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SIVE II: an evaluation of the seasonal influenza vaccine using routine data sources

Submission date 17/11/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 17/11/2014	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 12/03/2021	**Condition category** Respiratory	[_] Individual participant data

Plain English summary of protocol

Background and study aims

Globally, it is estimated that seasonal influenza is responsible for five million cases of severe illness and 500,000 deaths per year, in particular older adults aged 65 and over and people with underlying diseases such as asthma. National influenza vaccination strategies using primary care represent a potentially important approach to reduce both influenza-related illness and death, hence the considerable investment in this preventive approach in many parts of the world. In Scotland new policy interventions are imminent and will result in the broader coverage of the vaccine, e.g. a new type of influenza vaccine (live attenuated influenza vaccine) is being introduced this year to all children (between 2 and 17 years). However, the evaluation of changes to immunisation programmes can be problematic given that randomised controlled trials of the vaccine are impractical and also viewed as unethical by some sections of the medical community. These policy changes therefore typically go unevaluated, making it difficult to inform ongoing policy deliberations. Building on our substantial track-record of evaluating vaccine programmes using linked healthcare electronic record-derived information, we will conduct an evaluation of the live attenuated influenza vaccine.

Who can participate?

Rather than recruiting participants, the SIVE II project instead uses data collected from routinely available datasets.

What does the study involve?

Rather than recruiting participants, the SIVE II project instead uses data collected from routinely available datasets.

What are the possible benefits and risks of participating?

The observational study design being used to assess the effectiveness of influenza vaccine does not influence the care that is provided or the people who receive it. Therefore there are minimal risks and no direct benefits to patients.

Where is the study run from?

Centre for Population Health Sciences (UK).

When is the study starting and how long is it expected to run for?
The study will run from October 2014 to April 2017.

Who is funding the study?
NIHR Health Technology Assessment - HTA (UK).

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 13/34/14

Study information

Scientific Title
Seasonal Influenza Vaccination Effectiveness II (SIVE II): use of a large national primary care and laboratory-linked dataset to evaluate live attenuated and trivalent inactivated influenza vaccination effectiveness

Acronym
SIVE II

Study objectives

To provide early estimates of the uptake and effectiveness of LAIV administered to children (from 2013) and explore indirect effects of LAIV on the general population. Our secondary aim is to evaluate the effectiveness of seasonal TIV amongst older people (65 years and older) and those with asthma under 65.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Edgbaston, 22/01/2015, ref: 15/WM/0035

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

Primary study design
Observational

Study type(s)
Prevention

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

Interventions
16 influenza vaccine programmes implemented in Scotland will be evaluated for effectiveness.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Primary outcome(s)
Influenza positivity from virological swab data in vaccinated and unvaccinated patients stratified by at-risk populations, age, sex and socioeconomic status

Key secondary outcome(s))
1. 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
2. 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

Completion date
01/04/2017

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
1250000

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/10/2014

Date of final enrolment
01/04/2017

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Centre for Population Health Sciences
Edinburgh
United Kingdom
EH8 9AG

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
NIHR Health Technology Assessment Programme - HTA (UK) (HTA 13/34/14)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	12/03/2021	Yes	No
Protocol article	protocol	28/02/2017	23/10/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes