



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

This information sheet is designed to give you more information about the research project.

Your practice is being invited to assist with a new Scottish project, which will help provide the information required to evaluate seasonal influenza vaccination.

Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

Immunisation programmes delivered in primary healthcare settings have been shown to be acceptable (as evidenced by previous high uptake rates) and effective, and this route is likely therefore to be the mainstay of vaccination efforts.

We wish to determine the:

- Uptake of seasonal influenza vaccine by the relevant at risk populations i.e. age 6m - 65yrs in at risk clinical groups, pregnant women and age 65+;
- Reduction in the expected incidence of influenza related serious morbidity and mortality in these at risk groups, since this is the major rationale behind any immunisation policy (if a vaccine is available);
- Whether the new nasal vaccine confers any indirect or herd immunity.
- Whether there are any adverse events associated with the vaccine

Why have we been chosen?

We are approaching you because your practice is able to provide information via the Escro reporting software without incurring the administration time required for similar large scale studies. We will link selected primary care data with data about hospital admissions and mortality held by the Information Services Division (ISD) as well as laboratory information from any swabs you have returned to Health Protection Scotland (HPS).

The usefulness of these Scottish data is for example reflected in a study which your practice may have previously participated and is attached for your information (Simpson CR, et al. Effectiveness of H1N1 vaccine for the prevention of pandemic influenza in Scotland, UK: a retrospective observational cohort study. *The Lancet Infectious Diseases* 2012; 12:696-702).

What data will be used?

The three kinds of data are already held by the NHS for your patients:

1. Hospital data/mortality data – held by ISD (Scottish Morbidity Record - SMR). This dataset already contains CHI number.
2. Primary Care data - this dataset will contain no practice or patient identifiable information except for an encrypted CHI, which will be used for linkage.
3. Laboratory returns data – held by HPS. Data on laboratory tests (from swabs) to determine diagnosis of influenza. This dataset contains the CHI number.

How much time and effort is required?

Albasoft Ltd (<http://www.albasoft.co.uk>) acting as a TTP and data processor on your behalf will carry out the data extraction using the [ESCRO](#) reporting system (used for STU or Enhanced service reporting). This will require minimal input from your practice. However, an email will be sent with a clickable link with some T&Cs which will need to be agreed to and electronically signed to consent to the extraction. This extraction will be scheduled out of hours and will **not** affect the performance of your practice systems.

Will my practice receive a payment if we take part?

Yes. In acknowledgment of the contribution practice staff make in maintaining high quality medical records a fee of £50.00 will be paid

What will happen to this additional data we provide?

- Albasoft Ltd, HPS and ISD will handle all data sent using well-established protocols to ensure security and complete confidentiality.
- The CHI will be encrypted to ensure anonymity of this identifier. The CHI and clinical data will then be compressed and further encrypted by the Escro software.
- The primary care data will be pre-processed within Albasoft's secure repository based at the Centre for Health Science adjacent to Raigmore Hospital in Inverness.
- Access to data will be limited to SIVEII authorised researchers.
- Access to encrypted CHI will be restricted to use for data linkage and handled separately from clinical data by the Farr Institute National Safe Haven.
- The data will NOT contain names or addresses, and the analysis will not identify any practices.

What are the risks of the practice participating?

Minimal risk, Albasoft as data processors are bound by the data protection act (seventh principle) to provide the same level of security and governance with respect to the information it processes as the data controller (the practice). By using automated procedures the risk of exposure to information that has not been explicitly specified in the study parameters to researchers is greatly reduced.

Within Albasoft Ltd, ISD and the Farr National Safe Haven, data confidentiality is paramount. Only authorised team members as well as authorised individuals from Albasoft Ltd will have access to the extracted data file, and this will only be used to create the research dataset using well-established, safe and secure procedures to maintain absolute confidentiality. The final analytical dataset will be held on a secure server used by the approved SIVEII project team members. We will adhere to The Data Protection Act, the RCGP & BMA guidelines for handling patient data for secondary uses.

Why use a trusted third party (TTP)?

While the project does not require identifiable data the process involved in the collection and transformation necessarily requires exposing certain pieces of information, for example the source practice, DOB to calculate age banding or post code to calculate SIMD/DataZones. The accepted method of addressing this is to appoint an unrelated third party to process and anonymise the information prior to this being released to researchers. A TTP must have a proven track record and no "interest in" nor be affiliated to any organisation (public sector or commercial) that makes use of health information.

What are the benefits of the practice participating?

There are no direct or immediate benefits to you or your patients. However, evidence from our data analysis will help policy makers throughout the UK (and the world) further develop the seasonal influenza vaccine programme.

Do we have to take part?

Your participation is entirely voluntary, and whatever you decide, there are no implications for you.

What will happen to the results of the study?

The results will be reported to the National Institute for Health Research, submitted for publication, and if you wish, we will communicate the findings to you once the study is finished.

Who is organising and funding the research?

The research is funded by the National Institute for Health Research. The researchers are a Scottish wide collaboration of General Practice academics, epidemiologists and statisticians from the NHS and Universities. The project is being co-ordinated by The University of Edinburgh.

Who will be reviewing the study?

The design and conduct of the study is being reviewed by an expert independent committee. We also have all the relevant ethical, NHS R&D, National Caldicott and Privacy approvals in place. Approval letters can be forwarded to you if required.

Contacts for more information

Further information can be obtained from:

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