

**INFORMATION LEAFLET FOR PARENTS/GUARDIANS:**

**PATIENT/PUBLIC INTERVIEWS**

**Investigating health care professional and patient views and experiences of FeNO-guided asthma management**

**Interviews with patients/citizens with asthma**

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. *If there is anything that is not clear, or if you would like more information, please ask us.*

# What is the purpose of the study?

Asthma is a common condition that affects the airways of the lungs. In people with asthma, swelling (also known as inflammation) can occur in the linings of the airways and make them narrower than usual. This can cause symptoms such as wheezing, coughing, chest tightness and shortness of breath. If these symptoms flare up badly, people may get asthma attacks, which might need treatment with medicines to reduce inflammation (such as steroids) or, in severe cases, admission to hospital.

At the moment, most health care professionals rely on patients’ symptoms to help them decide how to treat their asthma. However, how someone feels does not always match how much inflammation is in their airways or how likely they are to have an asthma attack. We are therefore developing an online package to support health care professionals in general practices using a simple breath test called fractional exhaled nitric oxide (FeNO), which measures inflammation in the airways.

At the moment, FeNO is mainly measured in patients with severe asthma who attend hospital clinics. However, very few GP surgeries routinely use FeNO to help them monitor treatment in patients with milder forms of asthma. We would therefore like to find out why this is and ensure that our online package helps health care professionals in GP surgeries using FeNO to get patients onto the right treatments at the right doses to prevent asthma attacks.

The main aim of the study is to find out patients’ views on the acceptability of using FeNO during asthma review consultations in primary care to guide management of their asthma and their views on patient information about FeNO. This research is funded by the National Institute for Health Research (NIHR). This study has been reviewed and received favourable opinion by Berkshire B Research Ethics Committee (REC Ref: 20/SC/0235).

**Why has my child been invited?**

You have been invited because your child has had a diagnosis of asthma from a health care professional. You may also have been invited because your health care professional is taking part in the DEFINE study and your child has recently attended an annual asthma review.

# Does my child have to take part?

No, taking part is entirely voluntary and your child can withdraw at any time if they later change their mind, without giving a reason. Withdrawal or not taking part will not affect your child’s current or future clinical care in any way, as the research team is separate from your child’s health care team.

# What will happen to my child if they decide to take part?

We would like your child to take part in a telephone, online (e.g. using Skype or Microsoft Teams) or face to face interview, whichever they prefer, which you also participate in. If face to face, the interview can be done in your own home, on university premises or in a public place (e.g. café)- again according to your preference. The interview will be arranged at a time to suit you and your child and should take between 30 and 45 minutes.

If your child is interested in taking part, please contact the research team using the details provided at the end of this document.

Written consent will be taken from you and assent from your child in person at the start of the interview, otherwise, consent and assent will be obtained verbally at the start of interviews conducted over the telephone or online. You and your child will receive a copy of the signed consent and assent forms by email.

# What should my child consider?

The main things to consider are whether your child would be comfortable having a researcher asking them questions about their asthma and their views and experiences of FeNO-guided asthma management.

# What are the advantages and disadvantages of taking part?

There are no direct advantages or disadvantages your child. The information gained from this study will be used to support health care professionals to use FeNO measurements during asthma review consultations in primary care in the context of a wider intervention which may help to improve the care that patients receive.

# Will our taking part in the study remain confidential?

With your permission, the interview will be audio-recorded to make an accurate record of what is said and then stored on a secure computer on the University of Oxford premises. The recording will be sent securely to an independent transcription company who will transcribe the interview verbatim. This company will hold a confidentiality agreement with the University of Oxford. Once the written transcript is checked the recording will be destroyed. The written transcript will not include any names or other defining details that can identify you and your child or your practice, to ensure confidentiality. The company will retain no identifiable data about participants following transcription.

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. Personal data, including consent forms and demographic data, will be kept for 10 years following the end of the study at the University of Oxford following University of Oxford policies and then destroyed. De-identified transcripts will be stored at the University of Oxford and may be accessed by researchers for future research studies around the world and including commercial collaborators. They will be stored for 10 years following the end of the study and then destroyed. The findings from this study will be used in research reports but no names or other identifying details will be included in the report so any quotes from the interview will be anonymous.

Responsible members of the University of Oxford 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

# Will my child be reimbursed for taking part?

We are able to offer you £20 in e-vouchers for online shopping to reimburse your child’s time for taking part in the study. We can reimburse travel expenses to attend an interview up to a total of £15 where receipts are provided.

# What will happen to our data?

The University of Oxford will use your and your child’s name and contact details (practice, email address, phone number) to contact you about the research study, and make sure that relevant information about the study is recorded to oversee the quality of the study. Individuals from the University of Oxford, as sponsor, and regulatory organisations may look at your research records to check the accuracy of the research study. The only people at the University of Oxford who will have access to information that identifies you will be people who need to contact you to audit the data collection process as well as for any monitoring and audit that may be conducted. 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 or contact details.

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 and 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 Data Protection Officer at the University of Oxford at <http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>

You can find out more about how we use your information by contacting Sarah Tonkin-Crine, Chief Investigator for the study, using the contact details at the end of this Information Sheet.

**What will happen if my child doesn’t want to carry on with the study?**

Taking part is entirely voluntary and, if your child does agree to take part, they can withdraw at any time if they later change your mind, without giving a reason. Withdrawal or not taking part will not affect your child’s current or future clinical care in any way, as the research team is separate from your child’s health care team. Your child will have a choice if data collected to the point of withdrawal could be retained for the study or removed.

# What will happen at the end of the study?

The results will be published in scientific journals and meetings. A summary of the findings and full report will be made available online to all participants who would like to see the results.

# What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your 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 have been approached or treated during the course of this study, you should contact Dr Sarah Tonkin-Crine whose details are given below. Alternatively, you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email (ctrg@admin.ox.ac.uk).

# How have patients and the public been involved in this study?

Patients with asthma were involved in helping design this study.

# Who is organising and funding the study?

The study is funded by National Institute of Health Research (NIHR). It is part of the **D**evelopment and **E**valuation of an online **F**eNO-guided asthma management **IN**terv**E**ntion in primary care (DEFINE) research programme. This specific study is sponsored by The University of Oxford. The study team is co-led by Dr Kay Wang (University of Oxford) and Professor Mike Thomas (University of Southampton). Dr Sarah Tonkin-Crine is leading the research involving health care professional and patient interviews about views of FeNO.

# Who has reviewed the study?

This study has been reviewed and given favourable opinion by Berkshire B Research Ethics Committee. The reference number is 20/SC/0235.

# Further information and contact details:

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

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**Thank you for considering taking part.**