# **Fractional exhaled Nitric Oxide (FeNO) Test – case for change**

***Notes to author***

* *This is a template to describe a case for change to implement FeNO testing in your setting. It sets out the benefits of FeNO, the strategic positioning, and the health burden of asthma to make a case for implementing FeNO testing as part of a wider asthma pathway. The economic literature on FeNO is limited – this template does not look to describe a causal effect as a result of implementing FeNO testing (e.g. avoided admissions, change in drug budgets/spend, return on investment etc.).*
* *Sections highlighted green should be amended*
* *You are free to amend any other section of the document as you wish, but you do not necessarily need to in order to complete the document*
* *Text is red thought the document is for information and should be deleted on completion of the document*
* *The corresponding dataset in the FeNO Fractional exhaled Nitric Oxide (FeNO) Test - Case for Change dataset should be used to support completion of this document*

**Organisation:**

xxx

**Lead author and contact details:**

xxx

**Summary:**

To seek funding to implement FeNO testing across primary/secondary care within [xxx ICS/CCG/PCN/trust] and redesign the corresponding care pathway [through the creation of respiratory diagnostic hubs/by deploying FeNO testing across our PCNs].

The objective of this work is to; 1) improve outcomes for people with suspected asthma through improved diagnostic speed and accuracy; and 2) improve the outcomes for people with confirmed asthma through improved disease management.

**Geography covered in application:**

xxx

**Investment required:**

Investment Value

**Xxx £xxx**

**Xxx £xxx**

**Xxx £xxx**

# Document purpose and objective

**This document provides a case for change** to improve asthma pathways for [insert name ICS/CCG/PCN/group of PCNs] through the creation of [respiratory diagnostic hubs which include FeNO testing /by deploying FeNO testing across our PCNs]. This document provides a description of the proposal and associated project delivery plan.

**By delivering this proposal, we aim to improve outcomes** for people with suspected asthma through improved diagnostic speed and accuracy and improve the outcomes for people with confirmed asthma through improved disease management.

# Context and background

**Asthma is a chronic disorder** of the airways, caused primarily by inflammatory processes and constriction of the smooth muscle in airway walls. Symptoms include recurrent episodes of wheezing, breathlessness, chest tightness and coughing ([NICE, 2014](https://www.nice.org.uk/guidance/dg12)).

**Over 5.4 million people have a diagnosis of asthma** in the UK of which 1.1 million are children and 4.3 million are adults (Asthma UK – Severe Asthma Report, 2018).

The **NHS spends around £1.1 billion a year treating and caring for people with asthma** (Mukherjee et al. 2016), **with 90% being spent directly on asthma medication** including excessive prescription of steroid inhalers (Long Term Plan, 2019).

Statistics released from Asthma UK show that over 120,000 asthma sufferers in the UK are at risk from wrongly prescribed medication and NICE findings in **studies of adults diagnosed with asthma suggest that up to 30% do not have clear evidence of asthma** with other studies suggesting that asthma may be underdiagnosed in some cases. As a consequence, people could potentially be on medications that they do not need or not receiving the medication they require to control their symptoms.

A significant opportunity exists to improve accurate asthma diagnosis. Incorrect use of medication can also contribute to poorer health outcomes and increased risk of exacerbations, or even hospital admission (Long Term Plan, 2019).

**National policy context**

The Long Term Plan outlines a commitment to “**detect and diagnose respiratory problems earlier**” and supports the diagnosis of respiratory conditions through Primary Care Networks (PCNs). This work directly supports this national policy direction.

**Local policy context**

[Add any local ICS policy/direction for respiratory/asthma which may be relevant to this proposal]

# Proposal and opportunity for the ICS

This proposal is seeking to deploy FeNO testing at scale across [xxx ICS/CCG/PCN/Group of PCNs] through the creation of primary care respiratory diagnostic hubs which include [FeNO testing / by deploying FeNO testing across all [insert number] PCNs.

The aims of this work are to:

* Improve outcomes for **people with suspected asthma** through improved diagnostic speed and accuracy, thus supporting national [and local policy – if relevant]
* Improve the outcomes **for people with confirmed asthma** through improved management of their condition
* **Improve patient care** through better understanding of an individual patient's condition in relation to their fractional exhaled nitric oxide (FeNO) score
* **Improve system working** through more efficient respiratory management in primary care, reducing the demand on secondary and tertiary care
* **Support the response to the Covid-19 pandemic** by effectively managing people outside of a hospital environment
* **Further standardise the provision of respiratory care** for people by creating protocols for diagnosis, chronic disease management and acute disease management
* **Reduced use of SABA prescriptions** (associated risk with >12 inhalers per year) and prednisolone through accurate diagnosis of query asthma
* **Reduction in emergency hospital admissions** by diagnosing asthma earlier
* **Sustainably implement FeNO** testing into our care pathway
* **Address health inequalities** by improving access and outcomes for people, and empowering people to self-manage their respiratory condition

This proposal is seeking £xxx in order to achieve this – this funding is to support the implementation of xxx FeNO devices over [xx duration], along with implementation support, comprising; xxx [e.g nursing time etc].

The work will be delivery via the [Insert delivery mechanism – could be ICS / PCN development group, clinical respiratory network etc.] Further details on our project delivery plan are provided later in this document.

# Fractional exhaled Nitric Oxide (FeNO)

Airway inflammation is a core indicator suggesting asthma and other lung diseases. The production of Nitric Oxide (NO) is often found to be higher amongst patients with inflammatory conditions, such as eosinophilic (allergy-induced, type 2 inflammation) asthma.

Current conventional evaluation methods for respiratory conditions, such as peak flow and spirometry, only measure lung function and bronchoconstriction. They do not assess airway inflammation.

The measurement of exhaled Nitric Oxide, or FeNO (Fractional Exhaled Nitric Oxide) testing, is a simple point of care objective test which can be used to support the diagnosis and management of respiratory conditions including asthma, but also to differentiate between asthma subtypes as well as Chronic Obstructive Pulmonary Disease (COPD), Asthma-COPD Overlap Syndrome and other interstitial lung diseases that are not assessed by other means, such as lung function tests.

FeNO is recommended by NICE as an option to help diagnose asthma in adults and children by identifying people who are likely to respond to treatment with inhaled corticosteroids (ICS).

FeNO testing can help to address the over-, under-, and mis-diagnosis of asthma when the results are incorporated into an asthma diagnostic and management pathway. FeNO can also facilitate early detection of non-adherence to asthma medication.

By aiding to determine the correct asthma subtype, and address the diagnosis issues, FeNO testing can contribute to faster diagnosis of asthma, support decision making in relation to the best prescription and help tailor inhaled corticosteroid (ICS) dosage levels. The outcome of which contributes to the correction of prescription medication amongst people where it could be optimised, as well as the 50% of people who respond poorly to steroids.

The benefits of FeNO testing include:

* Being non-invasive, quick and easy to perform
* Increasing the diagnostic accuracy and speed for suspected asthma
* Showing a patient’s response to inhaled corticosteroid treatment, enabling the correct prescription of medication and safer/monitored adjustments
* Showing patient compliance
* Aiding identification of patients who do/do not require on-going treatment
* Shown to be superior to the majority of conventional tests of lung function, such as peak flow recording and spirometry
* Aiding definition between allergic, type 2 (eosinophillic) and non-allergic asthma
* Can be used to confirm diagnosis improving misdiagnosis rates for asthma and leading to more appropriate referral to secondary care
* The possibility of using FeNO for dose adjustments and monitoring purposes could result in a reduction in inappropriate inhaler prescribing.
* The simplicity of FeNO testing means that anyone can use a FeNO device. This would reduce dependency on GPs within primary care as FeNO testing could be conducted by a practice nurse or other healthcare professional.
* FeNO increases patient understanding of their condition as they can relate to their FeNO score

**Devices and NICE approval**

Two machines FeNO devices are currently approved by NICE (see NICE Diagnostic Guidance 12 - [DG12](https://www.nice.org.uk/guidance/dg12)) – provided by Circassia and Bedfont.

Both FeNO machines are small, portable devices – one handheld and one desk based. A FeNO test is performed by breathing into the device for (either via a tube attached to a hand-held monitor, or tube directly mounted to the handheld device). This measures the amount of nitric oxide in the air being breathed out. A high level of NO in this exhaled air can be a sign that there is inflammation within the patient’s airways. The results of this test are displayed on the hand-held monitor and are used as part of the diagnosis jigsaw puzzle and to aid ongoing condition management.

**Quality Outcomes Framework**

Practices are be expected to use a minimum of two diagnostic tests to confirm an asthma diagnosis as part of QoF.

FeNO is now listed as one of the tests to contribute to the achievement of QoF points.

# Current care delivery

[Author to describe their current approach to management of asthma / describe current protocols]

**Current FeNO use**

[Author to describe their current use of FeNO testing in their setting – if any]

# Local impact of asthma

**Asthma prevalence**

Across England, 6.48% of registered patients in primary care across England are recorded as having asthma - amounting to just over 3.9million patients (Source: Quality and Outcomes Framework (QoF) AST001, data for 2019-20). If 30% of these people have been misdiagnosed as NICE suggest, then approximately 1.17million people in England have potentially been misdiagnosed.

Within [insert name CCGs], asthma is shown to have the health burden described in table 1 below.

(Note – data relates to both pre and post April 2021 CCG boundaries, and is determined by the available datasets)

***Note to author – use the corresponding dashboard to determine the below data, or use locally derived data if preferred.***

Through the introduction of FeNO testing in our locality, we have the goal of improving asthma outcomes and reducing the health burden of this condition – contributing to the improvement in the metrics shown below.

 ***Table 1 – burden of Asthma***

|  |  |  |
| --- | --- | --- |
| Metric | Figure  | Data source |
| QoF – AST001: Number of patients registered with asthma (QoF AST001) | Xxxx – add from corresponding spreadsheet tool | QoF 2019/20 |
| QoF - AST002: With measures of variability/reversibility (8+), denominator inc. PCAs | Xxxx – add from corresponding spreadsheet tool | QoF 2019/20 |
| ED Attendances – activity | Xxxx – add from corresponding spreadsheet tool | HES data – 2019/20 |
| ED Attendances – Costs (£) | Xxxx – add from corresponding spreadsheet tool | HES data – 2019/20 |
| Emergency hospital admissions for asthma in adults (aged 19 years and over) | Xxxx – add from corresponding spreadsheet tool | PHE InHale dashboard, 2018/19 |
| Hospital admissions for asthma (under 19 years) | Xxxx – add from corresponding spreadsheet tool | PHE InHale dashboard, 2019/20 |
| Mortality data – number of asthma related deaths per 100,000 heads | Xxxx – add from corresponding spreadsheet tool | PHE InHale dashboard, 2017/19 |
| Proportion of patients prescribed a preventer inhaler without an antimuscarinic who were prescribed 6 or more SABA inhalers (%) | Xxxx – add from corresponding spreadsheet tool | NHS BSA EPACT2 dataset, 12 month period ending March 2021 |

# Proposed clinical pathway

[Describe the new clinical pathway which incorporates FeNO testing]

***Suggested*** topics to cover include;

* How the new care pathway will operate
* Improving access which will help reduce inequalities, including mobile services
* Reducing the use of secondary care services
* Age ranges – pathway(s) for 18+ or 5+ years?
* How to reduce frequent attenders?
* How it will address frequent exacerbations?
* How medication adherence may improve?
* How will be delivered, and in what setting?

# Delivery plan

**Project plan and stakeholders**

Describe your delivery plan in this section. A number of suggested topics to consider are listed below;

* Describe the project plan in order to implement – what, when, how?
* Goals in terms of minimum activity by a set date – number of people receiving the new service/pathway
* Key stakeholders and those organisations involved
* Roles and responsibilities to deliver the plan
* How the project will scale up with time
* How the service/pathway will be embedded as usual business and become sustainable in the long term
* Project governance – including necessary IG and decision making
* How you might collect patient feedback?

**See an example project plan, drive diagrams etc on the FeNO toolkit site** [here](https://wessexahsn.org.uk/projects/424/managing-the-change-process-from-implementation-to-reporting)

**All resources on the FeNO toolkit can be viewed** [here](https://wessexahsn.org.uk/projects/439/resources-at-a-glance)

**Project evaluation and impact**

Describe how you plan to measure the success of your project

**Preferred device supplier and device costings**

Two machines FeNO devices are currently approved by NICE ([DG12](https://www.nice.org.uk/guidance/dg12)) – provided by Circassia and Bedfont.

We have selected [Circassia/Bedfont] as our preferred supplier and propose we procure xxx devices – this is xxx device[s] per xxx PCNS/ xxx device per diagnostic hub. We plan to deliver xxx tests annually (or xxx tests per machine).

Costs are summarised in the table below:

**Notes to authors;**

* *Other suppliers are available, but are not currently NICE approved (See NICE DG12).*
* *It is a local clinical decision on which supplier is selected.*
* *An objective comparison of the two suppliers is included on the FeNO Toolkit website* [*here*](https://wessexahsn.org.uk/img/projects/FeNO_device_compare_V1.0_final%20%281%29.pdf)
* *Procurement teams should be engaged as part of supplier selection. A procurement process may be required to determine which supplier is the preferred one, depending on the procurement value.*

***The values for this table can be lifted directly from the accompanying spreadsheet – these values do not include any further discounts a locality may negotiate with a supplier, or delivery charges.***

|  |  |
| --- | --- |
| Total number of tests required per year | 1200 |
|  |
| Total number of devices required  | 3 |  |
|  |
| Total cost of devices (exc VAT, delivery and any agreed discounts) |  £2,640.00  |  |
|  |
| Total cost of mouthpieces (exc VAT, delivery and any agreed discounts) |  £7,390.00  |  |
|  |
| Total cost (Exc VAT, delivery and Exc deployment /staffing etc.) |  £10,030.00  |  |
|  |
| Cost per test (Exc VAT, delivery and Exc deployment /staffing etc.)  |  £6.69  |  |
|  |

***DELETE AS APPROPRIATE:***

**The Circassia machine** does not require servicing but does have a life span of five years after which we will need to replace the devices. Capital planning will be required to ensure replacement of all devices after 5 years of use.

**The Bedfont device** does require servicing , at the following intervals and costs. The device should be sent away for its service, and usually takes around 1 week.

* Years 1, 2, 3 and 4 - £150 +VAT
* Year 5 – major service at £600 +VAT
* The cycle is then repeated for years 6, 7, 8, 9 and 10

**Staff costs and other resources**

Describe the staff costs and other resources required to deliver this programme here…

# Next steps

Xxx board/group/forum is asked to approve the funding to deliver this programme.

# References

Asthma UK (2018) Severe Asthma Report – available at <https://www.asthma.org.uk/support-us/campaigns/publications/difficult-and-severe-asthma-report/>

Mukherjee et al. (2016) The epidemiology, healthcare and societal burden and costs of asthma in the UK and its member nations: analyses of standalone and linked national databases - Available at <https://pubmed.ncbi.nlm.nih.gov/27568881/>

NICE (2014) NICE guideline [NG80] Asthma: diagnosis, monitoring and chronic asthma management – available at <https://www.nice.org.uk/guidance/ng80>

NHS England (2019) – The Long Term Plan – available at <https://www.longtermplan.nhs.uk/>