



Public Health
England

Participant Information Leaflet

Study title: A study to assess the carriage of pneumococci in children aged 1-5 years, and their household contacts

Short Title: Pneumococci in the nose (study code: PIN)

At any time and without making them ill, about 50% of children carry germs called pneumococci up their nose, which can cause serious illnesses like meningitis and blood poisoning. Vaccines against pneumococci protect against these serious illnesses and help clear these germs from the nose. This protects the population from these infections as the germs do not move around so easily.

Your GP surgery is working with Public Health England (PHE), which is part of the Department of Health, to see how often these germs are found in the noses of children and people in their household.

Before you decide if you would like your family to join this study, please read this leaflet which tells you why the study is being done and what it would involve. Please talk to others about the study if you wish, including the study nurse and organisers, whose telephone numbers are at the end of this leaflet.

Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study.

PART 1

We would like to invite your child and all household members to take part in this study, which aims to recruit over 400 participants in Hertfordshire and Gloucestershire over the next few months. This will involve taking a single swab from inside the nose using a cotton bud and a saliva swab using a foam stick moved around the mouth like brushing teeth.

Why has my family been invited to take part?

Because at least one of the children in your household is aged between 1-5 years, they should have had the pneumococcal vaccine (Prevenar13®) at the GP surgery, as part of the UK childhood immunisation programme as a baby or a toddler.

Does my family have to take part?

You can decide whether you would like your family to join the study. If you agree to take part, you will be asked to sign a consent form for yourself and your child(ren). If possible, we would like all members in the household to take part and they will also be asked to sign a consent form. Taking part is entirely voluntary and you can withdraw at any time without giving a reason and this would not affect your family's routine medical care. If nasal swab(s) has already been taken, you will need to decide if you want the sample(s) to be destroyed, in which case you will need to inform us in writing. If you do not wish to take part in this study, then you do not need to do anything.

Background to the study

Pneumococci live in the space behind the nose and throat in up to 50% of children without causing any ill effects, but can spread from one person to another through touching, coughing and/or sneezing. Occasionally, pneumococci can cause serious infections (especially in young children), including meningitis, pneumonia and blood poisoning (septicaemia), as well as less serious infections such as sinusitis and ear infections like glue ear. The way pneumococci and other germs change from living behind the nose and throat to causing serious infections is poorly understood.

The UK national childhood immunisation programme includes a vaccine called Prevenar13, that protects against 13 different types of pneumococci. Prevenar13 not only protects against serious infections but can help to prevent pneumococci being carried in the nose of vaccinated children. This means vaccinated children cannot pass the germs to other unvaccinated children, adults and the elderly, so protecting them from these serious infections too. We would like to see how effective Prevenar13 is in preventing pneumococci being carried in the nose of young children and their family members. We are also interested in finding out which of the pneumococci types are being carried. We hope that the results of this study will provide useful information on the likely long-term benefits of Prevenar13® in the UK.

What will be involved if we take part in the study?

If you decide you are interested in taking part this study, a Study Nurse will arrange an appointment to meet you at your home or GP practice at your convenience. After answering any questions you may have and if you wish to proceed, the nurse will take your written consent for your child(ren) and you if you are joining, they will also ask the children to sign assent so they feel involved in the process. Any other adults in the household taking part will sign their own consent form. The Study Nurse will take a single swab using a cotton bud from the nose of each child and adult taking part. Taking a nose swab takes a few seconds but may be a little uncomfortable and may make the eyes water. They will also take a saliva swab using a foam stick, in an action similar to brushing teeth. Adults and older children can usually take this themselves. We will collect information about the medical and vaccination history of each member of your household taking part. The appointment should last around half an hour and, with each person's permission, we will inform GPs that they are taking part in the study.

Any child born after September 2004 should have received at least one dose of Prevenar13. In the rare event that your child has not received the appropriate vaccination, we will advise your GP, who should then arrange a vaccination appointment for your child at your convenience. They can still take part in this study whilst this is arranged.

What are the possible disadvantages or risks as well as benefits of taking part?

We cannot foresee any disadvantages or risks of taking part in the study, apart from minor discomfort when the nose swab is taken. There are no direct benefits for you or your family for taking part, but we hope that the results of this study will help us better predict the likely long-term effectiveness of the current pneumococcal immunisation programme and will be used to inform future vaccination policy by the Department of Health.

What happens when the research study stops?

Your family's participation in the study will be complete once the samples are taken. Because carriage of pneumococci is common in the community, even in healthy children and adults, antibiotic treatment is not generally recommended for those who have the germs in their nose. We will, therefore, not be providing participants with individual results. At the end of the study, however, we will write to all the families with the overall results of the study.

In summary:

Your family has been contacted because at least one child in your household is aged between 1-5 years and should have received the pneumococcal vaccine (Prevenar13®) as part of the UK immunisation programme

This study only involves taking one nasal swab and one saliva swab from each participant

If possible, we would like to include all members of your household

PART 2**What if there is a problem?**

- **Complaints**

If you have concerns about any aspect of this study, you can contact the study organiser, Professor Elizabeth Miller on 0208 327 7430, who will do her best to answer your questions. If you remain unhappy and wish to complain formally, then you can do this through the NHS Complaints Procedure, details of which can be obtained at www.nhs.uk or by phoning 0845 601 3012

- **Harm**

We do not anticipate any harm resulting from obtaining a nasal swab. If something does go wrong and a member of your family is harmed during the study because of someone's negligence, then you may have grounds for legal action for compensation against PHE, but you may have to pay your legal costs. The NHS complaints mechanism will be available to you.

Will my family's participation in the study be kept confidential?

As part of the study we will have to collect some personal data about your family, including full names, dates of birth, address, contact details as well as vaccination and relevant medical histories. The only people with access to this information will be employees of PHE, Department of Health or regulatory authorities who may wish to check the study is being carried out within the appropriate guidelines. The data will only be used for the purposes of this study, will be stored in secure PHE facilities and will be destroyed after an appropriate time period, which may be a number of years. You have the right to access any data relating to you and your family. If you wish to obtain any information, please contact us on the numbers provided.

What will happen to any samples from my family?

The swabs taken for this study will be tested in appropriate laboratories to identify any pneumococci on them and to determine its type. Once these tests are complete, there may be small amounts of swab material remaining. With your permission, we would like to store the remaining samples for future studies that might help us understand better how vaccines work to protect against germs such as pneumococci. You will be asked to consent for this specifically in the consent form. These samples will also be anonymised before any further tests are performed so that it will not be possible to link the results of these extra tests back to individual participants. If you are not happy for the swabs to be used for any other tests, then cross out the relevant section in the consent form and the swabs will be destroyed after testing. Your decision regarding the extra tests will not affect your or your family's participation in the study.

What will happen to the results of the research study?

We plan to publish the results in a medical journal which will be accessible to the public. The results of the study will also be reported to the Department of Health to help planning national vaccination programmes in the future. None of the reports will contain any information that might allow individuals who took part to be identified by those reading it. At the end of the study, we will also write to all participating families to summarise the overall findings

Who is organising and funding the research?

The study is funded by the UK Department of Health and is being organised by PHE. PHE is part of the Department of Health which protects the health and well-being of the population and plays a critical role in protecting people from infectious diseases

Who reviewed the study and is it registered on a public database?

All research in the NHS is looked at by an independent group of people, called a National Research Ethics Committee to protect the safety, rights, wellbeing and dignity of individuals. This study has been reviewed and given favourable opinion by NRES Committee London-Fulham (Ref: 15/LO/0458).

Further information and contact details.

If you have any questions, you can ask your Study Nurse or contact the organisers, Professor Elizabeth Miller on 020 8327 7430 or Dr Jo Southern on 020 8327 6084.

We do hope that you and your family will take part in this study. Your contribution could be an important step towards the continual improvement of vaccine policy in the UK.

You and your family may be invited to take part in future studies with us by virtue of the GP surgery you attend. We reassure you that invitations for future studies will not be related to individual results we obtain from this study.

Vaccine Research Nurse name and contact details
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