

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

<b>Submission date</b> 17/11/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 17/11/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/03/2021	<b>Condition category</b> Respiratory	<input type="checkbox"/> 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  
c.simpson@ed.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Colin Simpson

**ORCID ID**  
<https://orcid.org/0000-0002-5194-8083>

**Contact details**  
Centre for Population Health Sciences  
Medical School  
Teviot  
Edinburgh  
United Kingdom  
EH8 9AG  
+44 131 651 4151  
c.simpson@ed.ac.uk

## 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?
<a href="#">Results article</a>	results	01/12/2020	12/03/2021	Yes	No
<a href="#">Protocol article</a>	protocol	28/02/2017	23/10/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No