

**INFORMATION LEAFLET FOR PROFESSIONALS**

**D**evelopment and **E**valuation of an online **F**eNO-guided asthma management **IN**terv**E**ntion in primary care: feasibility study (DEFINE-Feasibility)

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 the 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 barriers and facilitators in the use of a FeNO-guided asthma management algorithm in primary care. We are doing this study to inform the implementation 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.

Currently, 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 general practice staff members’ views on the feasibility and practicalities of using FeNO. We will ask general practices to implement FeNO in their asthma review consultations and ask practice staff about their views on using FeNO. Health care professionals will also be asked about 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 by the North West - Greater Manchester East Research Ethics Committee (REC reference 21/NW/0078).

# Why have I been invited?

You have been invited to take part in this study because you work in a general practice surgery and/or 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?

Healthcare professionals and practice staff are expected to be involved in an implementation wave for about 4-6 weeks. Health care professionals at participating practices will be asked to undertake online training and use the FeNO-guided algorithm in their asthma review consultations. General practice staff will be asked about their views on implementation.

We would like you to take part in a telephone interview. The interview will be arranged at a time to suit you and should take between 30 and 45 minutes. Interviews may be able to take place in person at your practice if you prefer and if possible.

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

Informed consent will be obtained verbally at the start of interviews conducted over the telephone and a written record made by the interviewer. Written informed consent will be taken if interviews are in person. You will receive a copy of the recorded 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 by 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 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 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 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 6 years following the end of the study at the University of Oxford following the 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 including commercial collaborators. They will be stored for 6 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 not identify you.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 completing an interview. You or your practice can claim for this reimbursement by providing your bank details or providing an invoice. If the payment is by BACS transfer your bank details will be stored for 7 years in accordance with University of Oxford financial policy.

# 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 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 Kay Wang, 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 be able to choose whether 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 Kay Wang 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 the design of this study and the 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 Kay Wang is leading the research involving general practice staff and patient interviews about views of FeNO.

# Who has reviewed the study?

This study has been reviewed and given favourable opinion by the North West - Greater Manchester East Research Ethics Committee. The reference number is 21/NW/0078.

# 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.**