

## Information Sheet for GP practices

### A population –based system for the serological surveillance of influenza

#### **Full project title:**

**Establishing a population-based system for the serological surveillance of influenza and other infections: Pilot study in an English sentinel network**

#### **Overview**

We invite you to take part in a research study. Please take time to read the following information. The University of Surrey, in collaboration with Public Health England (PHE), are conducting a pilot study to set up a Serology Bank. The Serology Bank will consist of an archive of pseudonymised serum samples. Patients over 18 years old who visit their practice for a routine blood test will be recruited to participate in the study, and their consent to donate an additional blood sample will be sought. The serum from these blood samples will be extracted and analysed for the presence of flu antibodies at the PHE laboratory. These will then be stored in the Serology Bank for research purposes.

#### **Background and Rationale**

Serology banks could help detecting the presence of a new flu virus within the population. With this information, local, national and international pandemic plans can be modified to be more effective during an outbreak. Serological data potentially allows the assessment of the severity of a new influenza strain by providing the capability to detect asymptomatic and mild infections and thus determining the symptomatic proportion.

The number of infections can be determined if the age-specific prevalence of immunity prior to and then during and after the pandemic are known. Thus the number of people infected (and therefore no longer susceptible) can be calculated. If this data is available early (particularly the background immunity and the symptomatic proportion), it can be used to adjust planning assumptions and be used to help predict the impact on health care services.

The objective of the study is to establish a system to collect serum samples from the general population at different time points and use this information as a resource during a flu pandemic.

#### **What is the design of the study?**

We have recruited 6 practices who are members of the Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) sentinel network and are currently taking part in the nasopharyngeal virology swabbing scheme.

The method and governance procedure has been developed by the University of Surrey as part of previous work with RCGP RSC and PHE. The University of Surrey uses an approved provider, Apollo Medical Software

Solutions Ltd. Apollo extracts data from the practices using the Apollo automated extraction system. The data is pseudonymised as close to source and stored at the secure servers at the University of Surrey.

Communication is via a SOAP (Simple Object Access Protocol), a type of electronic communication protocol for which no special firewall configuration is needed. These arrangements may change from time-to-time and we will notify members if any changes occur.

Patients over 18 years of age who attend a surgery appointment for a routine blood test will be given the opportunity to consent to provide an additional blood sample for serology. Potential participants will be provided with Participant Information Sheet (PIS) and a Consent Form. If patient consents, they will need to sign and date the consent form and return to the practice.

The collected samples will be sent to the Public Health England (PHE) Seroepidemiology Unit (SEU) where they will be stored. Serum will be extracted from blood samples. The serum will be tested for flu antibodies and data from these tests will be pseudonymised and stored at the secure server at the University of Surrey - these results will not be sent back to General Practices. The results from these tests would give us information about background population immunity, which would in turn provide information needed for any vaccine for the new season of flu.

All data required for this surveillance and associated research will be extracted using existing pseudonymised processes developed by University of Surrey for RCGP RSC.

Data extractions will be conducted in accordance with the Research Group's standard operating procedures in data extraction, pseudonymisation, and transfer. All data are stored and managed by the University of Surrey. The information security policies and procedures of the Research Group have been approved by the NHS Health and Social Care Information Centre (HSCIC). Details of the departmental information governance policies and procedures can be found in: <http://www.clininf.eu/index.php/information-governance/>

### **Why have I been invited to take part?**

The study is part of a research programme which aims to establish a population- based system for serological surveillance of influenza. You have been invited because your practice has expressed interest in becoming part of a research network within the RCGP RSC, and because you meet representativeness criteria (geographic location and computerised medical record system) for this study.

### **What will happen if I take part?**

You will be contacted by RCGP RSC and Apollo Medical Software Solutions Ltd to sign data extraction agreements. The GP practices will be supported by the RCGP RSC and the Research Team led by Prof Simon de Lusignan. The responsibilities of the GP practices are outlined below.

**What are my responsibilities?**

If you agree to take part in the study, you will be required to provide such support as may be reasonably required to achieve its aims. Practices will be required to facilitate access for data extraction and staff will be required to invite patients to provide an additional blood sample following a routine blood test.

**What are the possible benefits of taking part?**

The proposed study will help assess the feasibility of setting up a Serology Bank for surveillance of influenza using routine data collected in primary care. This will provide high quality data about vaccine exposure, and any medically reported Influenza-like illness (ILI) or other condition of scientific interest, included within an approved scientific protocol, or meeting public health needs in a pandemic.

Additionally, practices would receive £5 per sample collected and sent to the PHE laboratory. Furthermore we would also provide feedback about data quality which could be used during CQC visits as a proof of continuous efforts on improving data quality.

**Who can I contact for more information?**

Prof Simon de Lusignan  
Professor of Primary Care & Clinical Informatics  
e-mail: [s.lusignan@surrey.ac.uk](mailto:s.lusignan@surrey.ac.uk)  
Telephone: +44 (0)1483 684802

Manasa Tripathy  
Practice Liaison Officer  
e-mail: [m.tripathy@surrey.ac.uk](mailto:m.tripathy@surrey.ac.uk)  
Telephone: +44(0)1483 688293