

**INFORMATION LEAFLET FOR HEALTH CARE PROFESSIONAL INTERVIEWS**

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

**Semi-structured interviews with health care professionals**

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?

We aim to explore health care professionals' barriers and facilitators to the use of a FeNO-guided asthma management algorithm in primary care. We are doing this study to inform development of a new online intervention for health care professionals who review asthma patients in primary care.

Decisions about changing asthma medications or adjusting treatment doses are often based on patient-reported symptoms and lung function tests. However, these are not reliable indicators of steroid-responsive inflammation.

To give health care professionals a more accurate measure of steroid-responsive inflammation in their patients’ airways, our intervention will give them the opportunity to measure their patients’ fractional exhaled nitric oxide (FeNO) using a simple non-invasive breath test. FeNO is a specific by-product of the type of inflammatory pathway which is likely to respond to inhaled steroids. FeNO levels are therefore higher in patients who are more likely to benefit from inhaled steroids.

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 clinicians’ views on the feasibility and practicalities of using FeNO to guide clinical decisions during asthma review consultations and their views on intervention materials designed to support the use of FeNo during primary care asthma review consultations. This research is funded by the National Institute for Health Research (NIHR). This study has been reviewed and received favourable opinion Berkshire B Research Ethics Committee (REC Ref: 20/SC/0235).

# Why have I been invited?

You have been invited to take part in this study because you conduct asthma review consultations in primary care.

# Do I have to take part?

No, taking part is entirely voluntary and you can withdraw at any time if you later change your mind, without giving a reason. Withdrawal will not affect your employment rights.

# What will happen to me if I decide to take part?

We would like you to take part in a telephone, online (e.g. using Microsoft Teams or Skype) or face to face interview in your general practice or, if preferable, another location (university premises, your own home, public place, e.g. café). The interview will be arranged at a time to suit you and should take between 30 and 45 minutes.

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

Written informed consent will be taken from participants in person at the start of interviews/consultations, otherwise, consent will be obtained verbally at the start of interviews conducted over the telephone or online. You will receive a copy of the signed consent form via email.

# What should I consider?

The main things to consider are whether you are comfortable having a researcher asking you questions about your views and experiences of FeNo-guided asthma management.

# What are the advantages and disadvantages of taking part?

There are no direct advantages or disadvantages to you. The information gained from this study will be used to improve the care of patients supporting health care professionals with using FeNO during asthma review consultations in primary care.

# Will my 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 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 has been checked the recording will be destroyed. The written transcript will not include any names or other defining details that can identify you 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 relevant 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 I be reimbursed for taking part?

We are able to offer you £80 to reimburse you for taking part in the study.

# What will happen to my data?

The University of Oxford will use your 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. The people who analyse the information will not be able to identify you 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 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 Dr Sarah Tonkin-Crine, Chief Investigator for the study, using the contact details at the end of this Information Sheet.

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

# Taking part is entirely voluntary and, if you agree to take part, you can withdraw at any time if you later change your mind, without giving a reason. You 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 and our information sheet and consent form for patients.

# 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.**