Wessex Academic Health Science Network

Accelerated Access Collaborative

Office for Life Sciences

National FeNO programme Impact report

May 2023

Part of The AHSN Network

Contents

This report provides a summary of the national FeNO programme's impact over the lifecycle of the programme, comprising:

Executive summary – background and ambition

The NHS England Accelerated Access Collaborative (AAC) supports the **NHS to more quickly adopt clinically and cost-effective innovations** enabling patients access to the best new treatments and technologies.

The **national FeNO programme is part of the AAC's Rapid Uptake Product (RUP) programme** – a programme to accelerate adoption of late-stage innovation (post-NICE appraisal) which ran from April 2021 to March 2023.

The **AHSN Network delivered this programme** as part of its commission from the NHS England Innovation Research and Life Sciences (IRLS) team. All 15 AHSNs in England actively delivered this programme in their local geography, with Wessex AHSN acting as the lead AHSN.

Increase in FeNO devices in England between March 2021 and March 2023

FeNO tests (Fractional exhaled Nitric Oxide) measure the amount of nitric oxide when someone exhales and provides an indication of eosinophilic (allergic) inflammation in the airways. The test takes around 10 second to complete and alongside a detailed clinical history and other tests, **FeNO can be used to support asthma diagnosis and management** in adults and children (5+ years).

The **programme set a goal of improving patient care and outcomes** through effective implementation and integration of FeNO testing to enable diagnosis and monitoring of asthma in primary care.

The programme **supported the NHS to increase patient access to FeNO testing significantly** (see mapping of FeNO sites, right) while simultaneously increasing staff capability through the creation of dedicated FeNO training describing use of the test testing and its interpretation. The **programmes greatest legacy is improving the lives of people with suspected or diagnosed asthma as a result.**

The following two pages of this executive summary **describe the impact of the programme in numbers**, and **suggest the critical factors** that contributed to this programme's success.

Executive summary – headline impacts

Implementation toolkit created with **13,592** views

1,244 new devices entering primary care

Estimated **53% of PCNs now with access** to FeNO testing in England *

Two training modules developed – resulting in **4,964 hours** of training

91% of people said the training will help them in their role

The programme has supported the **correct diagnosis of 58,000* new asthmatics** more accurately and faster

33 AAC Pathway Transformation Fund projects awarded – total value £915,000, supporting 118 FeNO devices become embedded and used

Supported **market stimulation** – growing the market and helping to drive down access costs

722 people joined our national learning collaborative series over 15 months – with 12 guest presentations

* - estimated, see slide 32 for further details

Executive summary - critical success factors

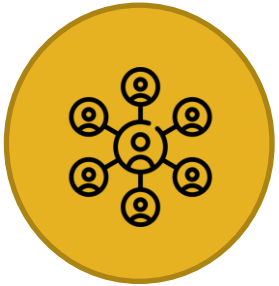
We've identified a number of critical success factors that have helped contribute to the success of this programme, comprising:

Take a pathway approach to transformation, focusing on adopters

Allow for local adaptability and local focus in the context of a wider ambition

Partnerships and collaboration are essential

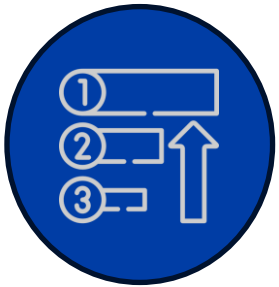
The right people are essential – including engaged patients and capable clinical leaders



Networked leadership, built on local knowledge

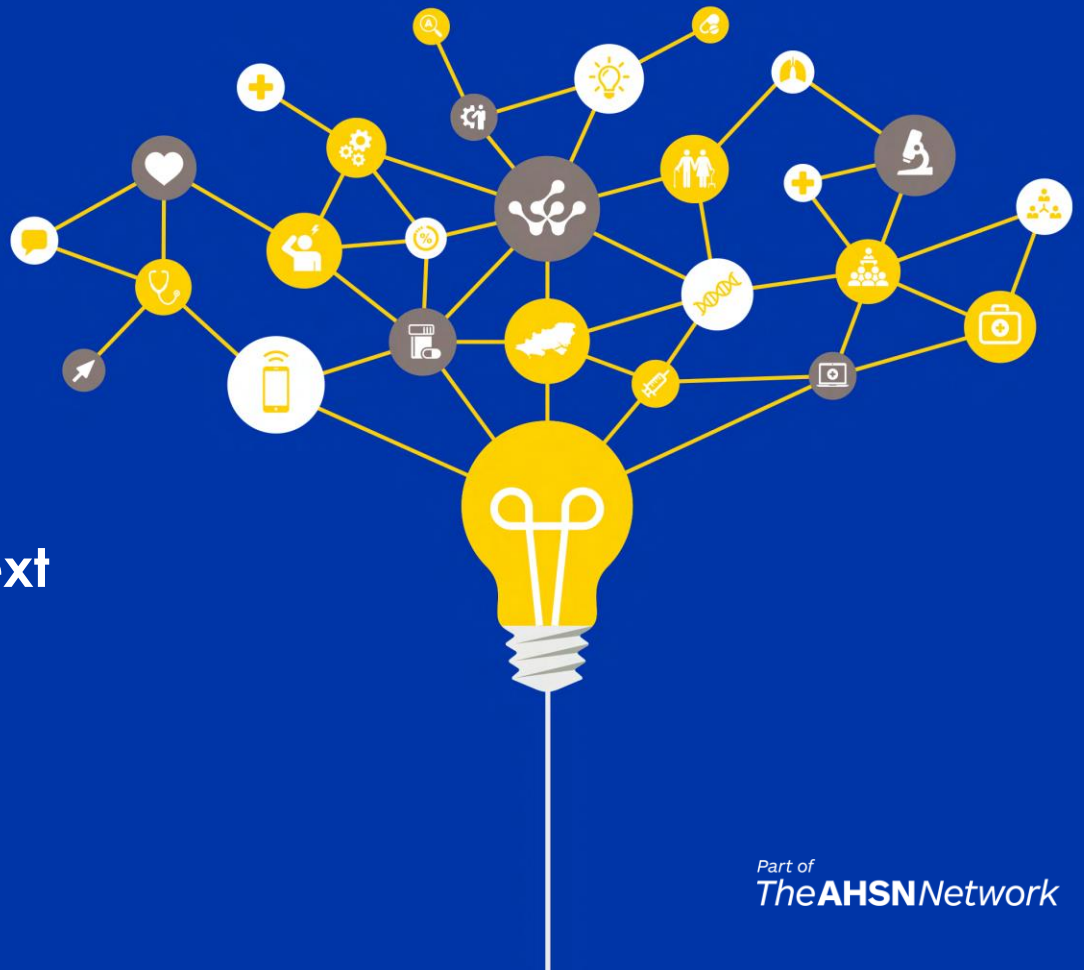
Underpin the programme with sound theory, planning and processes

Appetite and ambition



Clear vision and priorities that align with national, local and individual ambitions

A cohesive, diverse and empowered steering group



1. Introduction and context

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Introduction and background

The NHS England Accelerated Access Collaborative (AAC) supports the NHS to more quickly adopt clinically and cost-effective innovations enabling patients access to the best new treatments and technologies.

As part of the AAC's work to support stronger adoption and spread of proven innovations, the AAC has selected a range of late-stage innovations (post-NICE appraisal) to accelerate uptake in the NHS - 'Rapid Uptake Products' (RUPs).

This programme has been designed to identify and support products with NICE approval that support the NHS Long Term Plan's key clinical priorities, but have lower than expected uptake to date.

The national FeNO programme is part of the AAC RUP programme, and ran from April 2021 to March 2023 (2 year programme).

The AHSN Network delivered this programme as part of its commission from the NHS England Innovation Research and Life Sciences (IRLS) team. Wessex AHSN acted as the lead AHSN, providing national leadership and strategic direction to the programme, with all 15 AHSNs in England actively delivering this programme in their local geography. The national FeNO programme was delivered in partnership with the Asthma Biologic RUP, supporting the identification and treatment of severe asthma with biologic therapies. Wessex AHSN took an implementation science led approach to this adoption and transformation programme.

This report provide a summary of the national FeNO programme's impact over the lifecycle of the programme. Each AHSN may individually develop an impact report for their geography in addition to this report.

A brief introduction to FeNO testing

FeNO by NIOX®

bedfont est. 1976

NObreath®
Aids in the diagnosis & management of asthma, one breath at a time.

FeNO tests (Fractional exhaled Nitric Oxide) measure the amount of nitric oxide when someone exhales.

The score provides an indication of eosinophilic (allergic) inflammation in the airways. The test takes around 10 second to complete.

Alongside a detailed clinical history and other tests, FeNO can be **used to support asthma diagnosis and management.**

The national programme has supported to NICE approved suppliers – Niox, and Bedfont. Other FeNO testing equipment is available but was not part of this programme these suppliers did not have NICE approval at the time this programme commenced (April 2021).

FeNO can be used in **adults, and children,** from 5+ years

The opportunity for FeNO testing in primary care

The **first FeNO device was commercially released** in 2000 and became common place (but not universally adopted) in hospital settings by the early 2010s.

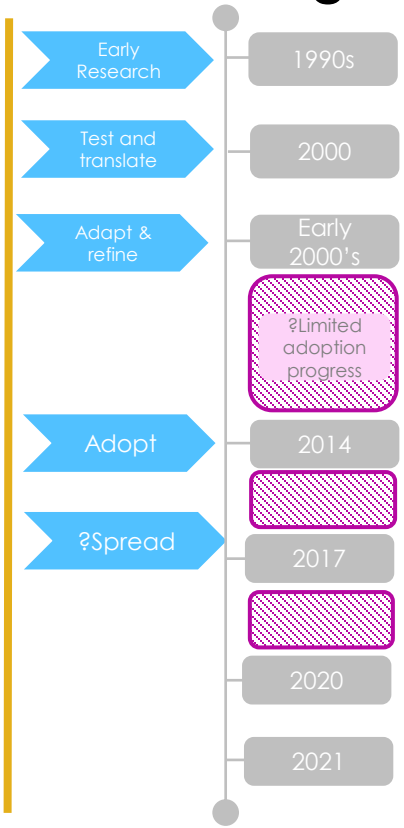
The Quality and Outcomes Framework (QOF, 2021/22) describes an asthma prevalence rate of 6.48% in England, **equating to 3.9 million people (aged 6+ years) with asthma**.

Between 2020/21 and 2021/22, the **number of asthmatics on the QOF register grew by 0.2%** - or around 8,000 people[1]. To diagnose 8,000 asthmatics, many more people need to present to health services with possible asthma. Literature estimates that 33% of people with an asthma diagnosis are misdiagnosed - i.e. that they may not even have asthma[2]. FeNO testing could contribute to reducing this rate.

Furthermore, **Asthma and Lung UK[3] estimates that there are 1 million+ asthmatics with poor asthma control**. It is these people who FeNO could best support with their ongoing asthma management, improving their lives as a result of better condition management.

FeNO has been rarely used in primary care, despite appearing in NICE guidelines (2017) and being referenced in QOF indicators from 2021/22. Most asthmatics are diagnosed and managed by primary care - and the NHS Long Term Plan (2019) describes an ambition to "do more to detect and diagnose respiratory problems earlier".

The wide-scale, systematic adoption of FeNO testing in England presents a significant opportunity to improve the lives of people with suspected and confirmed asthma.



1 - not an exact number due to annual variation in QOF denominator
2 - Aaron et al JAMA 2017 Jan 17;317(3):269-279
3 - https://www.asthmaandlung.org.uk/sites/default/files/Fighting%20back_V3.pdf

Programme ambitions

The aim of the FeNO programme was to:

- Improve patient care and outcomes by more effectively diagnosing patients with suspected asthma
- Increase widespread patient and clinician access to FeNO testing across primary care

These **ambitions are ageless** – looking to support both adult and children with suspected asthma

Four priority areas were identified through the national FeNO working group, which has representation from a wide range of stakeholders alongside clinical leads and public participants, all who were actively engaged with the programme throughout.

	Priorities/Areas of focus for delivery over the next 12 months
1)	Develop an educational training package for FeNO. Consider delivery through existing education providers. Pursue endorsement from NICE and PCRS
2)	Collect real world evidence with exemplar sites on cost and operational benefits realised and patient outcomes and document the model and approach
3)	Identify potential funding models and incentives to support uptake (prescribing savings achieved at GP level will be realised at system level) working with e.g. commissioners, STPs and ICSs
4)	Develop a rollout toolkit to support organisations to implement including; •Dissemination of emerging hub model from national respiratory programme GIRFT •Advice on how to implement FeNO •Business case and financial modelling support •Training package and deployment •Dissemination of exemplar pathway and clinical decision-making tools •Pathway Transformation Funding support •Summary of best practice case studies from exemplar sites

TheAHSNNetwork

NICE National Institute for Health and Care Excellence

PCRS

ASTHMA+ LUNG UK

Working with Accelerated Access Collaborative

ARTP

bedfont est. 1976

ARNS Association of Respiratory Nurse Specialists

British Thoracic Society

NHS England

FeNO by NIOX®

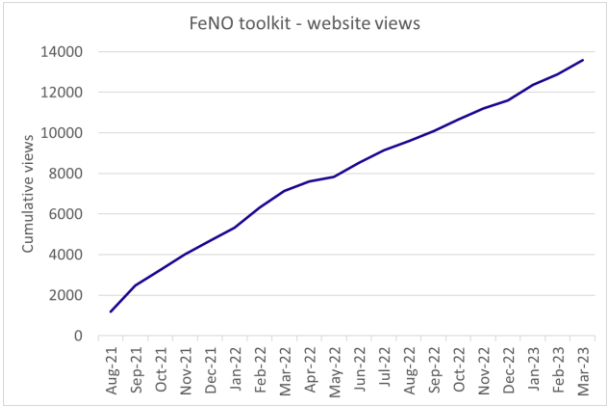
2. Core deliverables – FeNO toolkit

Part of TheAHSNNetwork

FeNO toolkit

Programme priority 4 - the **creation of an implementation toolkit** to support the delivery of the programme's aims - became a **core part of the programme**. Resources were created under three board headings:

- About the devices
- Clinical use and clinical guidance
- Implementation resources supporting transformation



We **saw continual use of the toolkit** throughout the programme – peaking at **13,592** views in March 2023. The toolkit remains open for use as a programme legacy.

In total, 15 sub-pages were developed, comprising **51 individual and original resources** (excluding re-hosted resources or resources created for the programme by other partners such as NICE FeNO case studies), with highlights comprising:

- Patient introductory video, blogs and podcast
- Patient leaflets and translated to 7 languages, alongside audio recordings of these languages
- AccuRx FeNO text message
- Two bespoke training modules (See further details at chapter 4) – which were the most commonly visited sub-page
- Ardens template to support data capture and record making
- Case for change templates and corresponding data packs

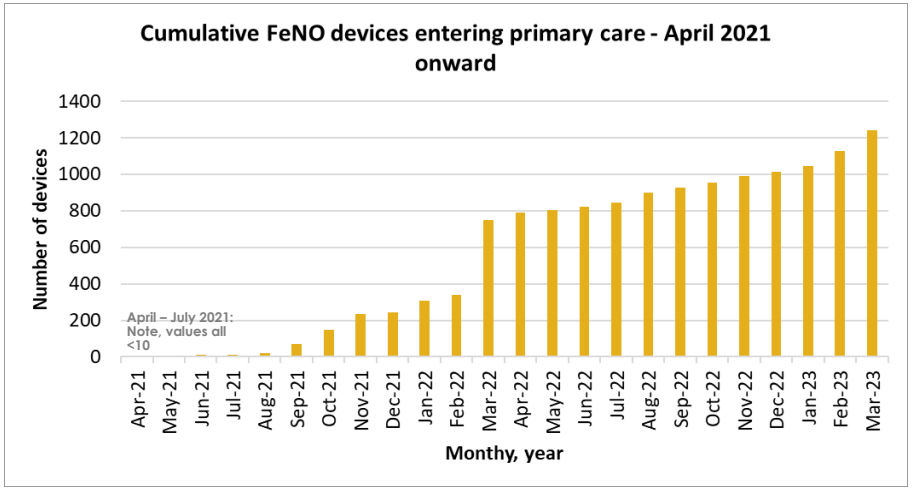
7040 views of patient video

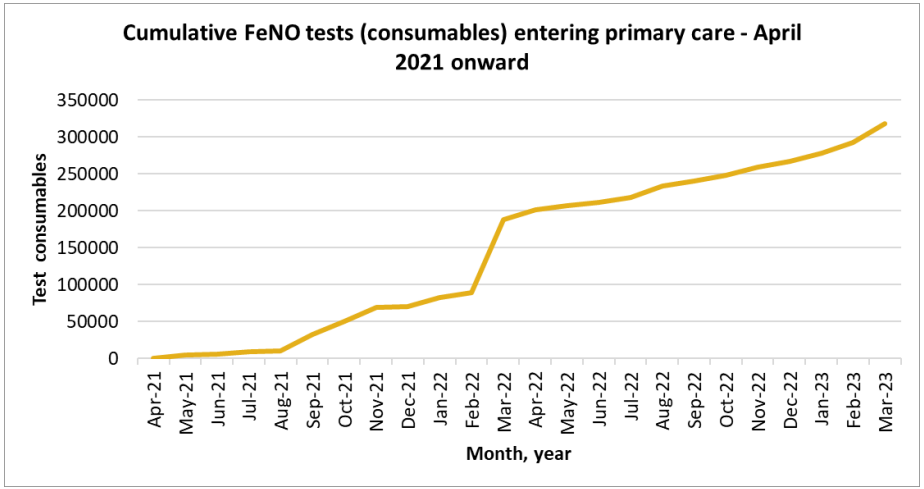
Devices and test entering use in primary care

Over the course of this programme, 1,244 new devices have entered primary care, 318,000 test consumables have been procured in primary care, and an estimated 89,040 people could be benefiting from FeNO testing in a diagnostic capacity*.

Data supplied to the AAC over the course of the programme illustrates the continual increase in the number of devices entering primary care in England (left hand graph), alongside the number of tests/consumables for FeNO devices also being procured (right graph).

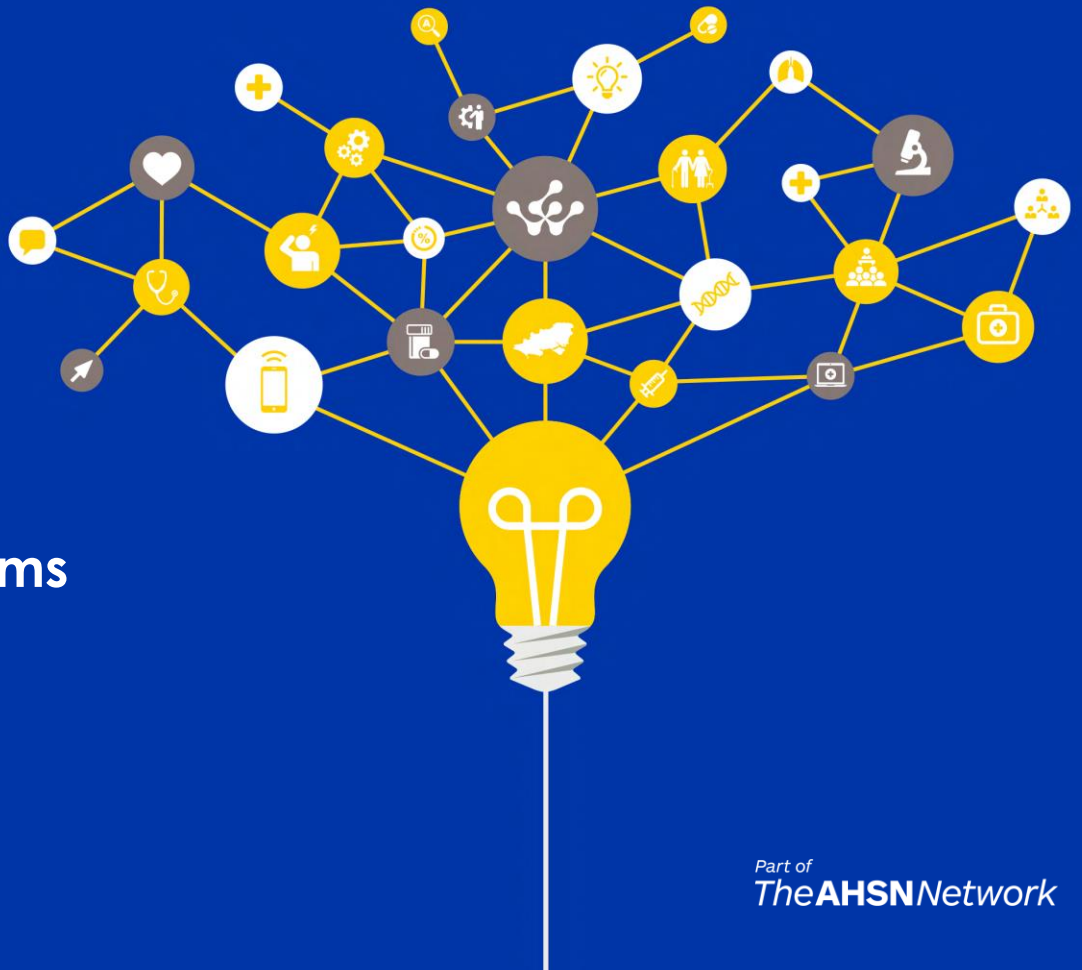
When commencing the programme, the AAC undertook research to make an estimated link between the number of tests being bought and the number of people benefiting from FeNO being used in a diagnostic way – estimated to be 28%.





* - The AAC undertook a literature review at the start of the national programme, and estimate that 28% of FeNO tests are used for a diagnostic reason, assuming all tests are used. This ratio has been used to estimate the number of people who could be benefiting from a FeNO test in a diagnostic capacity.

3. Impact on health systems



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Access to FeNO devices

The **density of FeNO devices** in primary care and across hospital settings care across England has **dramatically increased** over the course of the programme, representing improved patient access to FeNO testing.

The number of locations with 2 or more devices has also increased.

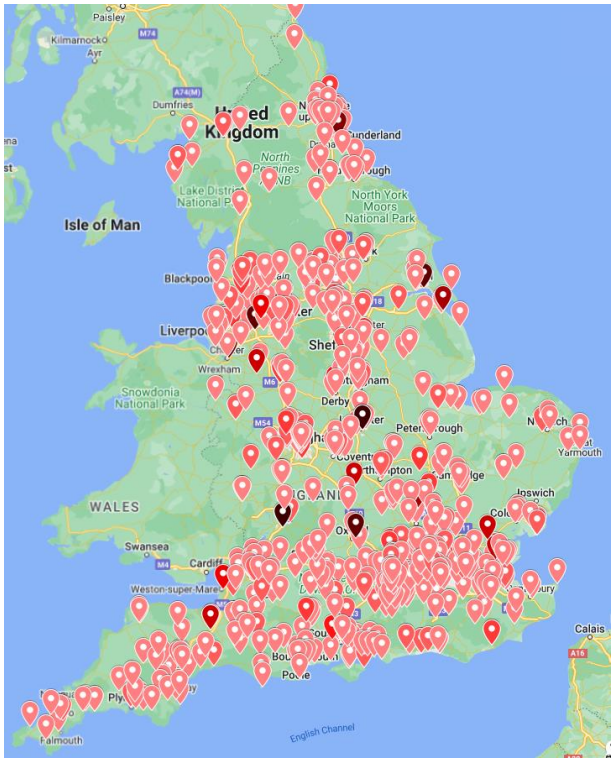
Data suggests **443 primary care locations took delivery** of 1+ device from April 2021 – March 2023

Baseline – Jan 2018 - Mar 2021

Key
Devices per site

- 0 - 2
- 3 - 5
- 6 - 7
- 8 - 10
- 11 - 13
- 15 - 23
- 24 - 28
- 31 - 32
- 35 - 76
- 80 - 145

End programme - Mar 2023



Data notes: Data supplied by two programme suppliers to AAC team and used with permission. Baseline data from Jan 18 to Mar 21. End of programme data represents data April 21 to Mar 23 comprising duration of programme plus baseline for cumulative total. Does not account for devices in use pre-Jan 18, or suppliers the programme does not support. Data does not include non-NHS/private settings.

Access to FeNO devices: National overview

Now estimate

53%

of PCNs in England have access to FeNO testing at the end of March 2023

The AHSN Network provided implementation support to teams adopting and implementing FeNO testing. Using a "best estimate" methodology based on the intelligence and insights of the 15 AHSNs, as estimation of PCN FeNO coverage has been made.

This describes the number of PCNs with access to a FeNO test – that could be, for example, through direct ownership at a practice level, through the provision of a FeNO device and testing service in a wider PCN, or through a local respiratory diagnostic service.

This highlights that accessibility to FeNO testing is becoming more common, and dispels a view that FeNO devices are not readily available in primary care.

What this analysis does not do is look at the density of FeNO devices within a practice group or PCN.

Pathway transformation fund

Open award site Bundle award site

The AAC and Office for Life Sciences (OLS) **funded 33 national FeNO projects through their Pathway Transformation Fund** (PTF) at a value of £915k, enabling 118 FeNO devices to enter use and support associated implementation.

The **PTF process aims to** support the important implementation activities that are essential when adopting a new technology, giving teams the resources, time and support they require.

Between February and April 2021, the **AAC ran a competitive process to award the PTF projects**, with project teams across England required to submit a written application describing their ambitions and project which was formally assessed. Wessex AHSN subsequently participated in a series of workshops to help iterate and develop the award process further, learning from our experiences on the FeNO programme.

The 33 national projects comprise two award categories:

- **Open awards** (N=8) where the applicants can apply for a grant of up to £250k, and define the own project within the scope guidance
- **Bundle awards** (N=25) which provide an implementation support package and grant 1 or 2 devices to a project team.

PTF – Impact and themes

As a condition of award acceptance, all project teams were required to submit an end project report to the national programme. A thematic report has been developed to summarise the success, learning and impact of the 21 PTF reports received. The full report can be found on the here, as can all original PTF reports.

Considering all reports :

- 21 of 33 projects returned PTF reports
- 8 projects achieved all set objectives (38%)
- All projects achieved or partially achieved all their objectives
- Collectively, **56 objectives were set across all 21 projects**, with 37 (66%) being complete and 19 (34%) being partially complete

Collectively, these reports self report that:

- **10,020** FeNO tests were undertaken (67% by open projects, 33% by bundle projects)
- **68%** (of 7433 tests*) **were for diagnosis** and **32% were for monitoring** – but projects reported great variance from 100% diagnostics to 100% monitoring and ranges between)
- Resulting in **1838 people with an asthma diagnosis** (64% of these diagnoses were in open projects)
- Suggesting that **FeNO has actively supported diagnosis in 36% of diagnostic tests** undertaken
- **242 staff were trained** within these projects – illustrating the reach of this programme as this is a small proportion of the total workforce trained (See section 4 on wider impact on the workforce)

** - different to total tests reported. Some projects cited different in total tests and number used for monitoring and diagnosis due to reason for use not being recorded*

PTF – Report headlines

There was an positive view toward FeNO, and a wide range of achievements reported;

- Achieving control and diagnosis for asthma without availability of spirometry due the impact of the Covid-19 pandemic
- Encouragement of collaborative working, through the release of acute capacity, improved system integration
- Improved clinical decision making and development and enhancement of standardisation of diagnostic pathways and improved detection
- Positive acceptance of a new innovation for patients and staff alongside upskilling the clinical workforce
- Beneficial impact on patients from a clinical outcome, satisfaction, and accessibility perspective

A number of challenges were however described by project teams, falling into four main categories;

1. Clinical applicability – the challenge back to project leaders and differing attitudes to FeNO testing across clinical teams. FeNO is not unanimously accepted.
2. Operational challenges, including staff recruitment and sickness issues, operational management of clinics, communication and engagement approaches, robust and accurate data searches and staff training
3. Logistical challenges – associated with limited clinical space to deliver the test if provided in a separate clinic, space to store the devices, and the logistical challenges associated with maintaining devices (where required)
4. Financial challenges – associated with ongoing funding for FeNO and renumeration routes for the test.

*"Having the ability to demonstrate a numerical response supported patient understanding. There were **some clear light bulb moments for patients** who commented that it had never been described like this before. One chap with diabetes likened it to measuring his blood sugar. **Really powerful**."* - Advanced Respiratory Nurse Practitioner, Hereford

PTF – Ingredients for success

A number of key ingredients for project success were identified through the analysis of the 21 PTF reports. We have summarised these below and suggest teams considering FeNO implementation should takes these into account early when planning their project;

- Staff involvement and pathway redesign is key
- Communication and partnership working are key to successful implementation
- Clinical leadership is fundamental – identify the right person
- Longer term financial considerations needs to be considered prior to implementation
- Measurement, data and longer term impact needs to be explored early in the project to support impact analysis and long term use
- Build on the broader health inequalities to optimise FeNO adoption
- Programme management, sharing of best practice and training is the key to success

Economic and environmental impact of FeNO testing – Examples from PTF projects

HMG, one of the 25 FeNO PTF bundle projects, successful implementation of FeNO into the respiratory diagnostic pathway. This project had a "*direct impact on patients through confidently confirming or refuting an asthma diagnosis*", resulting in **cost savings for drug prescribing due to deprescribing of inhalers** and **contribute to the Net Zero** agenda. Over the course of the project;

- **405** FeNO tests completed
  - 226 undertaken for diagnosis purposes, 179 for monitoring purposes
- **130** people received an asthma diagnosis as a result of the revised respiratory diagnostic pathway and from using FeNO
- The revised pathway impacted prescribing, with:
  - 20 MART inhalers stopped
  - 44 inhaled corticosteroid inhalers stopped
  - 10 Triple therapy inhalers stopped
  - 1 dual therapy inhaler stopped
  - 40 SABA stopped
- Equating to an annual prescribing saving of **£17,111** and **3166 miles driven from a carbon emissions perspective**
- **78** people were taken off the asthma register
  - Equating to **26 hours** of nursing time saved due to the reduction in number of annual asthma review (20 mins)

Durham Dales Health Federation were awarded a PTF bundle project to implement FeNO across three rural PCN geographies in the Durham Dales. The project team successfully implemented FeNO within clinical pathways, with regular clinics being offered via a static service at the GP overflow hub, alongside a roaming device covering all 12 practices. Around 50 staff were trained in FeNO testing.

As a result of the project:

- Conducted **129 FeNO tests** (on 129 individuals, no repeat tests)
- **31% of people (40)** tested had their medication checked / changed
- **37% of patients (49)** were ruled out of having asthma owing to their FeNO test result and therefore no longer required inhalers

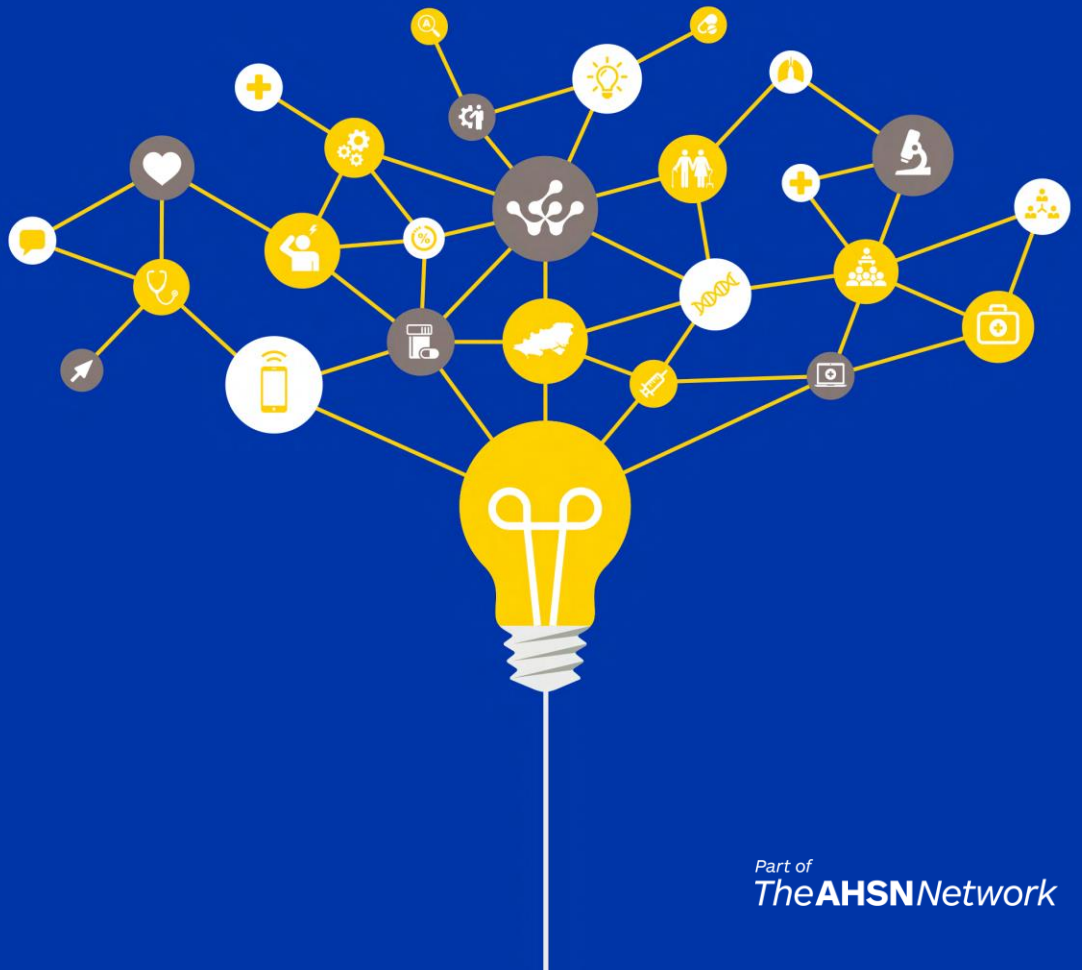
The project team reviewed all patients who received a FeNO test and determined what intervention, if any, was made. Where a patient was started on a medication or had a medication stopped, the team recorded the cost of the relevant inhaler (BNF list price). There was an **estimated net saving of £259 per month, annualised to be £3,108,** across the 129 patients.

Where a patient was ruled out of having asthma, they no longer require an inhaler. This equates to an approximate saving of £416.50 per month in inhaler costs (if they were prescribed one Clenil inhaler at cost of £8.50 per inhaler/month), or £4,998 annually.

Collectively, DDHF **estimate £8,103 annual savings across 178 patients**. This value could increase as more testing is undertaken, and excludes any associated cost impacts – e.g. cost of emergency department attendances or emergency hospital admissions for asthma.

The figures and impact described in these reports are self reported by each respective project – the national programme has not validated these claims

4. Impact on workforce



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National FeNO training

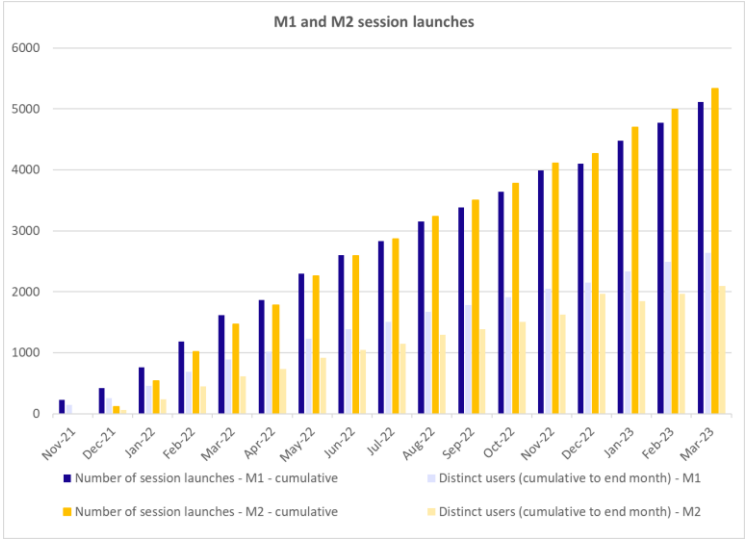
The programme **developed two national training modules**, funded by the NHS E AAC, to support the upskilling of the workforce with FeNO testing. Health Education England host the training in the e-Learning for Health Platform (e-LfH).

Module 1 focuses on the role of FeNO and how to conduct the test, while **Module 2** focuses on the interpretation of FeNO test results and the integration of a FeNO result into the wider asthma jigsaw.

- Generating a collective **10,449** session launches
- **2,584** individual people completed Module 1
- **1,840** individual people completed Module 2

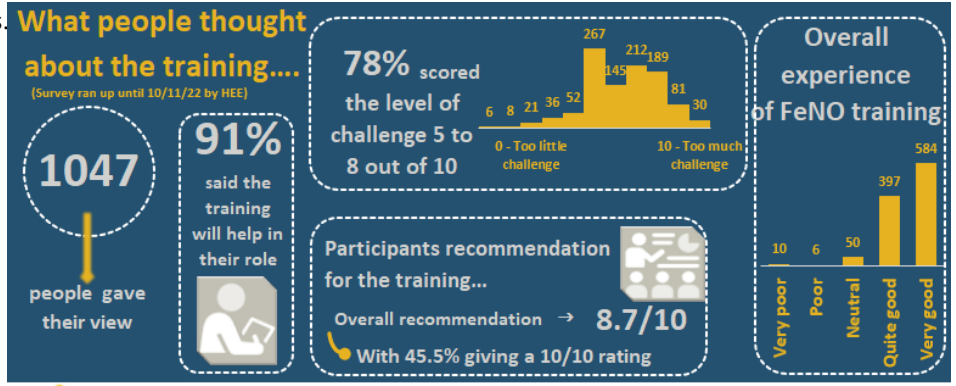
Partners supported the dissemination of the training, resulting in continual use by those wishing to upskill in FeNO testing.

4964
hours of training delivered



HEE ran a survey evaluation survey, which was completed by 1047 participants. What people thought about the training (1047 evaluation responses collected):

- **77%** of people completing the survey were based in primary care
- **52%** were general nurses, **14%** were respiratory specialist nurses and **11%** were doctors
- **37%** complete the training because they were about to commence FeNO testing, with **36%** completing for personal development reasons
- **90%** of those completing the training felt they were able to apply what they'd learnt



"FeNO has been a game changer for our PCN – it's facilitated the right conversation with patients, and its regularly informing clinical decision making for adults and children.

FeNO has been easy to adopt and is now part of our normal way of delivering care. It has been great to see the excitement and interest amongst our workforce too for something new!"

Andrew, a PCN based respiratory nurse in Plymouth

"FeNO has improved the safety of my patients and sped up the identification of diagnosis, phenotype and getting my patients on the right medication for them."

Respiratory Nurse Specialist, Portsdown Group Practice, Portsmouth

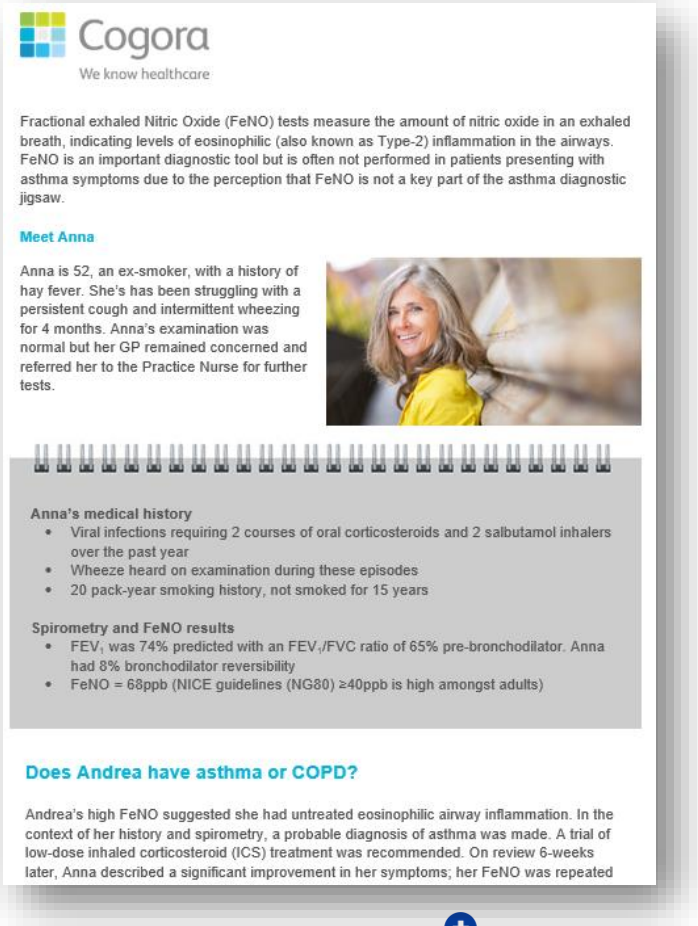
Trade press article in partnership with Cogora

The programme had an ambition to not only reach those in primary care who have a specific respiratory role (Respiratory Nurse, Respiratory Advanced Nurse Practitioner, GP with special interest), but wider members of the primary care workforce.

The national programme worked with Cogora, the media company behind publications such as GP Pulse and Nursing in Practice, to develop a trade press article.

This was sent to sent to over 16,000 members via the GP Pulse database, with adverts for FeNO testing printed in Nursing in Practice and GP pulse publications.

The email's open rate was 28% - c.4,480 members.



Cogora

We know healthcare

Fractional exhaled Nitric Oxide (FeNO) tests measure the amount of nitric oxide in an exhaled breath, indicating levels of eosinophilic (also known as Type-2) inflammation in the airways. FeNO is an important diagnostic tool but is often not performed in patients presenting with asthma symptoms due to the perception that FeNO is not a key part of the asthma diagnostic jigsaw.

Meet Anna

Anna is 52, an ex-smoker, with a history of hay fever. She's has been struggling with a persistent cough and intermittent wheezing for 4 months. Anna's examination was normal but her GP remained concerned and referred her to the Practice Nurse for further tests.

Anna's medical history

- Viral infections requiring 2 courses of oral corticosteroids and 2 salbutamol inhalers over the past year
- Wheeze heard on examination during these episodes
- 20 pack-year smoking history, not smoked for 15 years

Spirometry and FeNO results

- FEV_1 was 74% predicted with an FEV_1/FVC ratio of 65% pre-bronchodilator. Anna had 8% bronchodilator reversibility
- FeNO = 68ppb (NICE guidelines (NG80) ≥40ppb is high amongst adults)

Does Andrea have asthma or COPD?

Andrea's high FeNO suggested she had untreated eosinophilic airway inflammation. In the context of her history and spirometry, a probable diagnosis of asthma was made. A trial of low-dose inhaled corticosteroid (ICS) treatment was recommended. On review 6-weeks later, Anna described a significant improvement in her symptoms; her FeNO was repeated

National FeNO Learning Collaborative

The programme facilitated a regular national learning collaborative which **aimed to bring together professionals currently using FeNO, in the process of implementing FeNO, or considering use**.

Anyone was welcome to join the session - with some emerging international presence too; attendance from Canada, Australia, Austria, Germany

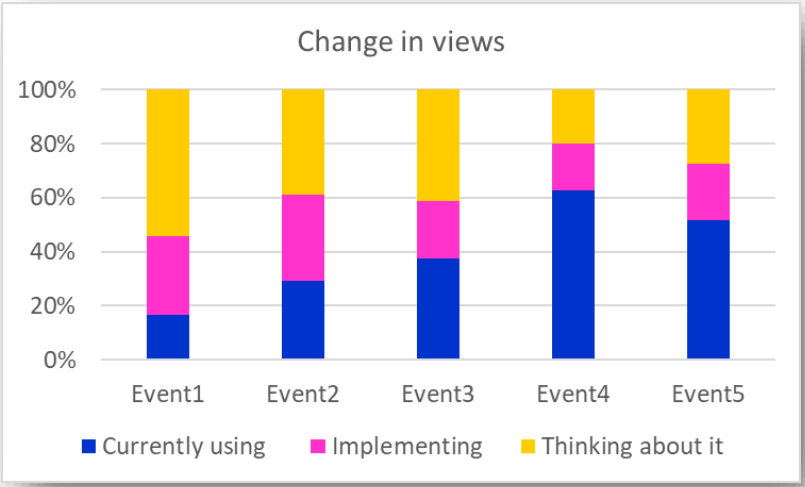
722 people joined 5 collaboratives over 15 months, comprising 12 guest presentations from across England
(Plus programme team presentations)

National FeNO Learning Collaborative: Changing views toward FeNO

At the start of every FeNO Learning Collaborative, we asked the same question (noting there was some consistency across the attendees, and many new people at each session) – Are you:

- Currently using FeNO
- Implementing FeNO as we speak…
- Thinking about it

We saw a broad trend toward more people using, than thinking about it. Feedback was positive.

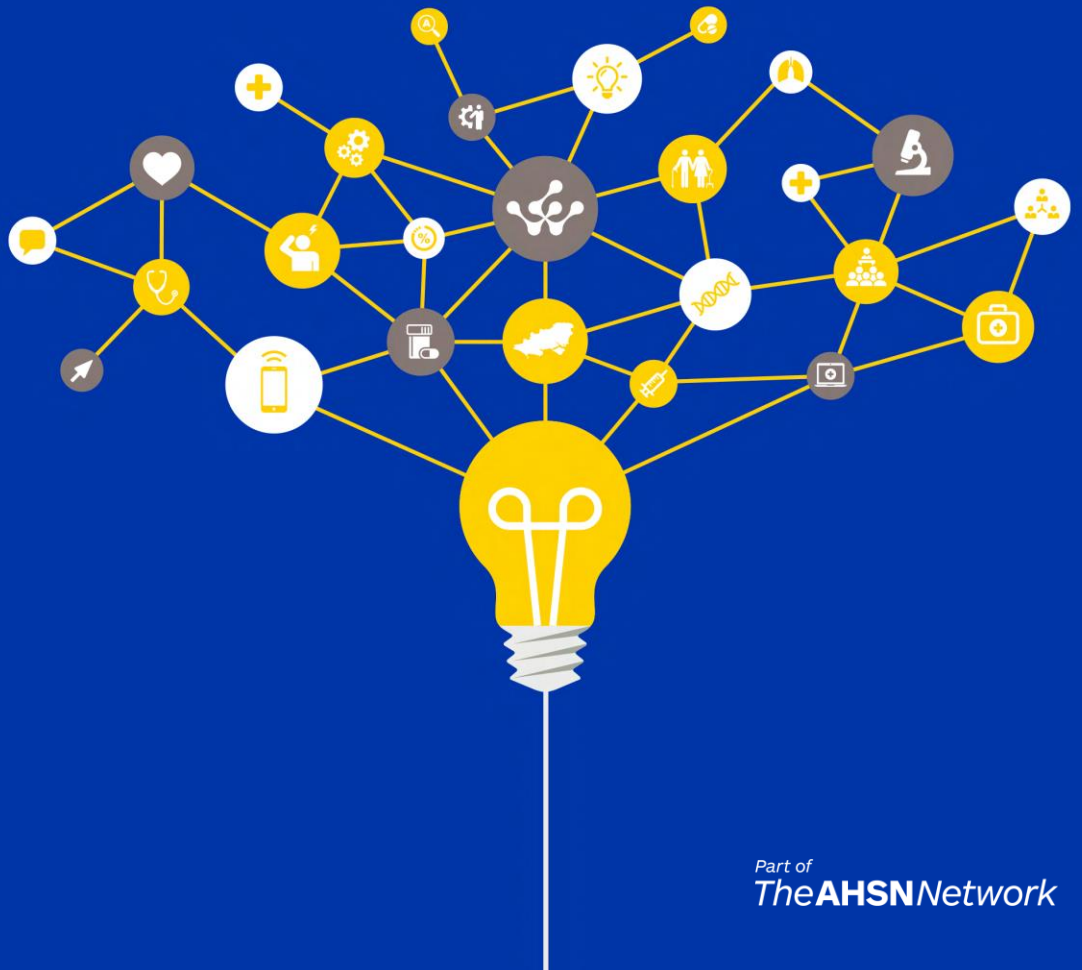


"Very helpful session, will revisit e-learning for a reminder. I have found FeNO really useful for helping with diagnosis"

"Lots of great work happening. Lovely to hear from a patient as they are the ones that count"

"FeNO is valuable in promoting compliance with treatment. Will encourage other clinicians to use it"

5. Impact on patients



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Emma's story

Emma has supported the national FeNO programme since inception, offering advice and guidance to the programme from her lived experience of severe asthma.

Emma joined the FeNO working group as a patient voice with her main focus being to help other asthmatics to have a quicker and easier route to diagnosis and subsequent treatment.

In this short video (1m49s), Emma describes the impact FeNO has had on her care

"Just finished our last FeNO working group call. So sad. But so pleased with what we achieved. Thank you to everyone! You've honestly no idea what this has meant. @SladenJoe @NicolaBentAHSN @WessexAHSN @robwessexahsn @athleticpie @stonny999 @bevbostock @76whit @AACinnovation"

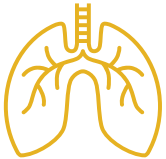
2 6 18 1,490

Impact on people – a projection

Potentially supporting the diagnosis of

58,000

new asthmatics in England over 2 years



The **ambition of this programme was to improve** patient care and outcomes by more effectively diagnosing patients with suspected asthma.

Between March 2021 and March 2023, 318,000 FeNO test consumables were sold to primary care providers by programme suppliers.

The **PTF end project report data suggests 68%** of test consumables are used in a diagnostic capacity.

Taking this estimate and applying an assumption that 75% of consumables are actually used (i.e. 25% optimism bias) and the data from the FeNO PTF reports (Suggesting that FeNO actively supported diagnosis in 36% of diagnostic test applications), **the programme has supported the correct diagnosis of 58,000** new asthmatics, more accurately and faster, enabling them to commence appropriate treatment sooner.

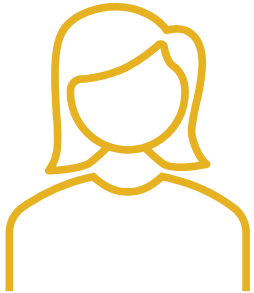
This analysis is a "what if" scenario to give one indication of how many people this programme may have impacted.

“I explain the test [to the patient] and what it means beforehand including what a high or low reading might mean. The patient does the test and sees the result and makes their own judgement of what it means.

For example when there is a high FeNO “perhaps I haven’t been using my inhaler every day?” or, for example when it is low “maybe it’s due to something else?” ”

Health Care Assistant, Portsdown Group Practice, Portsmouth

Isla's story*



Isla is 7 – and has been **experiencing recurrent/persistent chest symptoms for 3-4 years**. Different clinicians had felt it was due to Viral Wheeze with the occasional consideration of asthma. They had been tried on different treatments on and off – Clenil, Montelukast, Salbutamol. All intermittent in nature.

Isla was unable to perform spirometry, and her peak flows showed some variability but Isla found it difficult to do a reliable reading in clinic so her clinical team did not feel they could rely on the diary and results. Clinically there were features suggestive of asthma but it was her diagnosis was not clear.

Isla's mum was reluctant for her daughter to have medications as there were no obvious responses to those prescribed in the past and she was worried about potential side effects.

A FeNO test was performed – the result was high at 83 (above 35 in children is high, and used to diagnose asthma).

After explanation of the result, and reassurance about the low dose of steroids, the family **agreed to start on a low dose ICS. On follow up she was symptom free and had a FeNO of 19.**

The improvement in FeNO with **regular anti-inflammatory treatment has given Isla and her family confidence in the diagnostic process** and the effectiveness of the treatment.

Without FeNO, a more tentative approach towards diagnosis from the clinical team, and ongoing hesitancy from the patient/carers would have led to a continuing cycle of poor confidence in the medication and the clinicians, with poor adherence to preventative medication and annual reviews. This would have led to an increased risk of future symptoms, asthma attacks and impact on lung development.

* - Fictional name

Michael's story*

Michael is 7 although he's **had chest symptoms since 12 months old. He had a diagnosis of asthma added to his clinical notes aged 3** which is based on history of cough which seemed to be better with salbutamol. He was clearly too young to perform any tests.

Due to persistent symptoms different clinicians escalated his treatments, and is now prescribed a Seretide 50 inhaler, 2 puffs per day and Montelukast 5mg. Because of his regular symptoms **he has used 49 Salbutamol inhalers over a 6 year period** (Approx 8 per year!) despite apparent good adherence and inhaler technique. Owing to the presumed asthma diagnosis, Michael has been given 2 courses of Prednisolone when unwell (each occasion, he appeared to have a viral upper respiratory tract infections with worsening cough including night symptoms). The diagnosis of asthma appears to have biased the consultation towards assessment of asthma symptoms.

Both Michael and his family had accepted the asthma diagnosis and learnt behaviours relating to symptoms and treatment. On a review of his Salbutamol use, a detailed history revealed that his main symptom is breathlessness when playing football. He did have occasional cough, worse with colds and chest infections. **His current clinical team were dubious of the asthma diagnosis** and felt that there was a lot of learned behaviour relying on SABA (reliever) inhalers.

Michael recently had a FeNO test – which was 7 (anything less than 35 in a child is considered low) and his GP changed his inhaler to Clenil 50, twice a day. A second FeNO test scored 11 – allowing a further reduction in Michael's medication.

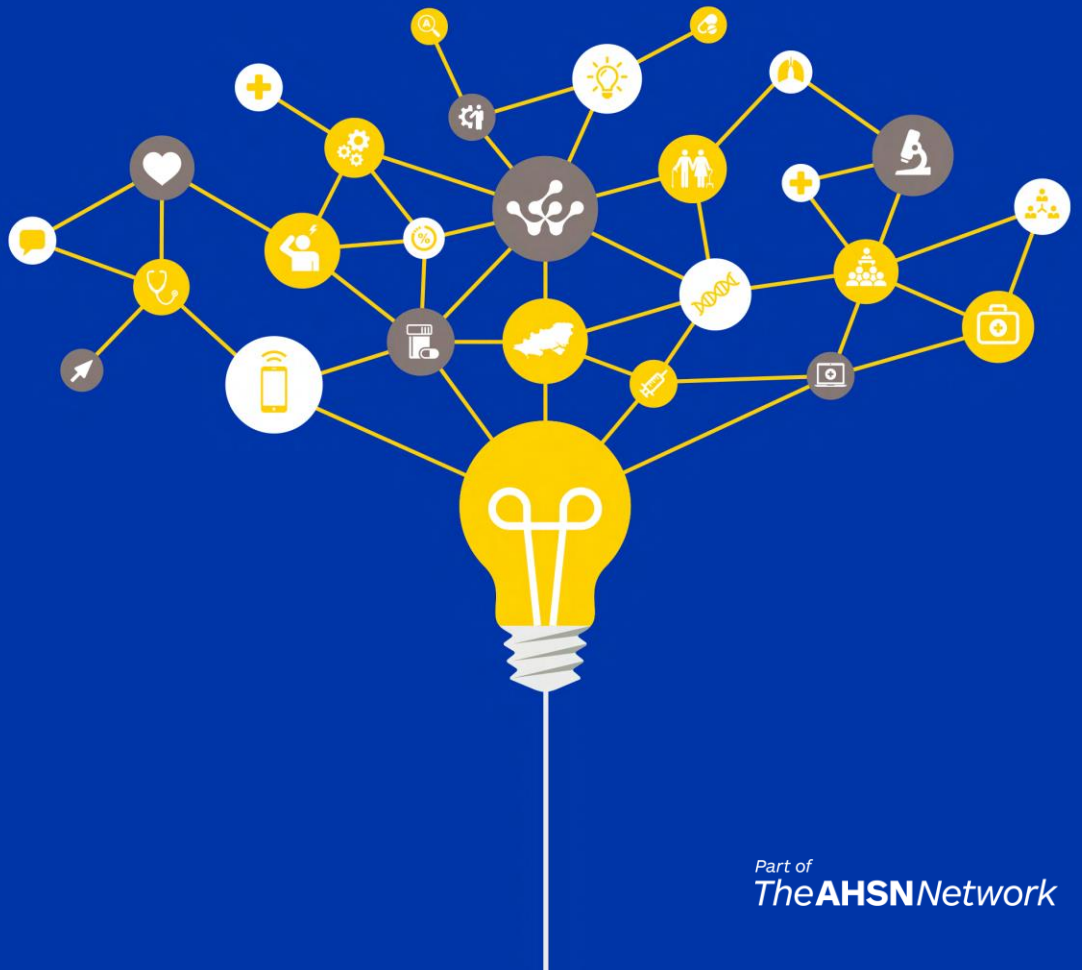
His low FeNO levels gave his GP an opportunity to ask important questions on what was going on and what the diagnosis might mean. Importantly the low FeNO levels gave his GP, the patient and his family confidence to reduce his medication. Michael's GP has committed to follow him up with a view to further reducing and stopping his medication.

If Michael's clinical team is able to stop his medication without a significant rise in his FeNO test result and his symptoms, they will likely reverse his asthma diagnosis.

The incorrect diagnosis, and incorrectly attributing his symptoms to this diagnosis has had a significant effect on patient/carer beliefs and behaviours. It has also misled clinicians to escalate treatment inappropriately and overtreat his symptoms with potentially harmful systemic steroids. There will also be a net reduction in the impact of Michael's inhaler usage on the environment.

* - Fictional name

6. Impact on industry



Part of
TheAHSNNetwork

Supporting suppliers

NIOXVERO®

NOBreath®
Aids in the diagnosis & management of asthma, one breath at a time.

The FeNO programme supported two suppliers – Niox (formerly Circassia) and Bedfont, distributed by Intermedical. Both were selected to join the programme owing to their NICE approval (NICE DG12, 2014) and were core members of the programme throughout.

Both suppliers were invited to provide reflections on the programme as part of this impact report. Collectively, they have offered how:

- Successful the programme has been, and how it has been significantly more successful that they first expected
- The programme has offered significant commercial development opportunities – both in terms of commercial growth, network, and awareness of how they can improve their commercial activities
- They have observed how FeNO has growing support and the appetite for use has grown accordingly – and that FeNO would not have the level of following it currently has without this programme.
- The wider resources created by the programme have been integral – especially the national training programme developed alongside HEE.

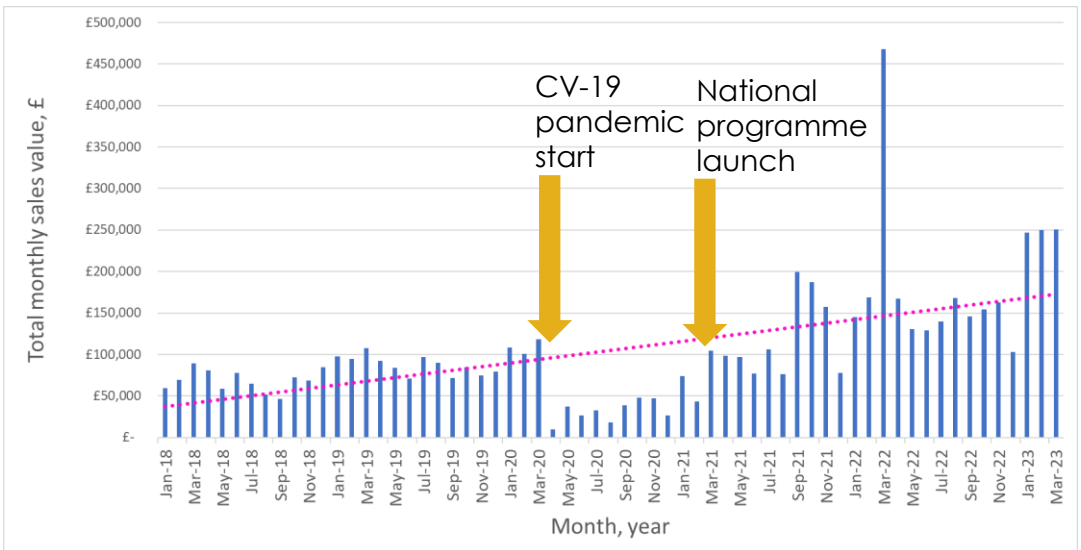
Market stimulation

The national FeNO programme **has stimulated the FeNO market in England** – both from a supply (industry supplier) and demand (NHS services) perspective. Slides 12 and 15 show the increase in uptake of FeNO in primary care.

Programme **suppliers have continually responded and developed their business model in response to demand**. Data shows a continual growth in consumables, despite the impact of the Covid-19 pandemic.

The **average per test cost (including device purchase/access) has reduced over the duration of the programme**, based on 100 tests and accessing a device in the lowest cost way (and noting there could be a multi year commitment to a supplier as a result).

Market value – NHS FeNO consumables*



Cost per test for 100 test – an example

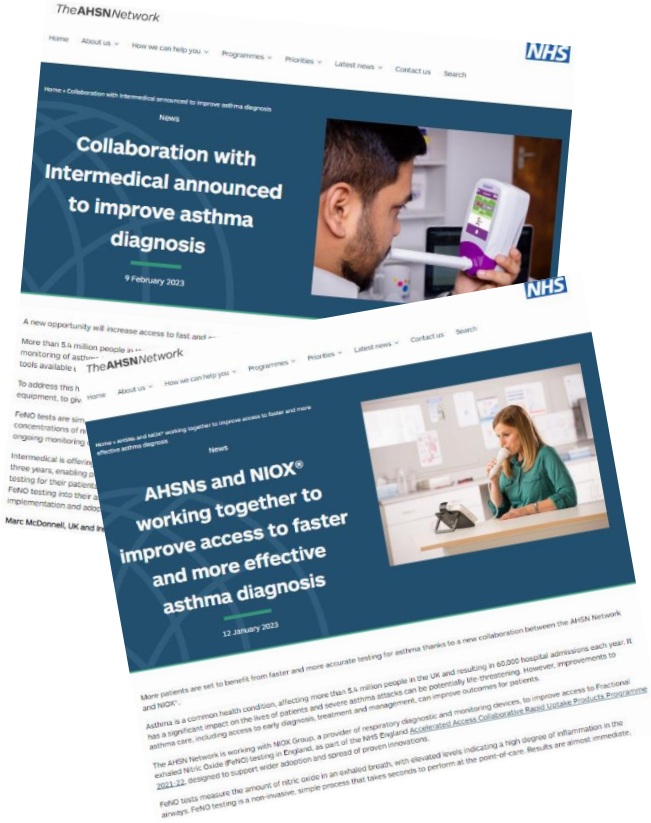
(To buy/access device, service where required, buy 100 test consumables, averaged over 2 programme suppliers, +VAT)

- **2020 - £30**
- **2023 - £10**

**- Graph derived from monthly sales data for FeNO consumables to NHS organisations, based on per test consumable average cost and sales volume reported. Note, Jan, Feb, Mar 2023 values appear very similar on the graph due to the scale of the vertical axis, and have been checked for error. Values are different.*

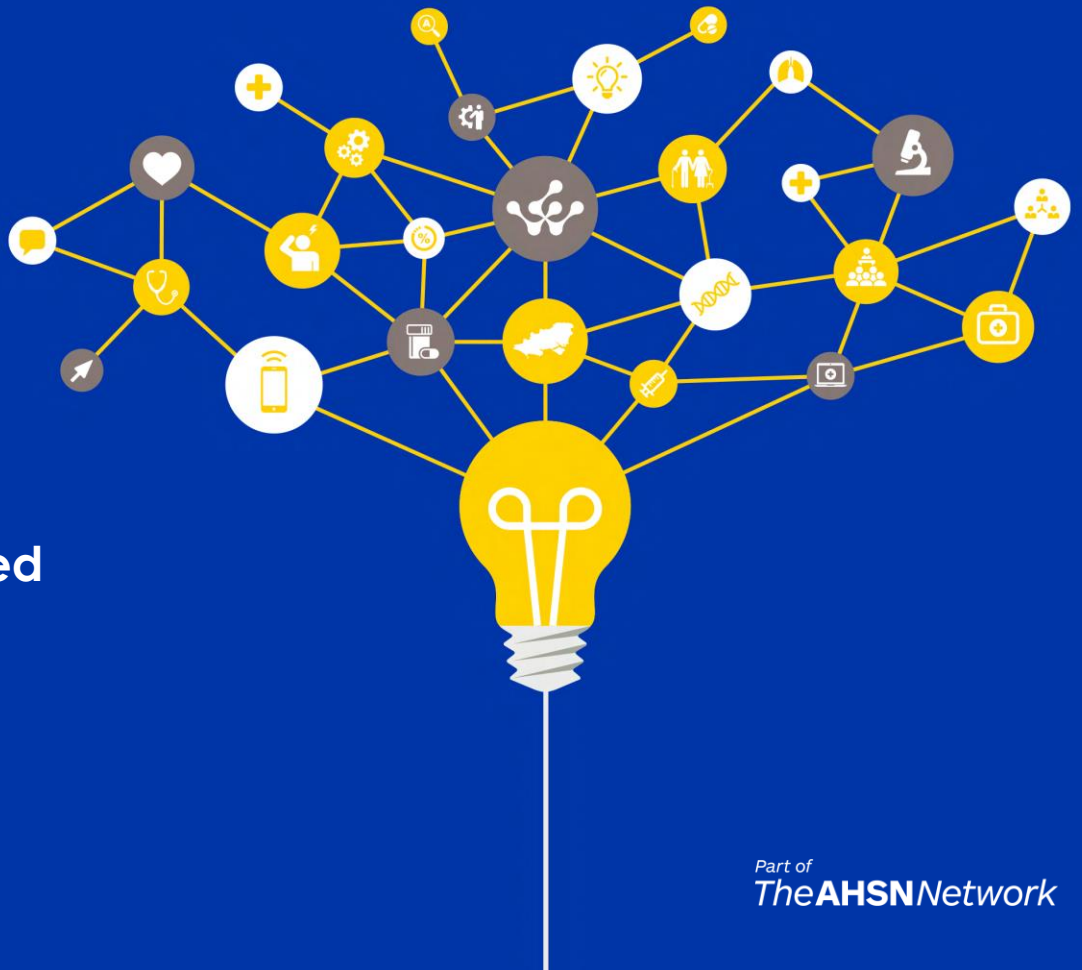
Examples of supplier response and market development

Niox worked with the national FeNO programme to develop an offer to primary care, comprising the loan of 300 FeNO devices over 3 yrs. This is built around the Core20Plus5 concept, with the AHSN Network working to support distribution to Primary Care Networks with greatest need (for example, considering, but not limited to deprivation, asthma prevalence, due to presence of plus populations). Participants were required to buy 100 test consumables per year to participate.



Intermedical, Bedfont distributor, offered a comparable 3 year loan agreement to primary care, with an ambition of making access to FeNO testing more equitable for primary care, and equitable for smaller practices. Participants could purchase test consumables at a pace they require in boxes of 50 tests.

7. Wider reflection and shared learning



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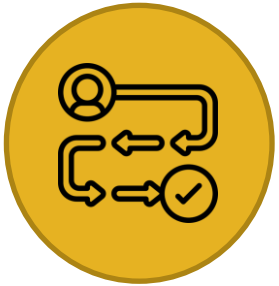
Critical success factors

We've identified a number of critical success factors that have helped contribute to the success of this programme.



Take a pathway approach to transformation, focusing on adopters

Focus on the pathway not the product. FeNO devices are an important, but small part of the programme, with most of the time, effort and focus being on the people adopting the innovations, the value they add to the clinical pathway, and what is required to successfully implement testing.

Allow for local adaptability and local focus in the context of a wider ambition

The programme set a national strategic direction which enabled local adaptability to focus on local priorities and need. Despite variation, all projects running nationally contributed to this overarching aim, using a set of common implementation tools.

Partnerships and collaboration are essential

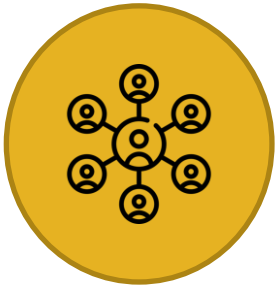
The programme has been underpinned by multi agency working and supported by a range of stakeholders – from public participants, clinical leads, professional societies, NHS England, charities, the AHSN Network and suppliers. Coproduction has been at the programme's core.

Critical success factors (2)

The right people are essential

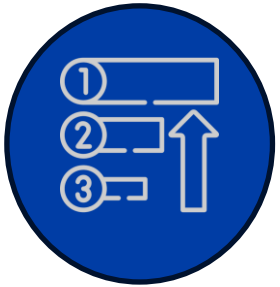
The programme was supported by a range of passionate, knowledge, and dedicated people who help drove the programme forward, including engaged patient representatives, strong clinical leadership, clinical champions, engaged and capable programme managers with specialist knowledge on how to support innovation adoption, and valued industry partnerships.

Clinical leadership advocating the need for FeNO was also key - including support from national clinical directors and nationally renowned FeNO advocates. They provided continual relevance for the programme, direction and momentum.



Networked leadership, built on local knowledge

The AHSN Network provided national leadership, along-side effective and engaged leaders across every AHSN, who owned and led their local transformation programme, applying their local knowledge, contacts and tailoring their approach to their specific context and needs.



Clear vision and priorities (and ownership) that align with national, local and individual ambitions

The programme's priorities were aligned with national policy and ambitions early enabling our priorities to resonate with those we were supporting and easy to support. Those working and linked to the project had a clear rationale for their work.

Critical success factors (3)

Underpin the programme with sound theory, planning and processes

The AHSN Network specialises in supporting innovation adoption – we applied current implementation science to work from an evidence-informed approach, which was underpinned by strong programme management.

Appetite and ambition

The programme witnessed an appetite and can-do attitude toward this work at every scale – from individual practices and PCNs, all the way through to system-wide approaches to FeNO adoption. This approach helped build momentum to the programme.

A cohesive, diverse and empowered steering group

The National Steering Group felt a sense of empowerment to design and deliver a successful programme and cohesively worked toward a collective ambition. Team work was critical to the success of the programme.

Emma, our patient representative said "Being a part of this group has given me the confidence to speak up for myself and to believe that I know my own body. I have learned so much and all of you have played a part in this. Thank you all for listening to me and trusting me."

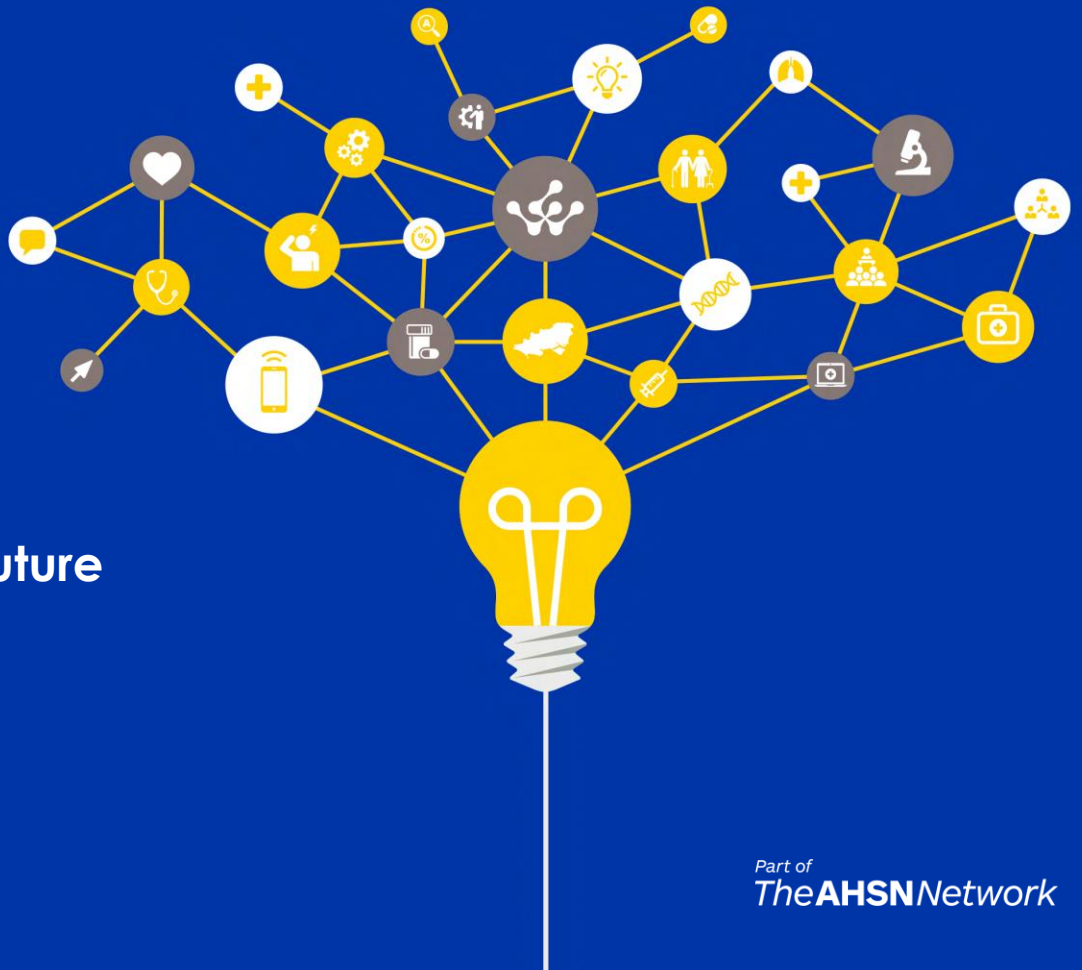
Dr Andy Whittamore, joint clinical lead said "I have really enjoyed the last 2 years. This was because of the people in the team but also the lack of barriers to how Tom [Joint clinical lead] and I thought we could help patients and colleagues through this work. Pretty much every other area of work that I have been involved in has had to compromise in too many ways and I never felt that in this project."

Marc McDonnell, industry partner said "Thank you all. Firstly, you've made being part of this working group an absolute pleasure but your support, advice and approachability (is that a word??) has made a job that I (naively) wasn't expecting to be too fulfilling in the first instance, a joy."

Programme reflections and learning

- **Time spent at the start of the programme** understanding the national context, understanding the innovation, understanding the adopters, understanding the strategic links (to e.g. health inequalities, national policy, to evidence) and understanding the value of FeNO to primary care **was critical to downstream success** – giving the programme the foundations on which to develop a programme vision, narrative for delivery, and delivery plan.
- **The journey was not straightforward and we countered a number of challenges** – there were numerous twists and turns that the national programme had to consider and navigate – one of the biggest being the delivery of a respiratory programme during the Covid-19 respiratory pandemic, and the subsequent competing demands on time in primary care. FeNO testing has a strong evidence base, but there is no evidence (including financial impact evidence) to describe the impact in primary care in England. Had this existed, we suspect the programme could have been even more impactful.
- **Success breeds success** – as the programme began delivering on its objectives, successful delivery opened up opportunities for further programme development and to build on what has already been established, snowballing the scale and impact of the programme.
- **Spreading innovation is an active process and doing it well takes time, focus and dedication** – the AAC and AHSN Network has invested significant time and resource into supporting the widespread adoption of FeNO testing in England. Every AHSN devoted a named project manager to supporting this programme, enabling the spread of FeNO in an proactive way. Without this level of investment, the pace and effectiveness of FeNO spread would have unlikely occurred as it did.
- **Pathway Transformation Funding** provided a key stepping stone to start to develop momentum for delivery and to act as a test ground for early use of the toolkit resources. However, further thought and a more robust plan to evaluating the collective impact of these projects need greater thought at the outset of the programme.
- **Impact takes time to deliver** – this was a 24 month programme, but results were not immediate. The programme had executive support and was given time to develop and deliver. Engagement takes time in primary care too – due to competing pressures.
- **No sustainable funding arrangements could be identified** to support the long-term use of FeNO testing in primary care. Contributory funding was identified (Innovation and Investment Fund, and QOF), but nothings that solely supported FeNO testing.

8. Programme legacy and future for FeNO



Part of TheAHSNNetwork

Our biggest impact and legacy is an impact on people

Our **fundamental ambition was to improve the lives of people with suspected or diagnosed asthma** – we believe we've done that – that is the biggest legacy we can leave.

Our original goals:
"**Improve patient care** and outcomes by more effectively diagnosing patients with suspected asthma"

"Increase widespread patient and clinician **access to FeNO testing across primary care**"

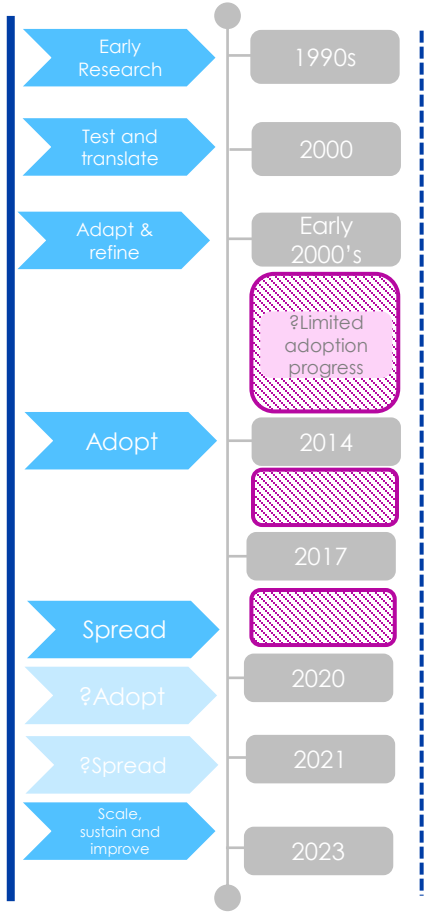
Beyond that, the programme's legacy continues in a number of other ways…

Legacy - A contribution to the adoption of FeNO testing in England

FeNO testing started its journey in the 1990s. There have been notable periods within the FeNO journey where limited progress has been made toward widespread use and adoption, despite regulatory support being gained (NICE approval gained 2014).

We see the greatest legacy from this national programme being the step change in rate of FeNO adoption in primary care in England and the supporting narrative surrounding the test and its role, adding to the adoption momentum.

Our hope is that the legacy of this programme continues to contribute to sustainable adoption in order to improve asthma outcomes.



In the early 1990s, researchers at the Karolinska Institute in Stockholm discovered the presence of NO in human lungs

Creation of the NIOX FLEX – First commercial FeNO device - and approved as a medical device in Europe in 2000

Early 2000s - Continued research showing relationship of NO and airway inflammation. Early adopters beginning to use FeNO testing

Adoption in hospital clinic settings in early 2000s, becoming common place in specialist hospital centres 10-15 years ago, and in general respiratory teams 5-7 years ago. FeNO is rarely used in primary care settings

NICE published DG12 in 2014 describing the positive impact of FeNO testing, but limited impact on pace of accelerated adoption

FeNO appears in NICE guideline (NG80) in 2017

Included in QoF 2020/21 as one of three objective tests which contributes to QoF achievement (ID = AST006).

National FeNO programme commenced December 2020, with programme formally launching March 2021, lasting two years (March 2023). All AHSNs committed to spreading FeNO testing to improve outcomes

June 2021 - £915k AAC pathway transformation fund invested in FeNO testing by OLS

Sustaining use beyond the programme is a core deliverable for the AHSN Network and a core focus of Y2 of programme.

Programme legacy

Beyond the contribution this programme had made to the FeNO adoption journey, the programme leaves a number of other legacies for the NHS:

- The programme has **significantly stimulated the FeNO market** from an innovation supply and demand perspective, collectively increasing access and the national density of devices;
    - Suppliers have continued to develop their offer to primary care, with different purchase models emerging
    - Hundreds of FeNO devices have been adopted by Primary Care in England, with growing demand from clinical teams for the test
- Learning from the programme has been **fed into the in-development NICE/SIGN/BTS asthma guidance**, expected in 2024, offering real world insights to implementation considerations within the guidance.
- The NHS will **continue to have access to the FeNO toolkit** and the large number of resources it contains – this resource will remain open and will continue to be free to access.
- The **two HEE training modules will remain available**, and free, to NHS staff.
- The AHSN Network is transitioning to support health inequalities as one of their national priorities – a number of AHSNs will support the respiratory aspect of the NHS England Core20Plus5 agenda, and continue to call on the approach and resources of this national programme.

Future opportunities for FeNO testing in England

Despite the success of the national FeNO programme, significant opportunities remain to improve asthma care in England making FeNO a commonality across clinical teams.

The programme has built a narrative around the role of FeNO at scale. There is still **further work to do to maintain this narrative**, and **cement the role of FeNO in asthma care** making it part of usual care. The programme believes there are further opportunities for professional societies, charities, and the NHS national respiratory programme to collectively support and grow the narrative around FeNO testing further, including creating best practice pathways. We look forward to the release of the combined NICE/SIGN/BTS asthma guideline in 2024, the role FeNO has within that guidance, and the **opportunities that guidance presents to enhance the use of FeNO** testing in England – including the mandated role of FeNO, and the role of FeNO in asthma monitoring.

Current access to FeNO testing is not equitable across England. Opportunities **remain to grow the role of FeNO in Primary Care and access to it as a test** – we have a long term ambition for all PCNs in England to have continue access to FeNO within their PCN.

A clear and **sustainable funding mechanism** needs to be secured for FeNO testing, enabling primary care to appropriately use the test indefinitely – this does not exist and something that the national programme was unable to influence.

Further opportunities remain in:

- Conducting **further research to evidence the impact** of FeNO testing in primary care settings – especially the economic case and cost effectiveness of FeNO in primary care (in England)
- **Enhancing the role of secondary care networks** in primary care asthma care
- Best use cases for **FeNO monitoring** respiratory disease
- Relation to the use of FeNO testing in **children and young people**
- The role of FeNO in **community diagnostic centres**, alongside primary care based asthma services
- The role of **patient self-testing**
- Use of FeNO as a biomarker to drive **personalised care and improved risk stratification**
- **Improving virtual multi-disciplinary team meetings (MDTs)** between primary and secondary/tertiary care
- For FeNO tresting to remain involved with the development of a **national secure data environments (SDE) use case** and support NHS England's policy to develop SDEs and understand whole system impact of innovation adoption – illustrated through FeNO testing.

With thanks to National Working Group members

- **Accelerated Access Collaborative (year 1 of programme only)**
  - Therese Dodoo
  - Vicky Spellacy
- **AHSN Network**
  - Stuart Monk
- **Association for Respiratory Technology and Physiology**
  - Rasheda Choudhury
- **Association of Respiratory Nurse Specialists**
  - Alison Hughes
  - Beverly Bostock
- **British Thoracis Society**
  - Kathryn Prior
- **Clinical leads**
  - Thomas Brown
  - Andrew Whittamore
- **Industry suppliers**
  - Marc McDonnell – Intermedical
  - Hannah Vince-Drew – Bedfont Scientific
  - Mark Dodd – Niox
  - Steven Adair – Noix
- **NHS England Respiratory Programme**
  - Sahera Ramzan
- **Primary Care Respiratory Society**
  - Carol Stonham
- **Public Participants**
  - Emma Thompson
  - Louise ReeseJones
- **Wessex AHSN**
  - Rob Payne
  - Joe Sladen
  - Nicola Bent

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