Participant Information Sheet

PHASED-IN   
PHarmacy partnership using decision-making tools and near patient testing for Antimicrobial Stewardship for EveryDay practice IN primary care *(baseline and audit period/control group – children 1-15yrs)*

Researchers: Prof Paul Little, Dr Mark Lown

**You are invited to take part in a research study.** To help you decide whether you/your child would like to take part or not, it is important that you understand why the study 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. 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 take part, you will be asked to complete a form that shows you have agreed to take part.

**What is the study about?**

One in three people see doctors, nurses or pharmacists each year with common infections, such as colds, flu, chest, ear, sinus and urine infections. More infections are being managed by trained pharmacists and studies suggests this is safe and could help reduce overuse of antibiotics. Overuse of antibiotics is a major concern and causes resistance where antibiotics no longer work well and could make much of modern medicine difficult or impossible. We have developed new ‘decision-making tools’ based on the best research studies, in order to improve the quality of care. These tools will help pharmacists identify people who do not need antibiotics, and those who might need them, or those who need further investigation. To test the new approach some surgeries will refer their patients to pharmacists and others will see their patients as usual.

**Why have I been invited?**

You have been invited as you have contacted your GP surgery your child has symptoms of a common infection.

**Do I have to take part?**

No, it is entirely up to you to decide whether or not to take part. If you are happy for your child’s data to be used, we will ask you to complete a form that shows you have agreed to take part.

**What will happen if I take part?**

1. Your child will be offered an appointmentat your GP surgery or with a pharmacist depending on usual care at your surgery.
2. After the consultation the GP, nurse or pharmacist will fill in a form to record your child’s symptoms and the care received. This information will be used to compare the care your child received with the care other patients receive.

At the end of the study, staff at the GP surgery or authorised members of the research team may look at relevant sections of your child’s medical records to find out what has happened after the consultation, about any prescriptions that have been given, and whether they have been referred for further treatment or investigation.

1. Participation in the study will only last the length of your child’s consultation. You/your child will not be required to do anything further or be contacted again regarding the study.

**Are there any benefits of taking part?**

This research will test if it is possible to refer patients with common infections to linked pharmacies where their infections will be managed with decision aids. If this is feasible, it could lead to a further large trial to find out if this can reduce the overuse of antibiotics.

**Are there any risks of taking part?**

We believe the risks of taking part in the research are very low. Your child will receive usual care from your GP practice or local pharmacy.

**What data will be collected and what will happen to the data?**

The University of Southampton Lifeguide software platform will be used to collect data for the study. Your consent to participate will be recorded directly on secure servers at University of Southampton and include your name, date of birth, GP practice and time of consent. This will allow researchers and your GP practice know who has taken part.

We will collect detailed information about your child’s symptoms, diagnosis, and treatments, and this will be linked back to your child’s medical records. Your child’s personal data and clinical data will be stored separately on secure computers at the University of Southampton, linked through a unique study number, and will only be accessible by the research team. We will use this data to see how GPs, nurses and pharmacists use the decision tool to manage infections and to follow-up how you are after your consultation.

**Will my child’s participation be confidential?**

Your child’s participation and the information we collect about your child will be kept strictly confidential. We will not share data with anyone who is not a member of the research team. We follow strict regulations about how health research is carried out. At times, individuals from regulatory authorities may require access to the information we collect about your child to check that we are carrying out the study correctly. These people have a duty to keep your information strictly confidential.

**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 will happen with the results of the study?**

Your child’s personal details will remain strictly confidential. The results of the study will be written up as a report for NIHR and will be published in scientific journals and presented at research conferences.

**Where can I get more information?**

Please speak to your GP or practice nurse at any time if you have any questions about your child’s participation in the study. If you have any further questions about the research, please contact:

Mrs Sam Williams, Trial Manager, Primary Care Research Centre, Faculty of Medicine, University of Southampton, Aldermoor Close, Southampton, SO16 5STEmail: [phased-in@soton.ac.uk](mailto:M.E.Steele@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 researcher ([Mrs](mailto:M.E.Steele@soton.ac.uk) Sam Williams) 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 of Ethics & Governance (023 8059 5058, [rgoinfo@soton.ac.uk](mailto:rgoinfo@soton.ac.uk)).

**What if I don’t want to take part?**

If after reading this information sheet you decide that you do not want to take part, you will have a consultation as usual. To help us understand why some people don’t want to take part we would be grateful if you could complete the online form [*insert MS Forms link*] to tell us why. You will also have the option to be contacted to take part in a brief interview over the telephone.

**Thank you**

Thank you for taking the time to read the information sheet and considering taking part in the study

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the

public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, ‘Personal data’ means any information that relates to and is capable of identifying a living individual. The University’s data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at [http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20I](http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf) ntegrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason (‘lawful basis’) to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University’s data protection webpage (https://[www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page)](http://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page)) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer ([data.protection@soton.ac.uk](mailto:data.protection@soton.ac.uk)).