The LAVA (Lateral flow Antigen Validation and Applicability) Study for COVID-19

Information for Parents

We are inviting you to take part in a study looking at the testing that is being undertaken for children with COVID-19. The current test for COVID-19 is taken from the back of the nose and the back of the throat which can be uncomfortable for some children. After the swab has been taken it can take about 24-48 hours for the test to be returned. For some children this can mean that there is a delay in diagnosing COVID-19. For others who are coming in for a planned procedure it could mean that whilst they weren't infectious with COVID-19 when the swab was taken, there is a risk that they have become infectious in the meantime. We want to look at a new test for COVID-19 which is taken from just inside the nostril and can give a result in 30 minutes. It is probably not as good as the usual test at diagnosing people with COVID-19 but in the laboratory tests that have been done it seems to be very good at picking up when people are infectious (i.e. when they are most likely to spread the virus).

What is the purpose of the study?
The study aims to assess how valid the results from the new test are compared to the current test. It also aims to see how often the new test fails, what is needed to use it , whether it causes any more or less discomfort to the child than the usual swab and whether it makes a difference to children in hospital.

Why has my child been chosen and what does it involve?
We are asking three groups of children to be involved:

1. Children who are undergoing a routine operation who will have a routine nose and throat swab taken before their operation. If you agree to going ahead with the study, the new nose swab will be taken at the same time as your child attends for the routine nose and throat swab. If you agree, we will also ask to perform the new nose swab at the time that your child is admitted to hospital for their procedure, before they go to sleep. To be able to determine how accurate that swab is, we will repeat the nose and throat swab again once your child is asleep to enable a comparison between the two.
2. Children who are admitted through A&E with possible COVID-19 will be asked to participate. All children being admitted to hospital currently have a nose and throat swab. We will ask to perform an additional nose swab when they are admitted.
3. Children who are on the intensive care unit, high dependency unit or transplant ward. Children in these areas are undergoing routine nose and throat swabbing once or twice a week to check whether they have COVID-19. We will ask to perform an extra nose swab every time that they have a nose and throat swab during the two weeks while the study is running.

The new nose swab will be taken from just inside both nostrils by rolling the swab over 5 times inside the nose. This will be done before the nose and throat swab which is placed further back in the nose and at the back of the throat.

Parent Information Leaflet and Consent v1 15/10/20 IRAS: 290989

We will ask you and your child to tell us how much discomfort they were in at the time of both of the swabs.
We will also look at how quickly the results of both of the tests come back and how often the tests do not work.
We will compare the results from the nose swab with the routine nose and throat swab results to see if they look accurate and will use these data to work out how many times we need to compare these results before we can confidently say how well the new test works.

Do we have to take part?
No, it is completely up to you and your child as to whether you take part. You or your child can also op-out of the study at any point and your child's care will not be affected by either of these situations.

What will happen to us if we do decide to take part?
If you do decide to take part you will be taken through a consent form, and so will your child if they are old enough. Your child will undergo the additional nasal swab when they have their routine nose and throat swab and if your child is having an anaesthetic they will have an extra nose and throat swab when they are asleep.

What are the possible disadvantages or risks of taking part?
Your child may find the nose swab is uncomfortable or tickles. There is a very small risk that it could cause a nose bleed, like any swab from the nose. The new test may not be able to give a result and if it does we cannot say how accurate the result is. If the result is positive for COVID-19 we would inform you by telephone or in person and would advise you to follow government guidelines about isolation. The nose and throat swab takes 24-48 hours to come back, if that is negative then we would advise you that you could come out of isolation. If you are attending for an elective procedure and the swab that you have just before your procedure is positive then the surgical and anaesthetic team will discuss with you what the options are. If a decision is made to delay the procedure we would ask your child if they are happy to have a nose and throat swab to enable us to compare the result and give you further advice about isolation.

What are the potential benefits of taking part?
There is the possibility that the new test is able to detect COVID-19 sooner than the normal nose and throat test. This would allow your child and the household to isolate more quickly, reducing the risk of passing on the infection to other people.

Will my participation in the study be kept confidential?
Yes, your child's name will not be disclosed outside of the hospital. Nurses who would not usually be part of your child's care team may be involved in their care to help with undertaking the study. They would also maintain confidentiality.

What will happen to the results of the study?
We will give the results, without any identifiable details about your child, to Public Health England to use for making decisions. We will also use these results to work out how many of the new tests we need to do to determine how reliable they are in a bigger research study.

Who is organising and funding the research?
This study is being organised and led by Miss Harwood, Professor Larru and Professor Kenny at Alder Hey Children's Hospital. They are not being paid for running this study. The new tests have been provided by Public Health England and funding for research nurses has been given by Test and Trace.

Who has reviewed the study?
This study has been reviewed by the Research Review Committee at Alder Hey Hospital and the Liverpool Research Ethics Committee.

What will happen to data about my child?
Alder Hey Children's Hospital is the sponsor for this study based in the United Kingdom. We will be using information from you, your child and their medical records 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. Alder Hey Children's Hospital will keep identifiable information about you for 5 years.

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 or your child 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.

You can find out more about how we use your information by contacting Miss Harwood at the address below.

Alder Hey Children's Hospital will use your name, NHS number and contact details to contact you and your child about the research study, and make sure that relevant information about the study is recorded for your child's care, and to oversee the quality of the study. Individuals from Alder Hey Children's Hospital and regulatory organisations may look at your child's medical and research records to check the accuracy of the research study. The only people in Alder Hey who will have access to information that identifies you will be people who need to contact you to send out questionnaires or audit the data collection process. The people who analyse the information will not be able to identify you or your child and will not be able to find out your name, NHS number or contact details.

Contact for further information:
Miss R Harwood
Paediatric Surgical Registrar
Alder Hey Children's Hospital
East Prescot Road
Liverpool
L14 5AB
Tel: 0151 2284811

Parent Information Leaflet and Consent v1 15/10/20 IRAS: 290989

If you are unhappy with the way in which this research is conducted or would like to make a complaint, the Patient Advice and Liaison Service (PALS) is available to discuss this with you. Their contact details are:

PALS,
Alder Hey Children's NHS Foundation Trust,
Eaton Road,
Liverpool,
L12 2AP
Tel: 0151 252 5374 / 0151 252 5161

Patient's Initials: _ _ _

Patient's Date of Birth: _ _/ _ _/ _ _ _ _

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Parent Consent form

	Please initial box
1. I confirm that I have read and understand the information sheet dated 15/10/20 for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
2. I understand that participation is voluntary and that I am free to withdraw my child at any time, without giving a reason, and without my child's care or legal rights being affected.	
3. I understand that relevant sections of any of my child's medical notes and data collected during the study may be looked at by responsible individuals where it is relevant to my child taking part in this research. These include individuals representing the trial team, trial sponsor (Alder Hey hospital), regulatory authorities or from other NHS bodies and the Independent Ethics Committee. I give permission for these individuals to have access to my child's records and to collect, store, analyse and publish information from this research even if I withdraw him/her from the study. I understand that my child's name will be kept confidential.	
4. I consent to the data collected to be processed and reported for medical research purposes.	
5. I agree for my child's data on NHS hospital admissions to be collected from routine NHS care records	
6. I agree to medical personnel responsible for my child's welfare being informed on my participation in this study.	
7. I agree for my child to take part in the above study.	
8. Optional: I agree that I may be contacted again in the future in relation to this study.	Yes …… No

_____ Name of Patient

_____	_____	_____
Name of Parent	Signature	Date

_____	_____	_____
Researcher	Signature	Date

original copy for participant, copy for site file, copy for patient notes