AvonCAP GP2: general practice study about chest infections

We are inviting adults with symptoms suggestive of a chest infection or worsening of heart failure, asthma or Chronic Obstructive Pulmonary Disease (COPD) to take part in some research. We want to understand how many of these illnesses could be prevented by vaccinations and what groups of patients might benefit most from vaccinations. The study is led by the University of Bristol and is funded by Pfizer. It has been approved by the NHS Health Research Authority and is taking place in General Practices in Bristol.

Why am I being invited to take part?

A GP, or other health professional from your GP practice thinks you may have a chest infection or worsening heart failure, asthma or COPD. These illnesses can be caused by many germs including viruses like COVID-19, respiratory syncytial virus (RSV), and bacteria like pneumococcus. We are inviting you to take part because we want to understand the impact these illnesses have on patients and the NHS.

Why are we doing this research?

We want to understand:

- the **impact** these illnesses have on patients and the NHS
- how many of these illnesses could be **prevented by vaccination** (e.g. with COVID vaccines and other vaccines that are being developed)
- what groups of patients might **benefit most** from vaccination.

What will happen to me if I choose to take part?

a) Collecting information about you and your illness

With your permission, we will collect information from your GP records about you and your illness. We will ask you some extra questions, like whether you have ever smoked, and measure your weight and height. This information will be recorded in your GP records.

b) Collecting samples

To find out which germ has caused your illness, we will take a nose and throat swab, a saliva sample and a urine sample. These tests are being done for the study and will not affect your medical care.

c) Symptom diary

We will ask you to fill out a diary about your illness every day until your symptoms have gone, for up to 28 days.

d) Follow-up diary

If you have not fully recovered from your illness by 4 weeks (28 days) after starting the study, we will ask you to complete a short follow-up diary at 6 weeks, 8 weeks, 3, 4, 5, 6, 9 and 12 months. Once you have fully recovered from your illness, you can stop the follow-up diary.

The symptom and follow-up diaries can be completed on paper, over the phone or online. If you choose to complete the diary online, we will ask your permission to send you a daily text message

or email with a link to the online diary. If you forget to complete it, we will send you a reminder via text message or email.

Do I have to take part in the study?

No. It is up to you to decide whether you want to take part in this study. Please take the time you need to consider the study and ask any questions you have. You may also wish to discuss this with other people including family or friends. If you choose not to take part, you don't have to give a reason, and your medical care won't be affected.

If you decide to take part but later change your mind you are **free to withdraw at any time**, without giving a reason. A decision not to take part, or to withdraw, will not affect your legal rights or your medical care outside of the study. If you do withdraw from the study, you can also withdraw your consent for further use of your samples that have not yet been processed or other information about you. If you lose capacity to provide consent during the study, data up to that point would be kept and used for the purpose of the study.

Do I have to take part in all parts of the study?

No. To take part in the study we need your consent to collect information from your GP record but giving samples and filling out the symptom diaries is optional. You can choose to provide some but not all the samples.

What are the potential benefits of taking part?

This study will not directly benefit you but taking part will help us to understand more about chest infections and who would benefit most from vaccinations. We hope this may benefit other patients like you in the future. As a thank you and to reimburse you for your time, we will send individuals a £20 "Love to shop" voucher for providing samples, a £20 voucher for completing the symptom diary and £10-£40 voucher for completing the follow-up diaries (the follow-up only applies to people who have not fully recovered after 4 weeks).

What are the potential disadvantages and risks of taking part?

Taking nose and throat samples can be a little uncomfortable during the collection, and can rarely cause a mild nosebleed.

What will happen to all the samples in and after the end of the study?

All the samples we collect will be used to test for germs that cause chest infections. These samples will be processed at University of Bristol and/or shared with, Pfizer Inc. in the United States for testing. Samples will be anonymised (so that no one can identify you) before sharing with Pfizer. Samples sent to Pfizer will be stored for up to 15 years and may be used for additional vaccine-related research (no genetic research), after which they will be destroyed. You will not receive the results from your samples as they are taken for research purposes only.
If there are any samples left over, and only if you agree, we would like to keep them in the Bristol Biobank (run by the University of Bristol), so they can be used in future research studies. If you

consent to storage and use of your remaining sample for future research, a copy of your consent form would be held securely by the Bristol Biobank, as evidence of your approval of this. This future research, which would need new ethical approval, could be related to vaccines or infectious diseases, and might involve testing human genetic material (DNA). Any such tests on samples would be anonymous so no one could identify you or your family. If you don't want us to keep your samples or to do DNA tests on them, you can say so on the consent form and you can still participate in the study.

What data will we collect?

We will collect information from your GP record about:

- **you,** including your date of birth, gender, NHS number, ethnicity and the area where you live
- **your current illness** including visits to your GP practice (e.g. appointment dates and symptoms), visits to hospital (e.g. date of admission and discharge) and any tests you had as part of your care (e.g. tests for COVID-19), diagnoses and treatments given.
- **your long-term health conditions** (e.g. high blood pressure, diabetes, asthma), whether you smoke or have smoked in the past and what **vaccinations** you have had (e.g. COVID-19, flu, pneumococcal vaccinations).

How will we keep information (data) confidential?

We are very **careful to keep information confidential**. Everything we (the AvonCAP GP2 study team) do is designed to protect people's privacy and we commit to using their information in an appropriate way. **The data will be anonymised - there will be no way of identifying the person from the data.** Any identifiable data (e.g. your NHS number or date of birth) will be stored securely and kept separately to the other data.

When information about your healthcare joins with information that can show who you are (e.g. your name or NHS number) it is called "identifiable patient information". It is important that identifiable patient information is kept confidential and there are rules to ensure it is kept safe and secure. The research team will be looking at some of your health records, using some data from your GP records. The information that is collected from the health records by the research team is called research data.

What happens to my patient data in the study?

The study team will enter your patient data into a database - a collection of information stored on a protected encrypted computer, which only a small number of authorised staff can access by using a secure password, in accordance with UK Government regulations known as GDPR (see below). Your information will be entered under a code number, so that it is not possible to identify you from this database (pseudonymised data). These data can only be matched up with data that identifies you (patient identifiable data) using the code number. These data will be held by the University of Bristol for up to 15 years. The anonymised data may be used for future research related to infectious disease prevention and vaccine development and may be shared with other researchers.

Monitors authorised by the University of Bristol may access your records to check the quality of the study. The wider research team and collaborators, including Pfizer, Inc, will only have access to the anonymised data.

Will the use of my data meet GDPR rules?

Yes. GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules. Universities, NHS organisations and companies may use patient data to do research to make health and care better.

When companies do research to develop new treatments, they need to be able to prove that they need to use patient data for the research, and that they need to do the research to develop new treatments. In legal terms this means that they have a 'legitimate interest' in using patient data.

Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'.

If they could do the research without using patient data they would not be allowed to get your data. Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

What if something goes wrong or I want to complain?

This study involves gathering information already collected in your GP records. We may ask some additional questions (e.g. whether you smoke) and will also ask to perform a few extra tests (i.e. urine samples, nose/throat swabs), which are considered minimally invasive. We don't expect anyone to be harmed by taking part in this study. There is no automatic insurance protection to compensate you if you are injured, but you can still make a legal claim (e.g. if you think someone has done something wrong), and the University has Clinical Trials Insurance that covers its legal liability in relation to study participation.

If you have any concerns that you would like to discuss or if you would like to make a complaint (for example, about the conduct of the study team), please contact the study team (contact details below). Alternatively, you can contact the Complaints and Freedom of Information Manager, NHS Bristol, South Plaza, Marlborough Street, Bristol, BS1 3NX or telephone: 0117 900 2494. If you're unhappy about the use of your data in this study, you can complain to the research team. If you are not happy with the response or believe we are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

What will happen to the findings of the study?

It is important to share the findings of this study with other scientists and healthcare organisations. We will publish what we learn from this study in scientific journals and at national and international research meetings. Any reports or presentations about the study will be written in a way that no-one can identify anyone who took part.

Who is organising and funding this study?

The University of Bristol is sponsoring this study. The research is funded by Pfizer, Inc.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect patient interests. This study has been reviewed and given favourable opinion by Yorkshire and the Humber – Bradford Leeds Research Ethics Committee.

What do I need to do now?

After reading this information sheet, if you would like to take part, we will ask you to complete a consent form, either on paper, online or by phone. We will ask your permission to contact you with information about future research studies that you may be eligible to join, but you don't have to participate in these. You can request a copy of the signed consent form for your records.

If you are unable to read the participant information sheet, the researcher will read through this with you and audio-record your consent. If you prefer, a friend, family member or carer can witness the consent.

Thank you for taking the time to read this information.

Professor Adam Finn (Chief Investigator), Head of the Bristol Vaccine Centre
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