AvonCAP GP2: general practice study about chest infections
Consultee information sheet

Summary

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.

A GP or other health professional from your GP practice thinks your friend/relative/care home resident 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 want to understand what impact these illnesses have on patients and the NHS.

Introduction

We feel your friend/relative/care home resident is unable to decide for himself/herself whether to participate in this research.

To help decide if he/she should join the study, **we'd like to ask your opinion whether or not they would want to be involved**. We'd ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide your friend/relative/care home resident would have **no objection to taking part,** we will ask you to read and **sign a consultee declaration**. We'll then give you a copy to keep. If you have any concerns or you think your friend/relative/care home resident should be withdrawn from the study, please contact the study team.

If you decide that your friend/relative/care home resident would not wish to take part, it will not affect the standard of care they receive in any way. If you are unsure about taking the role of consultee, you may seek independent advice. We will understand if you do not want to take on this responsibility.

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 your friend/relative/care home resident if they take part?

a) **Collecting information about them and their illness**

We will collect information from their GP records about them and their illness.
We will measure their height and weight, which will be recorded in their GP records.

b) **Collecting samples (optional)**

To find out which germ has caused their 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 their medical care. Your friend/relative/care home resident will not receive the results from your samples, as they are taken for research purposes only.

c) **Enrolment survey and symptom diaries (optional)**

We will ask you to consider whether your friend/relative/care home resident would want to join in with:

- **an enrolment survey** – this includes questions about your friend/relative/care home resident's illness.
- **a symptom diary –** this is a daily diary about your friend/relative/care home resident's illness, which continues until they feel better.

If you think your friend/relative/care home resident would want to join in with an enrolment survey and/or symptom diary, we will ask if you are willing to help with this.

- If you are interested in helping with this, we will give you a 'caregiver information sheet', and a 'caregiver consent form'.
- If you prefer us to ask someone else to do this, we will ask a caregiver, relative or friend (who knows them well). We would then give this caregiver, relative or friend a 'caregiver information sheet' and 'caregiver consent form'.

Does my friend/relative/care home resident have to take part in the study?

No. To help decide if he/she should join the study, we're asking your opinion whether they would want to be involved. 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 decide that your friend/relative/care home resident would not wish to take part, you don't have to give a reason, and their medical care won't be affected in any way.**

If you decide they would wish to take part but later change your mind you are **free to withdraw them from the study at any time**, without giving a reason. A decision not to take part, or to withdraw, will not affect their legal rights or their medical care outside of the study. If you do withdraw them from the study, you can also withdraw your declaration for further use of their samples that have not yet been processed or other information about them.

Does my friend/relative/care home resident have to take part in all parts of the study?

No. To take part in the study we need to collect information from their GP record but other aspects, such as giving samples, are optional. You can also choose for them to provide some but not all the samples.

What are the potential benefits of taking part?

This study will not directly benefit you or your friend/relative/care home resident 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 your friend/relative/care home resident in the future. As a thank you, we will send individuals a £20 "Love to shop" voucher for providing samples.

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 your friend/relative/care home resident) 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. They will not receive the results from their 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 agree to storage and use of the remaining sample for future research, a copy of your consultee declaration 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 your friend/relative/care home resident. If you don't want us to keep the samples or to do DNA tests on them, you can say so on the consultee declaration form and your friend/relative/care home resident can still participate in the rest of the study.

What data will we collect?

We will collect information from their GP record about:

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

How will we keep information (data) confidential?

When information about a person's healthcare joins with information that can show who they are (e.g. their 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 collecting some of your friend/relative/care home resident's GP records. The information that is collected from the health records by the research team is called research data.

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. NHS number or date of birth) will be stored securely and kept separately to the other data.

What happens to their patient data in the study?

The study team will enter their 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). Their information will be entered under a code number, so that it is not possible to identify them from this database (pseudonymised data). These data can only be matched up with data that identifies them (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 their 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 their 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 your friend/relative/care home resident smokes) 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 friend/relative/care home resident's 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?

If you decide this person would have no objection to taking part, we will ask you to read and complete a consultee declaration form, either on paper, online or over the phone. You can request a copy of the completed consultee declaration form for your records. We will ask your permission to contact you with information about future research studies that your friend/relative/care home resident may be eligible to join, but they don't have to participate in these.

If you decide that this person would not wish to take part, please contact the research team by phone, email or post (see contact details below). We will collect a small amount of information from their GP record only (e.g. their age, gender).

If anything is unclear or you would like more information, one of our team will be happy to go through the information with you and answer any questions.

Thank you for taking the time to read this information.

Professor Adam Finn (Chief Investigator), Head of the Bristol Vaccine Centre
Professor Alastair Hay (Senior Investigator), Professor of Primary Care
Dr Polly Duncan (Co-Principal investigator), GP and Doctoral Research Fellow
Dr Ruth Mears (Co-Principal investigator), Clinical Research Fellow

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Tyntesfield Medical Group	0117 958 1405	bnssg.avoncapgp.tmg@nhs.net
Wellspring Surgery	01454 550770	bnssg.avoncapgp.wellspring@nhs.net
Montpelier Health	01454 550770	bnssg.avoncapgp.montpelier@nhs.net