Understanding Pneumococcal Carriage and Disease 2017/2018

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www.noseswab.org.uk

Participant Information Booklet

Did you know that pneumococcal disease is the most common vaccine-preventable cause of death in children under 5 in the world?

Children are at risk of meningitis, pneumonia and septicaemia (blood poisoning) due to a bacteria called *Streptococcus pneumoniae* (pneumococcus). This bacteria is frequently "carried" (found) in the back of a child's nose without causing any symptoms.

We would like to know what types and how much pneumococcus bacteria is carried in the nasal passage of children in the Thames Valley and what factors may affect this.

The Oxford Vaccine Group (part of the University of Oxford) is inviting your child to take part in this study of the nasal carriage of pneumococcus.

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

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Before you decide whether you would like your child to take part, it is important for you to understand what the study is about and what participation would involve. Please take time to read the information carefully, and discuss with others if you wish.

If anything is unclear or you would like further information please contact the study team (details below).

Who are the Oxford Vaccine Group?

The Oxford Vaccine Group, part of the University of Oxford, is an independent research team of doctors, nurses and play assistants. We carry out research on topics related to infectious diseases and vaccines for children and adults and over 4000 children have participated in carriage studies with us over the last 7 years.

What is Pneumococcus?

Streptococcus pneumoniae is a type of bacteria that can live in the nose and most people will "carry" it there at some point in their lives. There are over 90 different types of the pneumococcus bacteria and occasionally it can cause severe infections such as pneumonia and meningitis (infection around the brain). The current vaccine that is used in the routine schedule in the UK is called PCV13 and protects against 13 types of pneumococcus. In the UK, children receive this vaccine at 2, 4 and 12 months of age.

Why has my child been invited to take part?

We are seeking healthy children whose immunisations are up to date and who are aged between 6 and 48 months (4 years).

You have been approached because your child is within the age range for the study and you live in the Thames Valley. If you have received this invitation through the mail this has either been posted to you by the National Health Applications and Infrastructure Services (NHAIS) who hold the central NHS patient database, the Child Health Information Service', an equivalent NHS database or by your GP surgery. Please note that the Oxford Vaccine Group has not been given your child's name and address.

What is this study about?

The main purpose of this study is to see if the current UK immunisation programme has changed which types and how much pneumoccal bacteria are "carried" in children's noses. This will help us see what changes in pneumococcal disease we are likely to see in the future. The study is funded by the manufacturers of PCV13, Pfizer Limited.

What happens in this study?

This study will enrol approximately 2400 children aged 6 to 48 months. There is only one visit in this study which will last approximately 45 minutes and it will be conducted at a central location and time convenient to you (either at home or in a study clinic).

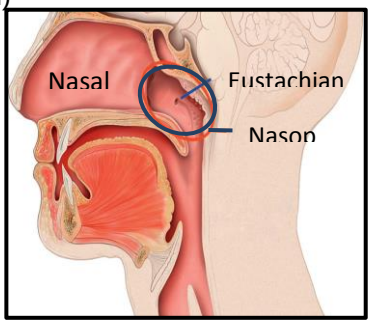
At the appointment, a study nurse or doctor will:

- Discusss the study with you, answer any questions that you may have,
- If you agree to take part, ask you to sign a consent form
- Review your child's red book to confirm vaccination history
- Ask questions on your child's medical history and family contacts
- Take your child's temperature and a nasal swab

We may also ask to take a blood sample (optional)

Nasal swab

We will tilt your child's head back then pass the swab towards the back of the nose and rotate it gently. This feels a bit tickly in the nose but will only take a few seconds.



Picture modified from: Shak, J.R., Vidal, J.E., & Klugman, K.P. 2013. Influence of bacterial interactions on pneumococcal colonization of the nasopharynx. *Trends in Micro*. 21:3 pp 129-135

Blood sample

The blood sample would be collected by finger or heel-prick. This would be 5 -10 drops in total.

Parking reimbursements will be made for study visits that take place at the Oxford University Hospitals.

Does my child have to take part in the study?

No, taking part in research is voluntary. If you decide not to participate this does not affect your child's routine care in any way. You are free to change your mind. Whatever you choose, it is important that you are happy with your decision and it is not the role of the study team to help decide for you.

What are the possible disadvantages and risks of taking part?

The swab will be passed to the back of the nose and some children may find this uncomfortable. Following the blood test your child might experience temporary soreness and bruising on their finger/heel.

What are the benefits of taking part?

There are no direct advantages for an individual participant to take part in this study. The information gained from this study will help us to learn how the pneumococcal vaccines prevent disease and may help in the design of vaccines in the future. If your child has a blood test and is found to have a significantly lower antibody response than expected for his/her age, s/he would be offered a further dose of vaccine through your GP. The individual results of nose swabs will not be provided as they will not impact on your child's health.

What will happen to the samples obtained in the study?

The swab and blood sample will be stored in a freezer at the Oxford Vaccine Group until the analysis takes place. The samples may be shipped outside of the UK, but within the European Union, for analysis.

Separately we will ask you for permission to store components of your child's blood, including DNA (genetic material), and nose swab in a collection of samples called a BioBank. Details of this will be available in a separate booklet provided to you before you are enrolled into this study. You do not have to consent to the Biobank. If you choose not to enrol in the Biobank, you can still and continue to take part in the pneumococcal study. If you have not given consent for the Biobank then the swab and blood sample would be destroyed when the study ends.

Would my child's taking part in this study be kept confidential?

With your permission we would inform your GP and health visitor that your child has been enrolled in this study. We may also require access to the healthcare records and vaccination history of your child.

The University of Oxford is the data controller for this study, and is therefore responsible for looking after your information and using it properly. All information and samples collected from your child will be coded with a study number and kept strictly confidential. Your child's information would be stored on a secure server hosted by

the University of Oxford, and paper notes would be held by the Oxford Vaccine Group in a locked filing cabinet. Only authorised study staff can access your child's data and samples. You and your child's personal information (name, date of birth, and contact information) is kept separately to your study results and will only be used to contact you about the study or for medical reasons. Following completion of the study, all study records (which includes some personal data such as name, date of birth and contact details) will be retained up to 3 years after the youngest participant reaches 18 years of age. We would also seek your permission to use your anonymised study data in future related research. Files will be confidentially destroyed when no longer required. Your rights to access, change or move your child's information are limited as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally identifiable information possible. You can find out more about how we use your information by contacting us as below.

Who else can see my child's study records?

In order to ensure that the study is being conducted correctly the study records can be inspected by the Clinical Trials and Research Governance Office (CTRG), University of Oxford, without violating your child's confidentiality. This group is responsible for ensuring the appropriate conduct of the research on behalf of the research sponsor (the University of Oxford).

By signing the consent form for this study you would be giving permission for the CTRG to look at your child's medical records, however they would not be able to remove information identifying your child from the Oxford Vaccine Group premises. Your child's study information, removed of any identifying information, might also be used for additional medical and/or scientific research in the future. If you do not want the information used in this way, or have any questions about the use of your child's information in the study, please inform the study team.

What will happen if I don't want my child to carry on with the study?

You can change your mind and withdraw your child from the study at any time without giving a reason. If you change your mind and withdraw your child from the study we would keep only the study data that we have already obtained and use the samples we have collected up until the point you informed us that you wanted to withdraw, unless you inform us in writing that you would prefer us not to.

What will happen at the end of the research study?

The results of the research will be published in a scientific medical journal; this can take up to 2 years. All OVG publications will appear on the OVG website and you will receive a letter containing these results. Your child will not be identified in any report or publication and we will not provide individual results.

If you are interested in hearing about other research studies that we may be running in the future you can sign up to our contact list. You are not obliged to take part in any future research.

What if I wish to complain?

If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, you should contact the Oxford Vaccine Group on 01865 611400 or email info@ovg.ox.ac.uk. You can also contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or email CTRG at ctrg@admin.ox.ac.uk . If you do not wish to receive invitations of this kind in the future, please register your child on the Oxford Vaccine Group opt-out list at www.trials.ovg.ox.ac.uk/trials/opt-out.

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that your child suffers any harm as a direct consequence of participating in this study. Similarly, the venues where the study will be conducted will also have appropriate insurance; more information can be provided as required.

What else do I need to know?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participant's interests. This study has been reviewed and given favourable opinion by Nottingham Research Ethics Committee 2.

What should I do now if I'm interested in taking part?

You do not need to make a final decision straight away. If you decide to take part in this study, the next step would be to proceed to www.noseswab.org.uk to complete the online eligibility and booking procedure. Alternatively, you can contact the research team, who will be happy to discuss the study with you, answer any questions you may have and may screen your child and book the study visit over the phone or via email. If your response reaches us after recruitment is complete we will

contact you to let you know. A postcard reminder may be posted to you by the National Health Applications and Infrastructure Services (NHAIS) as above. If we do not hear from you after this, we will assume that you do not want to take part.

Thank you for considering taking part in this study.

Yours sincerely,

Dr Matthew Snape
Principal Investigator
Consultant Vaccinologist and
Paediatrician

Contact Details:
Oxford Vaccine Group
Centre for Clinical Vaccinology and Tropical Medicine (CCVTM)
Churchill Hospital
Oxford, OX3 7LE

Tel: 01865 611400
Email: info@ovg.ox.ac.uk