



Primary Care Streptococcal Management Study. MREC No 06/Q1702/111

GP/Nurse Instructions.

Inclusion Criteria:

- Children and Adults aged **5 yrs** and above with acute sore throat (2 weeks or less with an abnormal examination of the pharynx).

Exclusion Criteria:

- Other unusual non infective causes of sore throat e.g. aphthous ulceration, candida or side effects caused by certain drugs eg carbimazole, ACE inhibitors
- Severe mental health problems (e.g. dementia – unable to complete patient diary)
- Poor English language skills which would prohibit completion of the patient diary.

Recruitment Packs

Take a Patient Pack for the appropriate age for your patient i.e.

Adult **blue** pack
Teen 13-16yrs **yellow** pack
Child 5-12 yrs **pink** pack

All the documents you need for yourself and the patient are enclosed in this pack.

Documents are coded with ID numbers so please ensure that all documents from 1 pack are used for the same patient.

If you run out of packs please contact your local study coordinator's Jane Barnett or Jo Kelly telephone 02380 241060 or email prism@soton.ac.uk

How to Recruit

Give patient a **Patient Information Sheet** (found inside the pack) to read and briefly explain the study to them or their parent/guardian. We suggest the main points to mention are:

- The study aims to compare different throat swabs and ways of diagnosing sore throats to find out which is the most effective method of detecting those sore throats that really need treatment with antibiotics and those that do not.
- We would like to take a throat swab and ask you to fill out a diary at home about your sore throat symptoms.
- Information about your sore throat will be sent to the researchers, who would like to check your medical notes at a later date to see if you have had any complications from the sore throat (very rare).
- All information will be kept anonymous.
- The study will help Doctors in future to prescribe antibiotics to those most likely to benefit.
- Ask if they have any questions about the study.

Any queries or problems please telephone study managers Jane Barnett or Jo Kelly on 023 8024 1060.

Consent.

There are two ways the patient can be consented

1. The patient has understood the study and is ready to sign **immediately** then please allow them to go ahead and sign. **THIS IS THE METHOD OF CHOICE.**
*You post the **white** copy in the FREEPOST envelope to the research team, the pink copy is for your reference and the blue copy is for the patient to keep.*
2. The patient is happy to enter the study and verbally consents, but would like to ask further questions **before** signing the consent form.

Advise them that they can phone Jane Barnett or Jo Kelly (study managers - number given on Patient Information Sheet) if they require further information. They should take the Consent form home and post it back to the research centre in the FREEPOST envelope provided.

*NB If the patient prefers to do this then **please** write down their details on **Consent Home Form** (found in your GP pack) as this will be the **only** reference we / you will have for this patient who may forget to complete and post the consent form back and they will not be able to be included in the study.*

Once the patient has verbally agreed to take part you can enter their clinical details onto the clinical proforma via the website.

As stated in the protocol, the research team will later dispose of all patient information if a consent form is not received (to account for any patient who is initially happy to take part but then fails to return the consent form.)

You have chosen to enter patients via the web.

Please note the web form is designed to be used live. If you do not plan to use it live during consultations then please contact your local co-ordinator and ask for paperpack entries instead.

The web address is: www.prismstudy.org
Your username is: [prism](#)
Your password is: [sorethroat](#) (all lower case)

A disposable thermometer for use during consultation is attached to the patient wallet.
If you have any queries or problems please telephone study managers Jane Barnett or Jo Kelly on 023 80241060

NB If you would like to practice entering a "dummy patient" please use an ID number starting with 901 eg 901 70006 and this will allow you to practice using the system and enter a patients details. We can then delete the "dummy" data from our database.

Explanations for terms used on the clinical proforma

Difficulty speaking

Throat is so sore or swollen that words cannot be formed properly, in contrast to laryngeal problems which are characterized by hoarseness.

Cervical glands

Select 'Large (>3cm)' for an enlarged node or confluent/ multiple nodes which together are >3cm.

Runny nose?

Select 'yes' for a runny nose or a runny nose causing a sensation of stuffiness, select 'no' for chronic causes of blocked nose (allergies, septal deformities, vasomotor rhinitis etc).

Rapid test ?

Select no

Throat swab?

Select yes

For the majority of questions please fill in the dots to record your answers.

Computer problems?

Should you have computer difficulties you can enter the patient using one of the spare copies of the clinical proforma which you can find in your blue folder. If you use them it is **ESSENTIAL** that you copy the **patient ID number** from the consent form onto the paper clinical proforma. Use the FREEPOST sticker provided to send the white copy to the researchers, you keep the pink copy. If you run out of paper clinical proformas please contact your local coordinator Jane Barnett/ Jo Kelly Tel: 023 8024 1060 or email prism@soton.ac.uk.

Your Notes

By following the instructions at the end of the web proforma, you can copy the short summary of the consultation. To paste it into your notes depends on the software you use for your notes. After you click on 'copy to clipboard' go to your notes, place the cursor where you want the text to be inserted and try

1. press 'Ctrl' + 'v'
2. right click your mouse then select 'paste'.
3. look for an edit button on the screen, select 'edit' then 'paste'.

Please record that the patient is entered into PRISM and the 8 digit Patient ID number.

Otherwise please record manually in your notes PRISM and the 8 digit Patient ID number.

Please record any **complications** (as below) or **worsening symptoms** and, if possible, encourage your practice colleagues to record similar details for returning PRISM study participants.

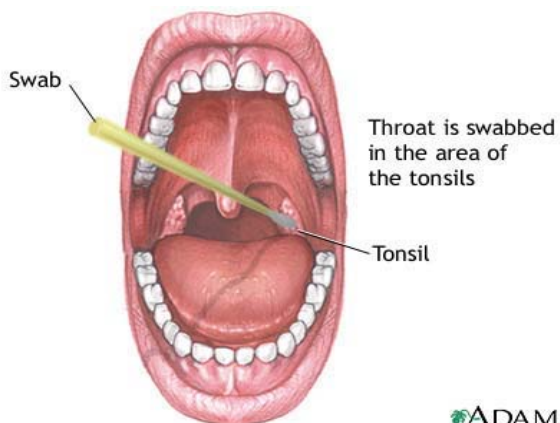
otitis media:	duration of pain/degree of inflammation/evidence of fluid
quinsy:	admission and treatment
cellulitis or impetigo:	diameter of the spreading erythema, systemic upset; any impetigo
sinusitis:	duration/purulence/lateral prominence (i.e. if worse on one side) of pain or discharge/"second sickening"

Taking Throat Swabs.

Inside the Patient wallet will be a folder containing the throat swabs with attached labels with pt ID numbers, lab form, and green and white FREEPOST envelope for postage of specimens.

The swabs are double swabs. In **adults** we would like you to take **2 double swabs i.e. one double swab from one side of the throat and one double swab from the other side** and in **children just one double swab**.

Instructions



1. Wash hands prior to taking specimen.
2. Place patient facing strong light source, depress the tongue using wooden spatula.
3. Swab the back of the throat firmly around the tonsillar area.
4. Place swab in transport medium and ensure lid is firmly secured.
5. Clearly label specimen with patient's name and d.o.b.
6. Stick patient ID label onto specimen tube.
7. Complete the Lab form and place it along with the specimen into the FREEPOST specimen envelope.

8. Post that day.

NB We have included some spare swabs/envelopes in your GP Pack for you to use if you need to.

Any queries or problems please telephone study managers Jane Barnett or Jo Kelly on 023 8024 1060.

Swab Results.

These can be accessed from the web page approx 48hrs after posting the swab.

Go to www.prismstudy.org click on **Enter Patients Details**, enter username: **prism**, password: **sorethroat** , you will then need to enter the patient's ID number (found on the pink copy of the consent form ...or Consent taken Home Form)

Click view lab results and the swab result will be displayed along with antibiotic sensitivity.

Documents to give the Patient

The patient takes home **Patient Pack** containing:

Patient Information Sheet

Consent Form (*blue copy*) if patient has signed in surgery OR

Triplicate Consent Form to sign at home and post back to the research team in the FREEPOST envelope.

Patient Diary, FREEPOST envelope and thermometers (*for them to complete at home over the next 2 weeks, they are asked to post it back to researchers once completed*)

A5 FREEPOST Postcard to take home (*for posting back to the researchers should their illness progress and they experience complications*)

Documents GP/Nurse to Keep

Consent Form (pink copy) for your notes. **White copy to be posted back to the researchers in the FREEPOST Envelope OR**

Consent Home Form (found in GP pack) Please fax back regularly to Study manager.

Clinical Proforma (pink copy for your notes). **White copy to be posted back to the researchers in the FREEPOST Envelope...you will only need to use this if you have had problems accessing the webpage.**

Payment

Please complete the Claim Form (in GP pack) and send to Research Centre in Freepost envelope.

You can do this monthly or whenever you have used all your packs.

(Please note in order to initiate payment it is essential that we have also received the signed consent form back from you or the patient as without this we will not be able to use the patient data.)

THANK YOU VERY MUCH FOR AGREEING TO TAKE PART IN THIS IMPORTANT RESEARCH.



Any queries or problems please telephone study managers Jane Barnett or Jo Kelly on 023 80241060