

## **This is a participant information sheet (PIS) for healthcare professionals to take part in an asthma study**



**This leaflet describes our asthma study and explains what we are asking you to do if you decide to participate.**

**Thank you for reading this leaflet and considering whether to take part in our study.**

## Background to the study

In the UK, asthma is most commonly diagnosed in primary care. Yet, reports suggest that over and under-diagnosis of asthma is common in routine practice in children and adults. An asthma diagnosis clinical decision support system (CDSS) for primary care professionals has the potential to facilitate best practice in achieving a diagnosis of asthma and help to improved shared decision making by providing a method of sharing information with patients.

We have developed an asthma diagnosis CDSS which uses a prediction model to calculate the probability of an asthma diagnosis from elements in the history, prescribing and past test results taken from the patient electronic health record. Depending on the probability of asthma, the CDSS provides information and suggestions (based on the most recent asthma guidelines) to help determine if asthma is the cause of symptoms or not. The CDSS has been designed to actively involve patients during the consultation, and we would like to understand how useful health professionals find it.

## Why have I been invited to take part?

You have been invited to take because you are a primary care clinician and your GP practice has agreed to be one of the research sites that used the asthma diagnosis CDSS. We want to get the thoughts and experiences of primary care clinicians who used the asthma CDSS.

## Do I have to take part in the study?

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to complete a consent form indicating your willingness to participate in the study. If you do decide to take part, you are still free to withdraw from the study at any time without giving a reason. Deciding not to take part or withdrawing from the study will have no impact on your healthcare role or your legal rights. You will be given at least 7 days after reading this information sheet to think about whether you want to participate in the study and make your decision.

## What does the study involve for healthcare professionals?

If you agree to participate in the study you will be asked to complete and sign a consent form stating that you have read this participant information sheet, and that you understand what the study involves and are happy and willing to take part. The consent form will be emailed to you and you complete it and return the form to the research team by email prior to the interview. You will be asked to take part in a semi-structured interview with a researcher that will last approximately 30 minutes.

We would like to hear your views and experiences on what it was like using the prototype asthma CDSS, whether it helped in the decision-making process around asthma and how compatible it was with the computer systems you currently use. The interview will be conducted at a time that suits you. Because of the lock-down restrictions related to COVID-19 the interviews will be conducted by telephone. If the COVID-19 restrictions are lifted, we will conduct either face to face interviews or telephone interviews.

With your consent the interviews will be audio recorded and everything that you tell us will be transcribed and anonymised before we review and analyse our findings.

## What happens to the results of the study?

The results of our study will help us understand what primary care healthcare professionals think of the prototype CDSS and whether it was helpful when assessing a patient who presents with symptoms suggestive of asthma. We will publish the results of the study in health-related academic journals however, no healthcare professional taking part in the study will be identified.

Direct quotes from your interview will be used in the reporting of the interviews but they will be anonymised and presented in such a way that prevents you from being identified in any way. If you would like to be informed about the results of the study, please let us know and we will send you a summary of the results.

### **Can I be sure that my participation in the study will be confidential?**

Yes. Any information about you, and everything that you say in the interview will be anonymised and no names of a healthcare professional will be used in any report or publication. All study documentation will be kept for a minimum of 3 years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor. Your data will be processed in accordance with Data Protection Law. All information collected about you will be kept strictly confidential. Your data will be referred to by a unique participant number rather than by name. If you consent to being audio recorded, all recordings will be destroyed once they have been transcribed by a transcription service. Your data will only be viewed by the researcher/research team and the transcribers at First Class Secretarial Services.

The data collected from you during the study will be looked at by this study's wider research team, individuals from the regulatory authorities and from the sponsors where it is relevant to you taking part in this research. All electronic data will be stored on a password-protected computer file and all paper records will be stored in a locked filing cabinet. Your consent information will be kept separately from your responses in order to minimise risk. The University of Edinburgh and NHS Lothian are the sponsors 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. All study documentation will be kept for a minimum of 3 years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor. For general information about how we use your data go to:

<https://www.ed.ac.uk/records-management/privacy-notice-research>

### **How will we use information about you?**

We will need to use information from you about your clinical background, your years of experience as a healthcare professional, and your current role. This information will include your name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will be unable to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

### What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. However, if you request that your data is deleted and not used in the study, we will remove all your data from the study.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, your anonymised data will be used in future research studies related to asthma CDSSs.

### Where can you find out more about how your information is used?

You can find out more about how we use your information from:

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- by asking one of the research team
- by sending an email to [asthma.diagnosis@ed.ac.uk](mailto:asthma.diagnosis@ed.ac.uk)
- by ringing us on 07766 772645

### Who is organising and funding the research?

A team from the University of Edinburgh is running the study. Professor Hilary Pinnock a Professor of primary care respiratory medicine and Dr Luke Daines a GP and clinical research fellow from the University of Edinburgh are leading the study and Dr Eddie Donaghy is the researcher who will be conducting the interviews and organising the data collection. The study is funded by Asthma UK/Innovate UK and has received ethical approval from South West - Cornwall & Plymouth Research Ethics Committee.

### Who are the commercial collaborators involved and how will they manage my data?

- Optimum Patient Care is a social enterprise supporting medical research and services to improve the management of long-term conditions within Primary Care.
- Tactuum is a healthcare software company, specialising in the design and development of software services and products within the clinical decision support domain.

Neither Optimum Patient Care nor Tactuum will have access to personally identifiable information about your patient. Tactuum will conduct an ongoing analysis of usage activity of the asthma CDSS in participating GP practices. This data will be securely transferred by Tactuum to the University of Edinburgh as it is collected from the CDSS's in participating GP practices. No personal patient or clinician related data will be involved or transferred, only usage data of the CDSS. The usage data will be stored on a password protected folder on the password protected server of the Usher Institute, University of Edinburgh.

Firestore (Google Analytics) will be used to collect usage data from the CDSS. Patient identifiable data (e.g. name, age, address, CHI number) is not required for usage data and will not be extracted. In order to track how the CDSS is used by healthcare professionals we will use an anonymous user ID (e.g. Vision#1435) within the CDSS. As an additional layer of security, the user ID is sent to Firestore, it will be hashed (e.g. turning it into "fgg2334v2x23zf4k2k34vvh23") to ensure the data is anonymous. We intend to collect usage data in real-time.

The firestore account will be setup by Edinburgh University with assistance from Tactuum. This means that Tactuum will not be storing any usage data as such but it will be held on secure cloud servers hosted by Google.

## Who can answer any questions I may have about the study?

- If you have any questions about the study or for more detailed information, please contact the study's researcher: Dr Eddie Donaghy  
**phone:** 07766 772645 and/or **email** [asthma.diagnosis@ed.ac.uk](mailto:asthma.diagnosis@ed.ac.uk)
- If you would like to speak to someone independent of our research team about taking part in the study, please contact: Dr Vicky Hammersley  
**phone:** 07969 775912 and/or **email:** [Vicky.Hammersley@ed.ac.uk](mailto:Vicky.Hammersley@ed.ac.uk)
- If you wish to make a complaint about the study please contact NHS Lothian: Patient Experience Team, 2 – 4 Waterloo Place, Edinburgh, EH1 3EG  
**Phone:** 0131 536 3370 and/or **email:** [feedback@nhslothian.scot.nhs.uk](mailto:feedback@nhslothian.scot.nhs.uk)