

What's the STORY?
(Serum Testing Of Representative Youngsters)

This information is available at www.whatsthestory.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)

Dear parent/legal guardian,

The Bradford Children's Research Team would like to invite your child to take part in a national study to look at the levels of immunity against infectious diseases in England. This study is a collaboration between Public Health England, the NHS, The University of Oxford and Bradford Teaching Hospitals NHS Foundation Trust. 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 Bradford Teaching Hospitals NHS Foundation Trust by calling 01274 366288 or email us at childrensresearch.nurses@bthft.nhs.uk

Who are Bradford Children's Research?

The Bradford Children's Research Team is a research Team of Doctors, Nurses and support staff who carry out research into a variety of topics to do with children and their families.

Why has my child been invited to take part?

We are inviting children and young adults aged between birth and 24 years of age to take part in this study. You have been approached because your child is within the age range for the study and you live in the Bradford BD6 and BD15 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. Please note that

the Bradford Teaching Hospitals NHS Foundation Trust has not been given your child's name and address.

What is this study about?

The aim of this study is to help understand the STORY of infectious diseases in England. 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 up to 3500 participants.

To start with we are looking at COVID-19, group C meningococcus (MenC) and diphtheria. By looking for antibodies against infectious diseases such as COVID-19 we can tell what proportion of the population have come into contact with the disease. This information will help Public Health England and the Scientific Advisory Group for Emergencies (SAGE) make decisions on how they manage the COVID-19 pandemic response now and in the future.

We are **not** actively looking to enrol individuals with known or suspected COVID-19, but instead want a snapshot of the general population. The test does not provide on the spot results and *it is important to understand that we will not be providing individual participants (or their families) the results of their laboratory test*. This is an important measure to try and make this study as accurate as possible as we do not want to recruit too many people who feel they, or their child, might have had COVID-19 and 'want to check'. This would give us inaccurate information about the spread of COVID-19 and immunity to this virus across the whole population.

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.

What is novel coronavirus (COVID-19)?

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 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. Following the introduction of the 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 happens in this study?

We will be recruiting up to 3500 individuals in multiple sites across England. There will be a single visit with a blood and saliva test, using anaesthetic cream or spray. Some participants will be invited to provide repeat blood and saliva samples at subsequent visits.

At the first visit we would ask you some basic information about your child's:

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

If you decide to take part we will arrange to see you and your child in a clinic in a location near to you. If you have multiple children within your household only one can take part unless they are more than 5 years apart in age.

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

- Discuss the study with you and answer any questions that you or your child may have
- Ask you to sign a consent form if you agree to take part
- Ask if you and your child would be willing to give future blood and saliva samples for this research study.
- Ask you the basic information listed above
- Ask questions on your child's medical history and family contacts
- Take a blood sample from your child (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.

Why are you asking for repeat blood and saliva samples from some participants?

When we produce antibodies to fight an infection they can be detected in our blood and saliva. After some infections these antibodies stay at high levels for long periods of time providing us with protection. For other infections they fall quickly meaning we can get the same infection again. Little is known about how the body reacts to COVID-19 especially for those with mild symptoms, and by taking repeat samples of blood and saliva we hope to look at how the antibody levels change over time. Therefore, we would like to take 1 to 3 additional blood samples at 2 to 3 month intervals from some participants, along with a saliva test as another way of testing for antibodies. At each of the visits we ask about COVID-19 symptoms you or any of your household contacts have had since the last visit. We will be asking for these repeat samples from a mix of participants testing positive or negative for COVID-19 antibodies at their first visit. If we ask you to come for a repeat blood/saliva sample you will not be informed as to whether you tested positive or negative for COVID 19.

Please note that you can say no to these repeat samples and still take part in the main study

Does my child 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 child's 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 your child might experience temporary soreness and bruising around the blood sampling area.

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 samples your child provides will be processed and stored at the Bradford Teaching Hospitals NHS Foundation Trust 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 your child 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 child's 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 child's DNA?

Your child's 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 affect 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 your child are 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 Bradford Teaching Hospitals NHS Foundation Trust in a locked cabinet. Only authorised study staff can access your child's data and samples.

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

What will happen if I don't want my child 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 your child has provided a blood sample you can inform us in writing and their 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. 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 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 with your child, the next step would be to proceed to www.whatsthestory.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 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 sample of participants in your region that represent the characteristics of the population as a whole. We also wish to recruit at a steady pace over the next few months to enable us to map the

progress of SARS-COV-2 through the community. Therefore we will be checking our information as we go along to see if we are achieving our aim. 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 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.

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 Bradford Teaching Hospitals NHS Foundation Trust 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 Bradford Teaching Hospitals NHS Foundation Trust will keep identifiable information about your child 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 Bradford Teaching Hospitals NHS Foundation Trust. Files will be confidentially destroyed if storage is no longer required.

Dr Sam Oddie, 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:

Telephone: 01274 364810, Mon – Friday, 9am – 4pm

(Messages can be left on the answering machine and will be answered within two working days.)

Email: patient.experience@bthft.nhs.uk

Address: Patient Experience

Bradford Teaching Hospitals

Duckworth Lane

Bradford

BD9 6RJ

In person: By making an appointment on 01274 364810 or speaking to a member of staff at BRI's main reception. However, a member of staff may not always be available immediately.

OR

If you do not wish the NHS to use your child's 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 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 the London - Surrey Research Ethics Committee.

Yours sincerely,



Dr Sam Oddie