



PRISM: The Primary Care Streptococcal Management Study

INFORMATION SHEET FOR PARENTS

MReC Number 06/Q1702/111 (Version 3 29.09.06)

What is the purpose of this study? You are being invited to consider allowing your child to take part in a research study to improve the care in general practice of children with sore throat. Before you decide whether you want your child to take part, please take time to read the following information carefully. The study aims to find which children with sore throat get better without problems, and whether we can use tests to target children with bacterial infections - particularly infections caused by the bacteria 'streptococcus' - who are more likely to benefit from antibiotics. As general practitioners, we want to move beyond saying, "it's probably just a virus" and to make a firmer diagnosis of the cause and likely outcome of the infection. We want to be able to make a better decision about which children need antibiotics to reduce the severity of their symptoms and to avoid serious complication. Targeting antibiotics will help avoid side effects when antibiotics are not needed, and to reduce 'resistance' resulting from overuse of antibiotics.

Why has my child been chosen? Your doctor/nurse thinks your child is suffering from a sore throat infection based on how sore the throat is and the inflammation (redness) in the throat.

Does my child have to take part, and does this study affect my rights? Taking part in the study is voluntary. It is up to you and your child to decide. If you decide your child can take part, you are free to withdraw your child from the study at any time without giving any reason and without affecting your child's current or future treatment in any way. Taking part in this study does not affect the care your doctor/nurse gives your child (the study is simply observing the treatments the doctor/nurse provides, not asking doctors/nurses to do anything different), nor alter your rights to compensation or right to complain under normal NHS procedures.

What will happen to my child if I take part, and what do I have to do?: If you agree for your child to enter this study:

- You will need to answer a few questions from the doctor/nurse about your child's symptoms which will take 1-2 minutes (e.g. how sore the throat is, how difficult it is to swallow, how unwell your child is etc). This and other information (e.g. age, gender etc) will be used to try and predict those who need antibiotics.
- The Doctor/nurse will take a swab from your child's throat which will be sent to the laboratory to test for streptococcal infection. A swab is sometimes taken by doctors and nurses when seeing children – it is part of everyday practice. In this study the difference is that everyone is asked to have swabs taken. Some children find the throat swab slightly uncomfortable, and it can make some children feel sick for a few seconds.
- You will be given a post-card to return if you see the GP again, or if you need hospital admission (very rare).
- You will be asked to complete a diary of how your child's symptoms are at home, including measuring the temperature, answering a few questions, then returning it in the Freepost envelope provided. The diary is simple, takes about 3 minutes to complete each day, and has room for up to 14 days entries if necessary. If questionnaires aren't returned we send brief reminders and if necessary a follow-up phone call. A research assistant is responsible for collecting the data in the study. He/she will probably not need to get in touch with you again about this - but may possibly, to clarify some questions if you are filling out the diary. You can

also ask us any questions you like- for example if you find some of the questions difficult to answer.

- The research assistant may ask you to consider talking confidentially about the concerns you have about your child's sore throat in a one to one interview. This information will be recorded and transcribed for research purposes only, and remain strictly confidential

Will any other information be collected? With your permission GP notes will be accessed to find out about previous infections and treatments, and any other treatment or care your child might have needed for this infection. All these details will be kept fully confidential and used for research only.

What are the advantages and disadvantages of the study? The main disadvantage in taking part is the time involved in the diary. The main advantage is that you will help doctors and nurses better manage children in the future.

What will happen to the results? The research will be published in medical journals. We will provide you with a summary of the results, but results will not be available for 3-5 years.

Will my taking part be kept confidential? All the information will be kept fully confidential. Even your GP will not see your answers to the questionnaire/diary. Your child's name will not appear on any papers or reports. To keep your information confidential all questionnaires will be identified by a number only, and stored on password protected computers in locked buildings which are alarmed when staff are not there. The computer based systems have secure encryption to ensure confidentiality for any data collected or sent over the internet. Regulations require that questionnaires are kept in secure locked cabinets for 15 years, after which they can be destroyed.

What if something goes wrong? If you have complaints about the way your child's illness was managed, this study will not affect your normal rights to pursue a complaint within the NHS in the normal way.

Who is organising, reviewing and funding the research? The study is funded and reviewed by the NHS Health Technology Programme and is coordinated by three sites in the UK. Southampton University is coordinating the study locally. It has been approved by the Multi-Centre Research Ethics Committee (application no 06/Q1702/111).

Thank you for taking the time to read this information sheet and considering participating.

What next?

If you are happy for your child to participate please sign the assent form to agree to participate, and a consent form for yourself which must be returned to the research team. Then, if you are happy to do so, you may leave the top two copies of the forms with your GP in the freepost envelope and they will send the researchers their copy, (or alternatively post them in the freepost envelope which goes to the researchers). Take the bottom copy of the forms as your record of consent. If you have any queries before you sign the assent form or consent form, or at any stage in the study please contact: Jo Kelly or Jane Barnett, Aldermoor Health Centre, University of Southampton, Aldermoor Close, Southampton SO16 5ST. Tel: (023) 8024 1060 (N.B. this number is only for queries regarding the study; if you have an urgent medical problem please contact your doctor in the normal way).

You can also contact lines which provide general information about research:

Patient Advice and Liaison Service, Southampton City Primary Care Trust 023 8029 6929