Participant Information Sheet (PIS)

Exploring factors associated with antimicrobial prescribing in adults with Acute Respiratory Infection (ARI), amongst UK secondary care prescribers and the potential utility of host response testing to improve use: a focus group and questionnaire-based survey.

Chief Investigator: Professor Tristan Clark BM FRCP DTM&H MD

Research Study

We would like to invite you to take part in this study, but before you decide if you want to take part, it is important for you to understand why the research is being done and what it will involve. Please ask us to clarify anything that is not clear or if you would like more information. Please take time to read the following information carefully and discuss it with others if you wish. Thank you for reading this information sheet.

What is the purpose of this study?

Acute respiratory infection (ARI) is a common presenting condition for adults to secondary care either via the Emergency Department (ED) or Same Day Emergency Care (SDEC). Although most are caused by viruses, patients are often given antibiotics, which do not work against viruses. Unfortunately, this overuse of antibiotics can be harmful to patients and lead to antimicrobial resistance, where antibiotics stop being effective. Antimicrobial resistance is such a serious threat to our health that measures to prevent it are now a priority for the UK government and the NIHR.

Therefore, we would like to gain a greater understanding of prescriber's views on why they prescribe antibiotics and the utility of potential features of new diagnostic tests which are designed to reduce antibiotic prescribing. This information can help us better design future impact trials.

Why have I been asked?

As a prescriber working within secondary care who treats adults who present with ARI, your views on what influences your decisions is valuable to us.

We would like you to undertake a structured questionnaire to explore what features in patients presenting with ARI lead you to prescribe antibiotics.

Do I have to take part?

Taking part in this study is entirely voluntary. We are more than happy to take you through the information sheet in more detail. If you agree to take part in this study, please say yes to the first question in the questionnaire.

What will happen if I take part?

If you have any further questions, you can discuss the study in more detail with a member of the research team via email on at1g20@soton.ac.uk.

If you would like to take part:

- Please complete the questionnaire. You will be asked questions regarding factors which influence your decisions regarding prescribing antibiotics. Additionally, we will ask questions about which features of any new diagnostic tests you would find most useful.

If you have any questions a member of the research team can be contacted and would be more than happy to answer.

What data will be collected?

In this research study we will use information from you regarding factors influencing your decisions regarding prescribing antibiotics. Additionally, we will ask questions about what features of new diagnostic tests you would find most useful. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data (in case we need to check it) or for future research. We will make sure no-one can work out who you are from the reports we write.

How will we use information about you?

We will need to use information from you for this research project. As responses to the questionnaire are anonymous, we do not need to collect your name. People will use information collected in your answers 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.

University Hospital Southampton NHS Foundation Trust is the sponsor of this research. As the sponsor they are responsible for looking after your information. They will share your information related to this research project with the following types of organisations: University of Southampton, Regulatory Bodies and other ethically approved research projects.

We will keep all information about you safe and secure by:

- Responses are anonymous
- Any quotes used for publication will be anonymous
- Data will be sorted on encrypted servers which are only accessible to approved members of the research team

International transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

- We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.
- We may share the anonymous quotes or results from the questionnaires with other research groups for ethically approached research or use the results to help design future research studies.

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 access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. 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 this
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- On the Health Research Agencies
  Website: **www.hra.nhs.uk/patientdataandresearch**
- By asking a member of the research team
- By sending us an email to at1g20@soton.ac.uk
- By sending an email to the sponsor's data protection team on dataprotection@uhs.nhs.uk

What about confidentiality?

We take participant confidentiality very seriously. Only a very limited amount of personal identifiable information is requested from you, and when we come to look at and publish any results, all information is presented anonymously – i.e your details and personal information are never made available.

We follow strict regulations about how health research is carried out. At times, individuals from regulatory authorities may require access to the information we collected about you to check that we are carrying out the study correctly. These people have a duty to keep your information strictly confidential.

How will you look after collected data?

The Research and Development department (R&D), University Hospitals Southampton NHS Trust (UHS) is the sponsor for this study. It is based in the United Kingdom. Data will be sorted electronically on password protected servers. It will only be accessible to members of the research study. We will delete all your personal details and interview recordings at the end of the study. Completed consent forms and anonymised transcripts will be kept for a period of 10 years.

A person's rights to access, change or move their information are limited, as data must me managed in specific ways for the research to be reliable and accurate. If a participant withdraws from the study, we will keep the information already obtained. To safeguard people's rights, we will use the minimum personally identifiable information possible.

What happens if I change my mind?

You have the right to change your mind and withdraw from the study at any time without giving a reason. If you decide to withdraw, any data you have provided will be deleted if you request this, unless it has already been used anonymously in the analysis or results of the study.

What are the risks and benefits to taking part in this study?

Although this is considered a very low-risk study to be a part of, no research is without risks. One risk would include the impact it will have on your clinical working day through the time taken to complete the questionnaire.

The benefits of taking part in this study would include helping to generate new knowledge which will influence the design of future clinical trials and hopefully limit the impact of antimicrobial resistance.

What will happen to the results of the research study?

We intend to publish the results of our research in medical journals and to present the results at scientific meetings. The information from these journals may be available on the internet. All the results (including quotes) are completely anonymous in these publications, presentations and online prints. We would like any useful results to form the basis of other studies looking at ARI and prescribing habits.

Who is organising the research?

This study is being organised by University Hospital Southampton. The NHS research authorises may examine the data we have collected from you to ensure it is accurate.

Who has approved this study?

The Health Research Authority has reviewed the design of this study and approved it.

Who can I talk to further?

The research team are very happy to answer any of your questions and discuss things further with you. Should you have any specific concerns you are welcome to discuss these with a research doctor, or the chief investigator.

Professor Tristan Clark, Chief investigator Professor and Consultant in Infectious Diseases, University of Southampton and University Hospital Southampton NHS Foundation Trust.

Telephone: 023812840. T.w.clark@soton.ac.uk

Dr Alex Tanner, Academic Clinical Fellow. Infectious Diseases and General Internal Medicine Registrar, University Hospital Southampton NHS Foundation Trust.

Email: At1g20@soton.ac.uk

What happens if there is a problem?

If you have a concern about any aspect of this study, please email the research team at: at1g20@soton.ac.uk and they 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 hospital's

Patient Advice and Liaison Services (PALS) (Tel 02381 206 325 Email: pals@uhs.nhs.uk available 9 am to 4.30 pm Monday to Friday, out of hours there is an answer phone).