbidities and those >65 years) and the general population recorded by general practices

Key secondary outcome(s))
1. Influenza positivity from virological swab data in vaccinated and unvaccinated patients stratified by at-risk populations, age, sex and socioeconomic status.
2. Influenza positivity from serology data in vaccinated and unvaccinated patients stratified by at-risk populations, age, sex and socioeconomic status, which will permit the estimation of incidence of influenza.
3. Consultation for influenza-related morbidity (e.g. influenza, pneumonia, chronic obstructive pulmonary disease [COPD] and cardiac related consultations) and issue of antiviral therapy from general practice data in vaccinated and unvaccinated patients stratified by at-risk populations, age, sex and socio-economic status
4. Mortality and influenza-related serious morbidity (e.g. influenza, pneumonia, COPD and cardiac related death and hospitalisation from SMR01 records) in vaccinated and unvaccinated patients stratified by at-risk populations, age, sex and socioeconomic status
5. For patients with stored serology (and prior to the introduction of any vaccination) whether cross-reactivity occurs due to previous exposure to A/H1N1 or A/H1N1 vaccination, other pandemic influenza or other seasonal influenza vaccination or exposure.

Completion date
01/01/2050

Eligibility

Key inclusion criteria
All (anonymised) patient data will be collected

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2013

Date of final enrolment
01/01/2050

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Edinburgh
Edinburgh
United Kingdom
EH89AG

Sponsor information

Organisation
Academic and Clinical Centre Office for Research and Development (ACCORD) (UK)

ROR
https://ror.org/01x6s1m65

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2015		Yes	No