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**Determining the Effectiveness of a FeNO-guided asthma
management Intervention in primary care (DEFINE)**



www.definestudy.com

Lead investigator: Dr Kay Wang

**Participant Information Leaflet for parents/guardians of
patients aged 12 to 15 years**

We would like to invite your child to take part in our study.

This information leaflet explains why we are doing this study and what it will involve for your child if you allow them to take part. Please read it carefully before deciding whether you would be happy for your child to take part. If you have any questions, please get in touch with us using the contact details at the end of this leaflet.

Why has my child been invited to take part in this study?

We are looking for people with asthma aged 12 years and over who have their asthma reviewed at their GP surgery. Your child has been invited to take part in this study because they are due for their routine asthma review.

What is the purpose of the study?

We want to find out whether using the FeNO test during asthma reviews can help improve care for asthma patients and reduce costs to the NHS.

What is the FeNO test?

The FeNO test is a breath test which measures the amount of nitric oxide in the air you breathe out. Nitric oxide is an indicator of possible inflammation in the airways, which can sometimes be found in people with asthma. Everyone breathes out some nitric oxide but people whose airways are inflamed breathe out more nitric oxide than people whose airways are not inflamed. Many asthma medications aim to reduce inflammation to help prevent asthma attacks.



The FeNO test is safe and non-invasive. It involves blowing out into a mouthpiece in one long, slow breath. You can watch a short video on how the FeNO test is done here: <http://tinyurl.com/fenodemo>

*Please note that the nurse in the picture above is not wearing a face mask because this photograph was taken before the start of the Covid-19 pandemic. However, your child's health care professional will take the necessary steps to protect them from Covid-19 infection where required.

Does my child have to take part?

No, your child is free to decide whether or not to take part. If your child decides to take part, they are still free to withdraw at any time, without giving a reason. Withdrawing or not taking part will not affect your child's current or future standard of clinical care in any way.

What will happen if I allow my child to take part?



Your child's health care professional or someone from the research team will **talk to you and your child about the study** and ask if you have any questions about taking part.



We will ask you to complete a **consent form** to say you are happy for your child to take part. We will also ask your child to complete an **assent form** to say they are happy to take part. You and your child may complete these forms in person, online or over the telephone.



Your child will then be randomly allocated to either having their asthma reviewed **with the FeNO test** or having their asthma reviewed **without the FeNO test** over the next year. Half of people in the study will have the FeNO test; the other half will not. This will be decided at random, like tossing a coin, to make sure the results are fair. Neither your child's health care professional nor the research team will have any control over whether or not your child will have the FeNO test.



We will ask your child to measure their **peak flow** when they enter the study and again one year later.



We will ask your child to **fill in some questionnaires** about their asthma and general health when they enter the study and every three months after that for a year. Most of the questionnaires will need to be filled in when your child enters the study. Filling in each set of questionnaires should only take about 10 minutes and no more than 15 minutes. They can ask you to help them with these questionnaires if they wish. We will ask you how you would like us to contact you when we need you to fill in your questionnaires.



We will collect some information from your child's **medical notes** shortly after they enter the study and again after about a year. This will include information about their asthma, general health, medications, and times when they or you have had to seek advice about their asthma or problems caused by their asthma.

What will happen if my child takes part and their asthma review is done without the FeNO test?

If your child is allocated to the group of people who will not have the FeNO test:

- Their health care professional will do their asthma review as they normally do. At the moment, GP surgeries do not normally do a FeNO test as part of a routine asthma review. Your GP surgery may do your asthma review face-to-face or remotely (e.g. telephone or video consultation).
- To help us understand how the FeNO test might influence the care patients receive for their asthma, we will still ask your child to fill in our study questionnaires and provide peak flow readings. We will also still collect information from your child's medical notes for our study.

What will happen if my child's asthma review is done with the FeNO test?

If your child is allocated to the group of people who will have the FeNO test:

- Your child will be sent a short booklet about the FeNO test and how it can help manage their asthma.
- They will have a FeNO test done. Their health care professional will use an online tool to consider their FeNO result along with other information about their asthma.
- This will help them plan with you how to manage your child's asthma going forwards.
- Your health care professional may ask them to come back for more FeNO tests during the year that they are in the study.
- The FeNO test will only be done during **planned reviews** of your child's asthma. It will not be done if your child has an asthma attack or if your child consults their GP surgery for reasons other than their asthma.

What are the possible advantages and disadvantages of taking part?

The main advantage of taking part is an opportunity for your child to contribute to research to improve how asthma is managed in GP surgeries. We do not yet know whether the FeNO test and online tool will improve care for patients with asthma; that is why we are doing this research.

If your child is allocated to the group of people who will be having the FeNO test:

- Your child's health care professional will be able to consider their FeNO result alongside the other information they normally consider during your asthma review.
- If your child normally has their asthma review done over the telephone, they may have to go to the GP surgery or another clinic to have their FeNO test done.
- You and your child may have concerns about Covid-19 infection as a result of your child having to be seen in person by a health care professional for their FeNO test. However, your child's GP surgery or clinic will put all necessary measures in place to keep you and your child safe from Covid-19.

It is not essential for your child's health care professional to do a FeNO test to be able to safely review your child's asthma. You may have concerns about researchers seeing your child's medical records. However, we would like to assure you that all data will be kept secure and confidential.

Will my child taking part in the study remain confidential?

Yes. It will not be possible to identify who your child is from their study data. Your child will be referred to only by a unique study identification number. We will keep a separate record of people's real names and corresponding identification numbers. We will use the minimum personally-identifiable information possible.

What will happen to my child's data?

We will be using information from your child and your child's medical records in order to undertake this research. This research is being carried out with the aim of improving care for patients with asthma. Data protection regulation requires that we state the legal basis for processing information about your child. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your child's information and using it properly.

Your child's GP surgery and the research team will use your name, NHS number and contact details (address, telephone number, email) to contact you, on behalf of your child, about the research study, to make sure that relevant information about the study is recorded for your child's care, and to oversee the quality of the study.

Where will my child's data be kept?

We will store research data linked to your child's unique study identification number and any research documents with personal information (such as consent forms) securely at the University of Oxford for up to ten years after the end of the study. This will ensure that we have enough time to analyse it all, and to write papers and reports. After the end of the study, we will fully anonymise all our research data. This will mean that we can still do further analyses if needed but there will be no way of linking your child's data to any personal information about them.

Who will be able to see my child's data?

Responsible members of the Universities of Oxford, Southampton, Nottingham, Bristol and Bath, and the Clinical Commissioning Group may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

The only people who will have access to information that identifies your child are people who need to contact you for the research study, collect information from your medical records or audit the data collection process.

The people who analyse the information we collect during the study will not be able to identify your child and will not be able to find out your child's name or contact details.

What are my child's data rights?

Your rights to access, change or move your child's information are limited, as we need to manage your child's information in specific ways for the research to be reliable and accurate.

To safeguard you and your child's rights, we will keep the amount of information we use which could potentially identify your child to a minimum.

Where can I find out more about how my child's data are used?

Data protection regulation provides you with control over your child's personal data and how it is used. When you agree to your child's information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate.

Further information about your child's rights with respect to your child's personal data is available at

<http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>

You can find out more about how we use your child's information by contacting the research team using contact details at the end of this leaflet.

What will happen if my child does not want to carry on with the study?

If your child decides they no longer wish to take part in our study, please let us or your child's health care professional know. You can find our contact details at the end of this leaflet.

Your child can withdraw from the study at any time without giving a reason. If your child wishes to withdraw, we will still keep and use any information we have already collected about them. We will, however, ask your permission to extract information from your medical records. If your child decides not to give permission, that is OK. If your child decides to withdraw, this will not affect the standard of care they receive. The research team will respect their decision and will be happy to answer any questions you or your child may have.

What will happen to the results of this study?

The results will be published in scientific journals and on our website (www.definestudy.com) for you and your child to read. Your child will not be identifiable in any reports or publications arising from this research study.

Will my child be reimbursed for taking part?

If your child fills in all our study questionnaires (with your help if needed) and provides us with a peak flow reading after a year, we will be able to offer you and your child £10 in e-vouchers for online shopping or a suitable alternative.

Will my child be asked to take part in further research?

We may also invite your child to take part in an interview with a researcher about your care. If we invite your child, we will provide you with another participant information sheet and consent form. Your child will also receive another participant information sheet and assent form. If your child agrees to an interview, we will be able to offer your child an additional £20 in e-vouchers or a suitable alternative. However, taking part in an interview is optional. Even if your child decides not to take part in an interview they may still take part in the rest of the study.

Who is organising and funding the study?

The study is funded by National Institute for Health Research (NIHR). It is part of the **D**evelopment and **E**valuation of an online **F**eNO-guided asthma management **I**NtervEntion in primary care (DEFINE) research programme.

The University of Oxford is the research sponsor. The study team is led by Dr Kay Wang (University of Oxford). The Primary Care Clinical Trials Unit at the University of Oxford has set up and is running the study.

How have patients been involved in this study?

Patients with asthma were involved in helping prepare this leaflet and design this study.

What if there is a problem?

The University of Oxford has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your child's participation in this study. NHS indemnity operates in respect of the clinical treatment that is provided.

If you wish to complain about any aspect of the way in which you or your child have been approached or treated during this study, you should contact the research team whose details are given below. Alternatively, you may contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) office on 01865 616480, or the head of RGEA (ctrgea@admin.ox.ac.uk).

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC). The REC is there to protect your child's safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by London – Fulham East Research Ethics Committee. The reference number is 22/LO/0139 (IRAS no: 307116).

Contact details

Please contact the research team if you would like further information:

Trial manager: Samuel Paul

Email address: define@phc.ox.ac.uk

Phone number (office hours only): 01865 289350

***Thank you for considering taking part in this study.
Please ask if you have any questions.***