OXFORD VACCINE GROUP

Understanding Pneumococcal Carriage and Disease 2017/2018

Participant Information Booklet

Children are at an increased risk of meningitis, pneumonia and septicaemia (blood poisoning) due to a bacteria called *Streptococcus pneumoniae,* or pneumococcus. This bacteria frequently lives in children's noses without causing any symptoms, and studying the frequency and nature of nasal 'carriage' of pneumococcus may help us to prevent this disease in the future.

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

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).

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

Dear Parent/Legal Guardian,

The Oxford Vaccine Group (OVG) would like to invite your child to be involved in a study assessing the carriage of a bacteria called *Streptococcus pneumoniae* (pneumococcus) in the noses of children. Approval for this study has been gained from the Nottingham Research Ethics Committee 2.

Who are the Oxford Vaccine Group?

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

Why has my child been invited to take part?

We are seeking healthy children whose immunisations are up to date and who are between 13 and 48 months of age.

You have been approached because your child is within the age range for the study and you live in an area where the study is being carried out. 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?

Streptococcus pneumoniae is a bacteria that is carried (lives) in the nose of most individuals at some time in their lives and can sometimes go on to cause severe infections such as meningitis and pneumonia. There are over 100 types of pneumococcus, and children in the UK have been routinely immunised against pneumococcal disease since 2006. A vaccine against 13 types of pneumococcus (PCV13) was introduced into the UK in 2010, replacing a previous version that prevented 7 types. The main purpose of this study is to see whether the pneumococcal immunisation programme, part of the immunisation schedule that was available for your child, has changed the frequency and nature of pneumococcal bacteria carried by children, as this may

give us a clue as to what changes in pneumococcal disease we are likely to see in the future. The study is funded by the manufacturers of the pneumococcal vaccine, Pfizer Limited.

What happens in this study?

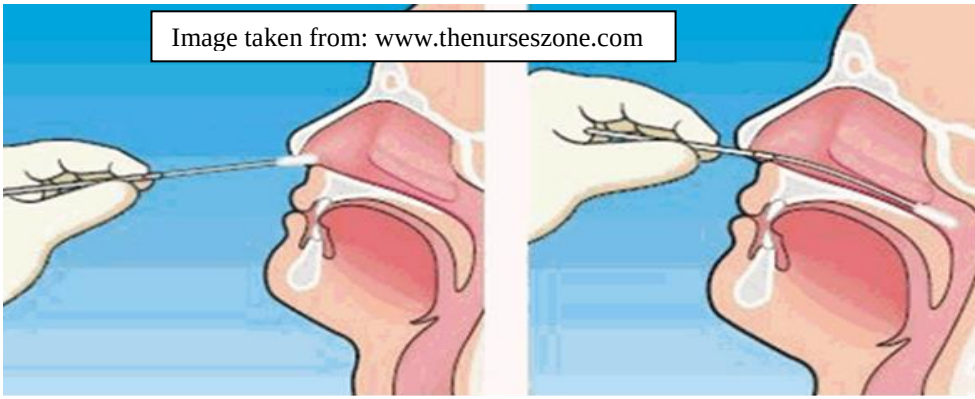
This study will enrol 1600 children aged 13 to 48 months and consists of a single swab from your child's nose. We may also ask your permission to take a finger-prick blood sample from your child, however you could choose to decline this and still enrol your child in the study. The study visit would be conducted at a central location and time convenient to you. At the study visit you would be given the chance to discuss the study in more detail, including the risks and benefits of participation, and we would answer any questions you might have. If you were to agree to have your child take part, we would ask you to sign a consent form and you would be given a copy of this to keep.

The study will involve one study visit that will last approximately 45 minutes. At this visit we would:

- Answer any questions you have and 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
- 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, as shown in the image on page 4. This feels a bit tickly in the nose but will only take a few seconds.



Blood sample

The blood sample will be collected by finger-prick and about 5-10 drops collected (0.2-0.6 ml). If the blood tests show that your child's antibody levels are significantly lower than most immunised children of his/her age we would inform you and your child's GP after the end of the study and recommend administration of a pneumococcal vaccine booster dose.

We would provide you with a 24 hour contact number for the study team should you have any concerns after the study visit.

Does my child have to take part in the study?

No, taking part in research is voluntary. If you decided not to participate this would 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 very back of the nose and some children may find this a little uncomfortable. Apart from the brief discomfort we do not anticipate any significant risks from having the swab done. Unfortunately, children who have a risk of developing nose bleeds will not be able to participate in the study.

Following the blood test your child might experience temporary soreness and bruising.

What are the benefits of taking part?

There are no direct advantages to an individual participant by taking part in this study. The information gained from this study will help to inform how to best prevent pneumococcal 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. For all other participants, individual results will not be provided; this is because these results 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 pneumococcal study, and you are free to say no to this and continue to take part in this pneumococcal study.

At the completion of the study the swab and blood sample will be destroyed, if you have not given consent for these to be retained in the Oxford Vaccine Centre 'Biobank'.

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 was enrolled in this study. We may also require access to healthcare records/vaccination history of your child.

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, 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. 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 the data in future related research. Files will be confidentially destroyed if storage is no longer required.

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 yours 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 CTRG to look at your child's medical records, however they would not be able to remove information that identified 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 projects 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 any reason. If you change your mind and withdraw your child from the study we would use the samples and data we have collected up until the point you informed us that you wanted to withdraw, unless you inform us in writing that you wish for your childs data and samples to be destroyed

What will happen at the end of the research study?

The results of the research will be published in a scientific medical journal; this potentially 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 would

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 then there is an option to sign up to a contact list through which we can get in touch. This does not oblige you in any way to take part in the 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 572224 or email the Head of CTRG Heather House ctrg@admin.ox.ac.uk . If you do not wish to receive invitations of this kind in the future, please contact the NIHR CRN: Thames Valley and South Midlands – Primary Care team on:
Email: optout.tvsm@nihr.ac.uk, Phone: 01865 223295
Address: Optout TVSM, NIHR Clinical Research Network: Thames Valley & South Midlands, TVCN Offices, Block-8, Nuffield Orthopaedic Centre, Windmill Road, Headington, Oxford OX3 7HE
Please provide your child's full name, date of birth and post code, if you do not provide this data it is difficult to ensure you are removed from future mail outs.

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.

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

So, in summary, what would happen if I decide to take part in the study?

- We would arrange a visit where we would take a nose swab and an optional blood sample from your child at a convenient location to you

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

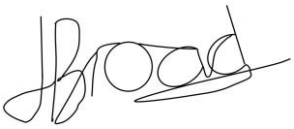
You do not need to make a final decision straight away. If you decide to take part in this study, the next step would be to proceed to www.noseswab.org.uk to complete the online eligibility and booking procedure. Alternatively, you can contact the research team, who will be happy to discuss the study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

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

Thank you for considering taking part in this study.

Yours sincerely,

Dr Matthew Snape
Principal Investigator
Consultant Vaccinologist and
Paediatrician
Honorary Senior Clinical Lecturer



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