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

We are seeking your consent to answer some questions about your friend/relative/care home resident and their illness. 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 your friend/relative/care home resident may have a chest infection or worsening heart failure, asthma or chronic obstructive pulmonary disease (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.

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 take part?

You can choose to take part in one or more of the following:

a) Enrolment survey

We will ask you some extra questions about your friend/relative/care home resident, like whether they have ever smoked, questions related to COVID-19 and questions about their quality of life.

b) Symptom diary

We will ask you to fill out a diary about your friend/relative/care home resident's illness every day until their symptoms have gone for up to 28 days. Each week, we will ask you to fill out some additional questions about their quality of life.

c) Follow-up diary

If they have not fully recovered from their 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 they 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 with a link to the online diary. If you forget to complete it, we will send you a reminder via text message.

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 friend/relative/care home resident's 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 friend/relative/care home resident's medical care outside of the study. If you do withdraw from the study, you can also withdraw your consent for further use of 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. You can choose to take part in as much or as little of the study as you wish. For example, you may choose to take part in the enrolment survey but not the symptom or follow-up diaries.

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 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?

One disadvantage is the time taken to complete the survey and diaries.

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**.

What happens to my patient data in the study?

The study team will enter your 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 or your friend/relative/care home resident 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 my data meet GDPR rules?

Yes. GDPR stands for the General Data Protection Regulation. In the UK we follow GDPR rules under the Data Protection Act 2018. 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. Researchers must show that their research takes account of the views of patients and ordinary members of the public. Researchers must also protect the privacy of people who take part. An NHS research ethics committee checks this before the research starts. This process makes sure that research using patient data can only be permitted as 'a task in the public interest', and only data needed for the research is used.

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

What if something goes wrong or I want to complain?

We don't expect anyone to be harmed by taking part in this study. There is no automatic insurance protection to compensate you or your friend/relative/care home resident 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 approval given 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. You can request a copy of the completed consent form for your records.

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

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
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