Participant Information Sheet

*(parents/guardians of children aged 1-15years – audit period)*

PHarmacy partnership using decision-making tools and near patient testing for Antimicrobial Stewardship for EveryDay practice IN primary care (PHASED IN)

Researchers: Prof Paul Little, Dr Mark Lown

**You are invited to take part in a research study.** To help you decide whether you 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.

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| **what blue.png** | **What is the study about?**   * One in three people contact their GP surgery each year with minor infections, such as sore throat, cough, cold, ear, urinary and skin infections. More infections are now being managed by trained pharmacists. This service is already offered in many areas, helping patients as well as helping to use our NHS services more efficiently. * We have developed ‘decision-making tools’ to help pharmacists improve the quality of care that patients receive. * To test this new approach some GP surgeries will refer patients with minor infections to pharmacists and others continue to see their patients as usual at the GP surgery. **Your GP surgery is in the group who offer a ‘fast-track’ appointment with your local pharmacist.** |
| **pharmacy blue.png** | **Will my child receive the same care from my pharmacist as from the GP?**   * **Yes –** they will receive the **same care**, at **no extra cost**, and have an appointment **sooner**. * Pharmacists are **highly trained experts** in **health and medicine.** They follow the **same medical guidelines** as GPOs, so your child will have the **same assessment, advice and treatment**. * Pharmacists are trained to **recognise symptoms of serious illness** – and will refer your child to the GP if necessary. * If your child needs **medication**, your pharmacist can provide it **straight away** (both over-the-counter and prescription). * Details of your child’s consultation will be given to the GP surgery for your medical records. |
| Telephone outline | **What happens next?**   * **Your pharmacy will call you to make an appointment** – you don’t have to do anything. Your child will be offered a consultation **in a private room at the pharmacy,** at a **convenient time** for you. |

**Why have I been invited?**

You have been invited as you have contacted your GP surgery as 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 decide not to take part, your child will be offered usual care by your GP surgery.

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

If you decide to take part the GP surgery will refer your child to a linked pharmacy where an appointment will be made with a pharmacist who will ask you about your child’s symptoms and do an examination. They will use the decision aids and further tests if necessary (including swab test, urine test) to help manage your child’s infection. The pharmacists are allowed to override the recommendation of the decision aid or to refer back to the GP or A&E if they have any concerns.

Your child’s participation in the Phased-In study will only last the length of the consultation with the pharmacist.

At the end of the study, staff at the GP surgery or authorised members of the research team will 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 you have been referred for further treatment or investigation.

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

The main benefit of taking part is that your child will be offered a ‘fast-track’ appointment with your pharmacist and will receive the same care as they would get from the GP surgery.

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. Receptions will be trained in referring patients to partner pharmacies (many GP receptionists already refer suspected infections to nurse practitioners and other health care professionals including pharmacists). If your child experiences any health issues as a result of taking part in this study/seeing the pharmacist about their infection, please let your GP know.

**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 for your child to participate will be recorded directly on secure servers at University of Southampton and include your child’s 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 at your GP surgery. 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 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 them 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 you 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 your child 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 pharmacist, GP or practice nurse at any time if you have any questions about your 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 are concerned about any health issues that have arisen as a result seeing your pharmacist about your chld’s infection, please contact your GP surgery.
* If you have a concern about any other aspect of this study, you should speak to the researcher ([Mrs](mailto:M.E.Steele@soton.ac.uk) Sam Williams, phased-in@soton.ac.uk) 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 your child to take part, you can contact your GP surgery for further advice.

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)).