Participant Information Sheet for Parents/Carers

Prescription Alerts for Reliever Inhalers in Children (PARC) Project

Chief Investigator: Dr Anna Selby

Ethics/IRAS number: 332076

You child is being invited to take part in a research project. To help you decide whether you would like them 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. You may like to discuss it with others, but it is up to you to decide whether your child takes part or not. If you are happy for them to take part, you will be asked to sign a consent form.

What is the project about?

Asthma is very common in children and young people. It is a long-term lung condition which causes wheezing and breathlessness. Severe asthma attacks may need hospital treatment and can be life-threatening. Two types of inhalers are typically used to treat asthma: Relievers (usually blue) and preventers (usually taken every day in the morning and evening).

Preschool children who wheeze may also be given inhalers. Children who need to use a blue reliever inhaler more than 2-3 times per week are more likely to have severe asthma/wheeze attacks. It has been recommended that children prescribed high numbers of blue reliever inhalers in the past 12 months should have a check-up.

We are aiming to find out whether an enhanced nurse-led check-up will reduce the number of asthma/wheeze attacks experienced by children and young people who are using too many blue reliever inhalers.

In this project, general practices across Hampshire, the Isle of Wight and Thames Valley region will be randomly divided into two groups:

1. Practices offering enhanced asthma or wheeze check-ups to children prescribed 7 or more reliever inhalers in the past year (intervention practices).
2. Practices providing usual care (control practices).

After one year, we will compare the number of severe asthma/wheeze attacks in children from intervention and control practices. At the end of the project, children from control practices (who have used 7 or more blue reliever inhalers in a year) will be offered an enhanced asthma/wheeze check-up. This will be exactly the same as the one offered to children from intervention practices. If your child takes part in the project, you will not be told which group their practice is in.

Why has my child been asked to take part?

Your child has been asked to take part because they have been prescribed 7 or more blue reliever inhalers in a year. This suggests that they may be at high risk of having an asthma or wheeze attack. They may therefore benefit from a check-up.

What will happen to my child if they take part?

If you would like your child to take part in this project, they will be invited for an enhanced asthma/wheeze check-up by a specially trained nurse.

The check-up will happen at a local clinic or virtually (if you cannot travel to a clinic). The check-up will last about 30 minutes. At the check-up, you and your child will be asked questions about their asthma or wheeze episodes including:

- What triggers their symptoms and how often they get them.
- Previous asthma attacks or episodes of wheeze.
- Any asthma medications.

Your child's inhaler technique will also be checked, and their asthma/wheeze action plan will be reviewed. We will also make sure that you and your child are happy that you know what asthma/preschool wheeze is, how it affects the lungs, how it is treated and how different inhalers work. Changes may be made to your child's treatment to improve their asthma control/reduce their chances of having episodes of wheeze. Any changes made will follow existing asthma/preschool wheeze treatment guidelines and your child's GP will be made aware. Approximately 4 weeks after your child's check-up, you will be contacted to find out how your child is getting on.

You may also be invited to take part an interview a few weeks later to ask how you found the check-up. This is entirely optional and your child can still part in the rest of the project if you choose not to have an interview.

Are there any benefits in my child taking part?

Taking part in this project may improve your child's asthma/wheeze control and reduce their chances of having asthma or wheeze attacks in the future. It may also improve their quality of life as asthma/preschool wheeze can affect people's sleep and ability to take part in activities e.g. sport. Their participation will also help to improve our understanding of how to manage asthma/preschool wheeze in children and therefore, may benefit others. If your child has a check-up, they will receive a £5 voucher to thank them for taking part.

Are there any risks involved ?

There are minimal risks associated with taking part in this project. The check-up is similar to a standard annual asthma check-up but will be longer and more detailed. No new medications are being tested and we are not doing any tests.

What data will be collected?

With your permission, we would like to collect information from your child's GP +/- hospital records. This will include information about prescribed medications, any asthma or wheeze attacks they have had, and any hospital care they have received for asthma or wheeze.

Personal data including your child's gender and ethnicity will also be collected. This information will help to ensure that we involve a wide range of people in the project. Project data (information collected during your child's asthma/wheeze check-up and from their medical records) and personal data (e.g. their name and date of birth) will be stored on separate databases and will be linked by a participant identification number. Only relevant people from the project team will have access to the databases.

Will my child's participation be confidential?

Your child's participation and the information we collect about them will be kept strictly confidential. Your child's GP will be informed of your child's participation and the outcome of their asthma/wheeze check-up. This is important because your child's GP is responsible for their ongoing care. We follow strict regulations about how health research is carried out. Sometimes, individuals from regulatory authorities require access to the information we collect about your child to check we are carrying out the project correctly. These people have a duty to keep information about your child strictly confidential.

Does my child have to take part and what if we change our minds?

It entirely up to you and your child whether they take part in the project. If you would like your child to take part, you will need to sign a consent form to show you have agreed to this. Depending on their age and level of understanding, your child will also be asked to sign an assent form if they agree to take part. If you child is over 16 years of age, they can sign their own consent form.

You and your child have the right to change your mind and withdraw from the project at any time without giving a reason. This will not affect their rights as a participant or their usual clinical care. If you would like to withdraw, please contact a member of the project team.

What will happen to the results of the research?

The results of the project will be written up as a report for the National Institute of Health Research (NIHR), who are funding the project. They may also be published in scientific journals and presented at research conferences. No information that could directly identify your child will be included in reports.

Will my child or I be asked to participate in further research?

We may invite you and your child (if they are aged 11 or older) to take part in an interview with a researcher about your child's involvement in the project and their asthma/wheeze check-up. If you are invited for an interview, we will provide you with another participant information sheet and consent form. If applicable, your child will also be given another participant information sheet and assent form. Taking part in an interview is optional.

Who is organising and funding the project?

The project is funded by the NIHR Research for Patient Benefit programme. University Hospitals Southampton NHS Foundation Trust (UHS) is the project sponsor.

Who has reviewed the project?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC). The purpose of the REC is to protect your child's safety, rights, wellbeing and dignity. This project has been reviewed and given a favourable opinion by the West of Scotland Research Ethics Service. The reference number is 24/WS/0004 (IRAS 332076).

What happens if there is a problem?

If you have a concern about any aspect of this project, you should contact a member of the project team who will do their best to answer your questions (contact details below). If you remain unhappy or have a complaint about any aspect of this project, please contact the Patient Advice Liaison Service (PALS) at UHS.

UHS has appropriate insurance in place in the unlikely event that you or your child suffer any harm as a direct consequence of your child's participation in the project. NHS indemnity operates in respect of the clinical treatment provided.

Contact Details

If you have any questions about this project or would like more information, please contact a member of the research team (led by Dr Anna Selby and Professor Graham Roberts).

Email: parc@soton.ac.uk

Phone: *TBC*

Thank you for reading this information sheet.

Data Protection Privacy Notice

How will the research team use information about my child?

We will need to use information that you, your child and your child's GP have given us about your child for this research project.

This information will include:

- Your child's name
- Your child's age
- Your child's gender
- Your child's ethnicity
- Your contact details

This information will be held securely at the University Hospitals Southampton NHS Foundation Trust (UHS)/University of Southampton. It will be used to do the research or to check your child's records to make sure that the research is being done properly. People who do not need to know who your child is will not be able to see your child's name or contact details. Your child's data will have a project ID number. We will keep all information about your child safe and secure. Once we have finished the project, 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 your child took part in the project.

Where can I find out more about how my child's information will be used?

You can find out more about how we will use your child's information:

- At www.hra.nhs.uk/information-about-patients/ and www.hra.nhs.uk/patientdataandresearch
- By contacting the research team (details above)
- By contacting UHS's Data Protection Officer (dataprotection@uhs.nhs.uk)

What are my choices about how my child's information is used?

You and your child can stop being part of the project at any time, without giving a reason. We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about your child.

For the purposes of data protection law, the University Hospitals Southampton NHS Foundation Trust (UHS) is the 'Data Controller' for this project, which means that UHS is responsible for looking after your child's information and using it properly. UHS will keep identifiable information about your child for up to 15 years after the project has finished. After this, any link between your child and their information will be removed. To safeguard your child's rights, we will use the minimum personal data necessary to achieve our research project objectives. Your child's 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. UHS will not do anything with your child's personal data that you would not reasonably expect.