



Oxford Vaccine Group
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What's the STORY?

(Serum Testing Of Representative Youngsters)

This information is available at www.whatsthehistory.org.uk in the following languages:

ਪੰਜਾਬੀ (Punjabi)

زبان اردو (Urdu)

Française (French)

Portugues (Portuguese)

Español (Spanish)

नेपाल (Nepalese)

عربي (Arabic)

বাঙালি (Bengali)

Somali

فارسی (Farsi)

The Oxford Vaccine Group would like to invite you to take part in a national study to look at the levels of immunity against infectious diseases in the UK. This study is a collaboration between Public Health England, the NHS, The University of Oxford and, the Oxford Vaccine Group. Before you decide whether you would like to take part, it is important for you to understand what is involved. Please read the information in this booklet carefully. If you have any questions please ask the study team at the Oxford Vaccine Group by calling 01865 611400 or email us at whatsthehistory@ovg.ox.ac.uk.

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 on topics related to infectious diseases and vaccines for children and adults.

Why have I been invited to take part?

We are seeking people aged up to 24 years of age to take part in this study. You have been approached because you are within the age range for the study and you live in the Thames Valley area. 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 name and address.

What is this study about?

The aim of this study is to help understand the STORY of infectious diseases in the UK. One of the ways our bodies develop protection against infectious diseases is by developing antibodies, either after an infection or following a vaccination. We can measure the antibodies to see how well protected we are from those infectious diseases.

To do this we are working with Public Health England to develop to collect blood samples from a selection of 0-24 year olds from across England. There will be at least 2300 participants.

The diseases we would look at to start with are Group C meningococcus (MenC), diphtheria and novel coronavirus (COVID-19). Looking at antibodies against MenC and diphtheria will help us understand how well the current vaccination programme is working and in particular whether there are any age groups or populations with differing levels of protection. By looking for antibodies against infectious diseases such as novel coronavirus (COVID-19) we can tell what proportion of the population may have come into contact with the disease in the past. Throughout the course of the study we can see whether this changes over time across the UK and build up a picture of disease circulation.

We are not actively looking to enrol individuals with known or suspected novel coronavirus (COVID-19), but instead want a snapshot of the general population. The test will not be able to tell if there is coronavirus present at the time of sampling. Also, while testing for any changes in antibodies against COVID-19 in the community will help us understand the spread of the virus at a population level, it will not provide reliable information about whether individual participants have had a COVID-19 infection. We will therefore not be providing individual participants with these results.

What is Meningococcal Group C?

MenC disease is caused by infection with group C meningococcal bacteria. MenC can cause meningitis, which is an inflammation or swelling of the lining of the brain, and sepsis. Both meningitis and sepsis are very serious illnesses which can be life-threatening and require hospital treatment. Long term effects of the diseases such as deafness and brain damage can be life changing and affect 10% of people affected.

MenC vaccines were introduced in 1999 and are now part of the routine immunisation schedule. Following the introduction of MenC vaccination there was a rapid fall in MenC disease in all age groups. However in the last few years there has been a small increase in the number of Men C cases. We want to see if this is due to fewer people in the population having high enough antibody levels against this bacteria.

What is Diphtheria?

Diphtheria is an easily transmissible bacterial illness. The bacteria produce toxins which can cause a sudden onset of fever, sore throat, swollen glands and sometimes skin lesions. It once was a common cause of childhood death. Countries that have good immunisation programmes have reduced the number of cases but new cases can be brought in from countries where the disease is active. In 2018 there was a rise in the number of cases compared to previous years, even though the people that were unwell had been vaccinated and had not visited a country where diphtheria is common.

What is novel coronavirus (COVID19)?

Novel coronavirus (COVID-19) is a new virus in humans. Coronaviruses are a large family of viruses with some causing symptoms similar to a cold and others causing much more severe infections. The coronaviruses are mainly transmitted by large droplets from coughing or sneezing. Not everyone who has had the virus will have had symptoms.

What happens in this study?

We are aiming to recruit at least 2300 individuals in six regions across the UK. There will be a single visit with a blood test. We would ask you some basic information including your

- Date of birth
- Gender
- Post code
- GP information
- Ethnic group
- Living circumstances
- Vaccination history
- History of recent respiratory infections (e.g. coughs and colds)

If you decide to take part we will arrange to see you either in a clinic in a location near to you or in your home.

At the appointment, a member of the study team will:

- Discuss the study with you and answer any questions that you may have
- Ask you to sign a consent form if you agree to take part
- Ask you the basic information listed above
- Ask questions on your medical history and family contacts
- Take a blood sample (the amount ranges from 2mls under the age of 2 months to 30mls in the over 15 year olds, this is between less than ½ teaspoon and 6 teaspoons.)

The whole appointment should take around 45 minutes.

Participants seen in clinics will be offered a £20 voucher as reimbursement for travel.

Do I have to take part in the study?

No, this is not part of routine care, taking part in research is voluntary. If you decide not to participate this does not affect your routine care in any way. You are free to change your mind at any time. 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?

Following the blood test you might experience temporary soreness and bruising on the blood sample site.

What are the benefits of taking part?

There are no personal advantages to taking part in this study, and participants will not be provided their individual results. The information gained from this study will help us to learn about infections such as novel coronavirus COVID-19 and how well the study population is protected against vaccine preventable illnesses such as Men C and diphtheria.

What will happen to the samples obtained in the study?

The blood sample will be processed and stored at the Oxford Vaccine Group laboratory and then transferred to Public Health England (PHE) laboratories where the analysis will take place. Any remaining sample will be stored by PHE and the Oxford Vaccine Group, University of Oxford, and may be used in future research related to infectious diseases. It will not be possible for you to be identified from the sample however it can be tracked if you wish to withdraw from the study. We may also ask your permission to take a DNA sample from your blood, but you can say no to this and still take part in the study. DNA samples from the study would be stored at the Oxford Vaccine Group, University of Oxford.

Why might you want to study my DNA?

Your unique DNA code can influence how your immune system responds to vaccines and infections. We would like to study how differences in people's DNA affects their immune response to vaccines or infections to improve our understanding of how to best prevent these infections.

Would my taking part in this study be kept confidential?

Yes. All information and blood samples collected from you are coded with a study number and kept strictly confidential.

Your information would be stored on a secure server, and paper notes would be held by Oxford Vaccine Group in a locked cabinet. Only authorised study staff can access your data and samples.

With your permission, we may check your vaccination and medical history from child health records, NHS databases or your GP.

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

You can change your mind and withdraw from the study at any time without giving a reason. If you change your mind after you have provided a blood sample you can inform us in writing and your sample will be removed and destroyed. There would be no further analysis on the blood sample.

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 several years. All publications from this study will appear on the Oxford Vaccine Group (OVG) website www.ovg.ox.ac.uk and you will receive a letter describing the main results from the study. You 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 should I do now if I'm interested in taking part?

You do not need to make a decision straight away. If you decide to take part in this study, the next step would be to proceed to <https://whatsthehistory.web.ox.ac.uk/oxford> 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 you and book the study visit over the phone or via email.

The recruitment will happen in stages, this is because we are aiming to recruit a representative sample of participants in your region and to recruit at a steady pace over the next few months. This may result in a delay, in us contacting you. You may be approached in later recruitment stage or potentially we may contact you to say recruitment for your area is complete. A postcard reminder may be posted to you by the Child Health information Services/ National Health Applications and Infrastructure Services (NHAIS)/or equivalent NHS database 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.

GDPR (General Data Protection Regulations) Statement

The University of Oxford is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly

We will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. The only people in the Oxford Vaccine Group who will have access to information that identifies you will be people who need to contact you to conduct the study or audit the data collection process. The people who analyse the information (Public Health England and Oxford Vaccine Group) will have access to the information listed above (in the section 'What happens in this study') but will not receive your name or contact details.

The Oxford Vaccine Group will keep identifiable information about you from this study, securely for at least 3 years after the youngest study participant has turned 18 years of age. We will store the anonymised research data indefinitely.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Once the study has been completed, all documents would be archived in a secure facility by the Oxford Vaccine Group. Files will be confidentially destroyed if storage is no longer required.

Professor Matthew Snape, or their successor, as the principal investigator will have the responsibility for custody of the data. Further information about your rights with respect to your personal data is available at: <http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>

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 the NHS to use your health records for the purposes of supporting any health related research, please visit <https://www.nhs.uk/your-nhs-data-matters/manage-your-choice> to make your choice.

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you 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 the London - Surrey Research Ethics Committee. This study is being funded by the National Institute for Health Research, part of the NHS.

Yours sincerely,



Professor Matthew Snape
Chief Investigator
Associate Professor in General Paediatrics and Vaccinology