Preventing and **L**essening **E**xacerbations of **A**sthma in **S**chool-age children **A**ssociated with a **N**ew **T**erm

PLEASANT

Information Sheet

We would like to invite your practice to take part in a Clinical Practice Research Datalink (CPRD) related research study. Before you decide please take time to read the following information.

Part 1 tells you the background and purpose of the study and what will happen if you take part.

Part 2 gives you more detail about the conduct of the study. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish your practice to take part.

Part 1

Background and purpose of the study

In the UK there is a pronounced increase in the number of visits to the doctor by school aged children with asthma in September. It is thought that that this might be caused by the return back to school, suddenly mixing with other children again and picking up viruses which can affect their asthma. There is also a drop in the number of prescriptions administered in August. It is possible therefore that children might not be taking their medication as they should or allow their medication to run low leading to them becoming ill when they return to school and mix with other children. In a preliminary investigation we took a random sample of around 75,000 school age (5-16 years) children, using a data set from selected general practices within the Clinical Practice Research Datalink, who had a documented medical diagnosis of asthma. Analysis shows that children with asthma are approximately twice as likely to have unscheduled medical contacts compared to non-asthmatic children in September.

We postulate that July and August are periods of reduced viral exposure (due to better weather and reduced contact with other children because of the holidays) and reduced pollen (antigen) exposure for asthmatic children. We hope that a simple intervention from practices around the school holiday period can help prevent increased asthma attacks in school aged children in September.

An economic evaluation will also be undertaken to compare the incremental cost per quality adjusted life year (QALY) of the intervention versus standard care. Data on the number and type of medical contacts will be collected through the CPRD.

Study design
This study is a cluster randomized controlled trial and practices will be randomised to either intervention or control arm. We need 140 practices to participate in this study. The intervention practices will be asked to send out a simple postal intervention and the control practices need do nothing else. The CPRD will collect all data required for the study for the 12 month period before and after the intervention, this includes all diagnostic, prescription and referral data.

Why has my practice been invited?
All general practices that contribute data to the CPRD are being invited to participate in this research.

Does my practice have to take part?
Participation in this research is entirely voluntary. It is up to your practice to decide and you are free to withdraw at any time, without giving a reason

What will happen to my practice if it takes part?
If your practice agrees to take part, we will ask you to sign a form agreeing to participation. The practice will be given a unique identifier and randomised to either the intervention or control group. Practices in the control group will continue with usual care, and no further input will be required. The practices in the intervention group will be asked to deliver a simple postal intervention to their school aged children with a diagnosis of asthma. Following randomisation the nature of the intervention will be discussed in detail to practices in that arm.

The CPRD will identify school aged children with asthma (from pre-identified code lists) registered with the practice, that are on prescribed medication, and that meet the eligibility criteria. We will then ask the practices to check this list and include any omissions or exclude any patients that are not deemed suitable for the study.

The intervention practices will then be asked to deliver a simple postal intervention to those patients identified. This will be a one-off activity, delivered within a set time frame at the start of the school holiday period (July/August 2013). The intervention has been developed with input from GPs, Paediatric Respiratory Consultant, children with asthma and their parents and a Health Psychologist. To reduce burden to practices and monitor that the intervention has been sent we are asking practices to use Docmail, which is a web based secure postal service. It is used frequently by NHS services and has certificates of security and data protection (which can be forwarded to you for information). Those practices that prefer not to use this option will be asked to confirm the intervention has been sent in the timescale set.

To ensure the control practices are blind we are not able to give detail on the specific elements of the postal intervention within this information sheet. However we can assure the practices that the burden in delivering the intervention will be minimal – it is a one-off

activity. You will not be asked to complete any other documentation, collect any data for the study or obtain consent from individual patients.

What are the possible benefits in taking part?
The results will tell us whether the intervention has had an impact on reducing the number of childhood exacerbations of asthma and subsequent unscheduled appointments. It will also tell us if there has been an improvement in the collection of prescriptions - thus suggesting greater adherence to medications and planned care. This simple intervention could therefore improve the management of childhood asthma over the summer and return to school period.

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence.

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2
What will happen if my practice doesn't want to carry on with the study?
You are able to withdraw your practice from the study at any time without giving a reason.

What if there is a problem?
If you have any complaints about the conduct of this study or any people involved in it, you may write to or ask to speak to the researchers who will do their best to answer your questions. Please contact the Trial Manager in the first instance: Dr Michelle Horspool on 0114 222 4303, e-mail m.horspool@sheffield.ac.uk

Will my practice's data be kept confidential?
All data will be collected within the framework already established by CPRD Data and will be retained in accordance with the Data Protection Act 1998. The research team will only have access to anonymised data. All source data will be retained by the study team for a period of at least 5 years following the end of the trial.

What will happen to the results of the research study?
The results will be published in recognised journals and also through international meetings. We will also be holding a local Patient and Public event to disseminate the results. All practices involved will receive a report on the outcome of the study with recommendations for future care planning if appropriate.

Who is funding and organising the research?
The research is funded by the National Institute for Health Research, Health Technology Appraisal programme. The project is being organised from the Clinical Trials Research Unit at the University of Sheffield and the CPRD Division of MHRA.

Who has reviewed the study?
This trial has been reviewed by the (to be added) Research Ethics Committee.

Contact Details for further information
If you have any questions regarding the study contact information can be found below.

Chief Investigator: Dr Steven Julious on 0114 222 0709, s.a.julious@sheffield.ac.uk.
Trial Manager: Dr Michelle Horspool on 0114 222 4303, m.horspool@sheffield.ac.uk

Thank you for taking the time to consider taking part in this study.