Participant Information Sheet

Study Title: Point of Care Testing to Inform Care for Chest Infections in Older Adults in Primary Care: A Randomised Feasibility Study.

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ERGO number: 93645

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others, but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

This study is part of a student led PhD project. The aim of this study is to see if using handheld tests (point-of-care tests), similar to COVID tests, can help clinicians make better prescribing decisions. This will be for older adults with flu-like illness or chest infections to see whether antibiotics and other treatments are likely to be helpful. This will be a small study which will help researchers design a similar study on a larger scale.

Chest infections are one of the most common reasons for antibiotics to be prescribed in general practices. This happens more for older adults as they have a bigger risk of becoming unwell. However, antibiotics only work against bacteria and most chest infections are caused by viruses. This means many prescribed antibiotics are not needed.

Prescribing too many antibiotics can be harmful as bacteria become resistant, making infections harder to treat. Unnecessary antibiotics can also be bad for the patient because they kill off the bacteria that help keep us healthy and may cause side effects like vomiting and diarrhoea. This means antibiotics should only be given when they are needed.

It can be very hard to tell whether a chest infection is caused by bacteria or a virus as the symptoms are often similar. Handheld tests that can be used in GP surgeries (point-of-care testing) can be used to help find out if a bacteria or a virus might be causing a chest infection. This helps GPs make decisions about prescribing antibiotics or antiviral treatments.

This will be a small, feasibility study to help us design of a bigger study. A future study will see if using point-of-care tests can improve the use of antibiotics for chest infections. While some data will be gathered about antibiotic prescribing, the study will mainly focus on how many people want to take part, opinions from doctors and participants involved, and how well the study works. By doing this research, we will be one step closer to understanding how point-of-care testing would work in GP surgeries.

Why have I been asked to participate?

You are aged 65 or over and have a cough or other symptoms that have resulted in you being diagnosed with a chest infection.

What will happen to me if I take part?

After you have signed a consent form, your healthcare professional will ask you some questions and complete a brief questionnaire. They may then ask you to undergo testing with one or two tests. There are several tests being used in this study:

1. A COVID-19/Flu lateral flow test. This test will involve a nasal swab to test if you have COVID-19 or flu.

COVID/Flu Test – https://www.surescreen.com/product/sars-cov-2-influenza-a-b-antigen-combined-rapid-test-cassette/
Nasal Swab - https://www.cidrap.umn.edu/covid-19/using-both-nose-throat-swabs-boosts-sensitivity-rapid-covid-testing

2. A FebriDx test. This is a finger-prick blood test for markers that indicate whether you are likely to have a bacterial or viral infection.

FebriDx – https://northerndiagnostics.com/febridx/
Finger Prick Blood Sample - https://www.cidrap.umn.edu/rapid-test-could-help-distinguish-bacterial-viral-infections

3. A CRP lateral flow test. This is a finger-prick blood test for a marker that indicates whether bacterial infection is likely.

SureScreen CRP – https://www.surescreen.com/product/crp-rapid-test-cassette/
Finger Prick Blood Sample - https://www.imperial.ac.uk/news/200713/biggest-study-antibody-finger-prick-tests-identifies/

You may be asked to have one test, two tests, or no tests. This depends on which group you have been randomly put into. The tests may cause you some mild discomfort because of the nasal swab and the finger prick.

After your appointment, you will be asked to keep a follow-up diary for the next 28 days. This diary is split into two parts, days 1-14 and days 15-28. Day 0 is the day of your appointment. We are looking to see how long it takes for your chest infection to get better and for you to fully recover to your usual activity.

We may contact you on or around day two to check if you have any questions. Additionally, we will contact you to remind you when to send your diary back either through phone call, or email. You may also contact our team during working hours using the contact details below.

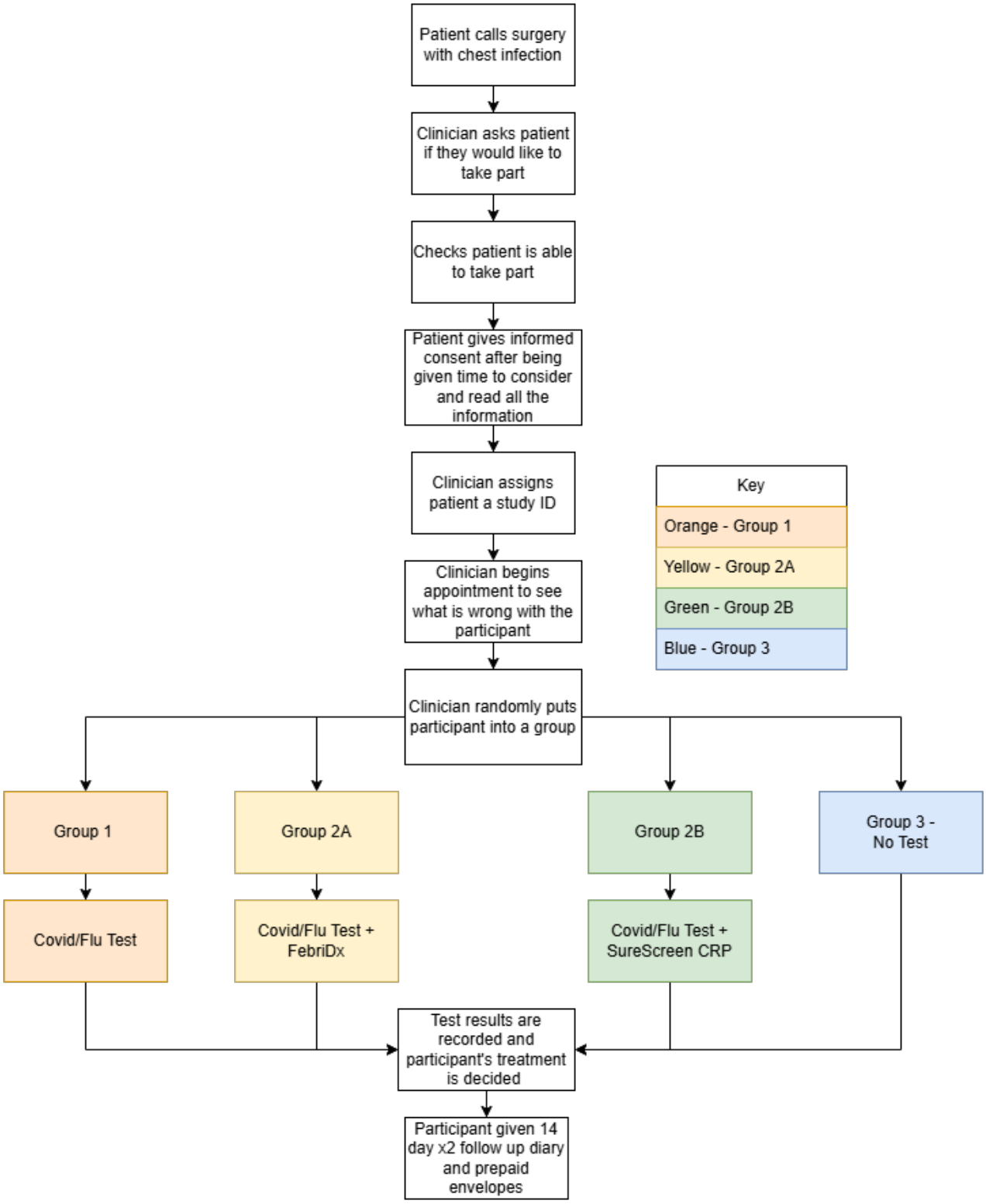
We also ask you to note down any other appointments about your chest infection, as well as any hospitalisations that are related. Part of the diary will be a questionnaire asking about your wellbeing. If you are experiencing any problems with your physical or mental health, both related or unrelated to your chest infection, we encourage you to contact your GP straight away who will be able to help you. Your health and wellbeing come first and it is important you speak to your GP if you are struggling in any way.

At 14 days and 28 days, we ask that you return the correct half of your diary to the healthcare centre using the pre-paid envelopes provided (no stamp required).

Once the study has finished, you may be contacted again to ask if you would be willing to be interviewed about your experience. You do not have to be interviewed. If you do consent to being interviewed, you will be asked questions about your experience with the point-of-care test and any thoughts you have about them. The interview will be done online and will be recorded. Only audio will be recorded from the interview.

Interviews will last an hour and will be done on Microsoft Teams or on a phone call, depending on your preference. The interview will involve questions about your experience taking part in the study and how you felt about the tests, if you were given any.

The study will be carefully explained to you by your GP or other healthcare professional. At any stage, feel free to ask any questions you might have, our contact details are shown below. You will also find a flow chart which shows the process of the whole study and everything that will happen during it.



Flow chart of what will happen during the study.

Are there any benefits in my taking part?

You may receive a test which may help decide whether you need antibiotics, but we don't know the benefits of this yet, which is why we are doing the study. This research will help us to find out if using tests for chest infections in GP appointments could be better for patients and society.
Your participation will help us with the design of a larger study to answer questions about point-of-care tests and if they are useful. It is important for us to know if people want to participate in this study, and if the tests are acceptable.

Are there any risks involved?

We do not yet know whether using point of care tests results in better outcomes for patients or not. There is a chance that testing could result in some cases where antibiotics are not prescribed when they are needed. , it may help avoid harmful effects by reducing unnecessary treatment. This is because the tests being used may help your doctor know if antibiotics will be helpful to you or not. Your healthcare professional will give you important information about what to expect and when to seek further help. It is important that you follow this advice and seek further help if you are getting worse. You will still have access to your usual care during this study so do not hesitate to contact your doctor if you are not getting better or are getting worse. We will be any problems you may have with your diary, where you are able to tell us if you have had to go back to the doctor with the same chest infection.

The University of Southampton (the sponsor of the study) has insurance arrangements in place to ensure your safety during your participation in the study.

What data will be collected?

We will be collecting some personal data during this study, such as name and contact details. This is so we can contact you about the study and can withdraw your data if you request. We will also be collecting some about your age, race, and postcode to make sure the study is inclusive.

Tissue samples will be collected for the tests you may be receiving. This will be a finger prick blood sample or a nasal swab. No samples will be kept after the test has been done.

Data about your test results and following treatment at your doctor's appointment will be recorded.

Finally, we will be collecting data about your recovery by using the patient diary. We will be collecting data about your symptoms, prescription relating to your chest infection, as well as future doctor's appointments and hospitalisations.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.
If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form.
If you do not wish to take part in this study, you will be offered whatever treatment your doctor thinks is best for you.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. Contact information for the study team has been provided. Simply email

Jenna Garrod at POCT65ABX@soton.ac.uk saying you wish to withdraw and quote your participant ID number.

If you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

What will happen to the results of the research?

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

We will look at your results in combination with everybody else's to help us understand the effects of testing.
We will also look at how GPs and patients feel about the testing itself.
The results will be published in one or more scientific papers.
The results of this study will be used to decide if we can do a larger study in the future.

Results of the study will be sent to you via email if you request them. You will be asked if you would like to receive a copy of the results at the end of your diary.

Where can I get more information?

Further information can be given by contacting the study team via this email – POCT65ABX@soton.ac.uk

What happens if there is a problem?
If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.
If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Head Research Ethics and Governance (023 8059 5058, rgoinfo@soton.ac.uk).

Data Protection Privacy Notice

1 How will we use information about you?
We will need to use information from you for this research project.
This information will include your name, contact details, and home postcode. People will use this information to do the research or to check your records to make sure that the research is being done properly.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
The University of Southampton is the sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- **Storing all personal information in a locked file on a University laptop that only the study team will have access to**
- **All personal information will not be backed up onto the cloud to ensure it is kept as secure as possible**
- **Any paper information will be locked in a filing cabinet at Aldermoor Health Centre and will only be able to be accessed by the study team.**

International transfers
Your data will not be shared outside the UK.
2 What are your choices about how your information is used?

- **you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have**

- **you have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do thisWhere can you find out more about how your information is used?**

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- **our leaflet http://www.hra.nhs.uk/patientdataandresearch**
- **by asking one of the research team**
- **by sending an email to POCT65ABX@soton.ac.uk**

Thank you.
Contact for further information

Jenna Garrod
POCT65ABX@soton.ac.uk

Please note that these contact details are specific to this study. If you have an urgent medical problem, please contact your own doctor in the normal way.

If you find the wording difficult to understand or would like us to explain things to you once more, please feel free to ask your doctor or nurse.

Thank you for taking the time to read this information sheet. If you wish to take part you will be given a copy of this information sheet and a signed consent form to keep.