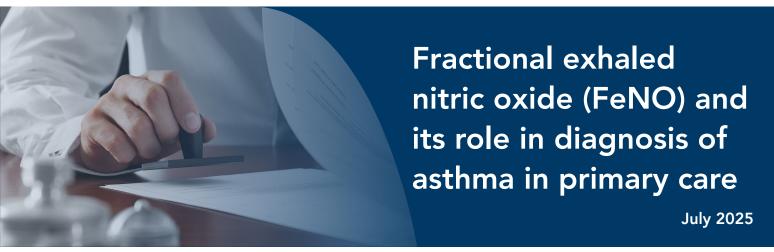


PCRS Position Statement



Introduction

The much-anticipated BTS/NICE/SIGN guideline, Asthma: diagnosis, monitoring and chronic asthma management (NG245),¹ was finally published in November 2024. The publication of a single guideline is very welcome after the confusion caused by two UK guidelines which were not aligned and at times contradictory. This guideline has caused some concern in the placing of fractional exhaled nitric oxide (FeNO) early in the diagnostic algorithm. Many healthcare settings do not have access to FeNO and are not therefore familiar with its use. For many Integrated Care Boards (ICBs) and health boards, this is a cost pressure too far – at a time when they are expected to drastically reduce running costs – and many primary care practices are themselves unable to fund the FeNO device and consumables. It is therefore important that, whilst the use of FeNO becomes embedded in everyday practice, a pragmatic and resource sharing approach is considered.

The PCRS policy document aims to address these issues and advocates that:

- Clinicians making a new diagnosis of asthma should be trained to do so and maintain their continued professional development (CPD) (PCRS Fit to Care).
- A pragmatic approach is taken to reduce the cost and training implications of the new BTS/NICE/SIGN asthma guideline and recommended use of FeNO in the diagnostic pathway.
- Novel ways of funding access to FeNO are explored by healthcare commissioners.
- Where Clinical Diagnostic Centres (CDCs)/Clinical Investigation Hubs (CIH)are available, a referral pathway for asthma diagnosis should be implemented with prompt and easy access for primary care.
- Primary Care Networks (PCNs) and Health boards should be encouraged to pool resources
 and expertise and establish diagnostic hubs to ensure patients are seen quickly by an expert
 with access to all necessary diagnostic tools and close to home.

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Background

Prior to November 2024, the UK had a dichotomy of opinion around how to diagnose asthma with different recommendations in guidelines from NICE (2017) and BTS/SIGN (2019) which resulted in some confusion.

The 2019 BTS/SIGN guidelines supported a pragmatic diagnostic approach, particularly in settings where objective tests like spirometry and FeNO were not easily accessible. It recommended a compatible clinical history as the primary tool, so a diagnosis of asthma could have been made with high clinical suspicion for asthma and a symptomatic response to treatment with inhaled corticosteroids (ICS). However, objective testing with spirometry and reversibility was recommended if available.

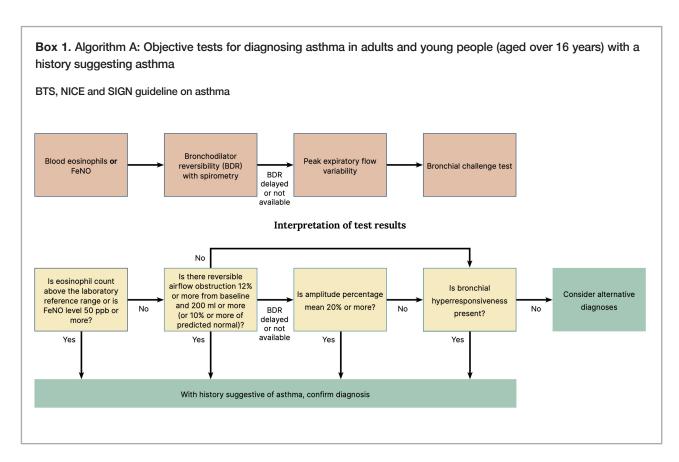
The 2017 NICE guideline (NG80), however, recommended a stricter test-based approach to asthma diagnosis, placing a strong emphasis on objective testing rather than clinical history alone with FeNO testing at the forefront. While the NICE model improves diagnostic accuracy, it posed major implementation challenges in primary care due to reliance on FeNO and spirometry, which were not widely available in GP practices at that time (nor currently). Hence, especially during the pandemic, many patients were diagnosed with asthma without any objective tests or clear documentation of how a diagnosis of asthma was made.

The new BTS/NICE/SIGN asthma guideline 2024

In November 2024, for the first time, we have a consensus for the diagnosis and management of asthma in the UK with the publication of the joint BTS/NICE/SIGN asthma guideline. The new 2024 guideline is more in line with the old NICE 2017 guideline with a stricter objective test-driven diagnosis so that a high suspicion of asthma from clinical history and response to inhaled steroids will no longer be enough. Now, an asthma diagnosis can be made in patients with eosinophil count > reference level OR FeNO >50 ppb (in adults) if asthma is clinically suspected (Box 1).

If there is no eosinophilia or FeNO is not >50 ppb, the next step recommended is spirometry with bronchodilator reversibility, with the usual requirement for 12% improvement from baseline and more than 200 mL. However, as a concession to primary care where spirometry or FeNO may not be readily available (and after a lot of lobbying from primary care practitioners), a two-week peak flow diary showing more than 20% variability in amplitude is accepted. If the diagnosis still cannot be confirmed, a referral on to secondary care for bronchial hyperresponsiveness (bronchial provocation testing) is recommended.

For children aged 5–16, the algorithm (see Box 2) is slightly different in that the blood eosinophil count is not included as a first-line option and the FeNO cut-off level for a positive test



is lowered from 50 ppb to 35 ppb. This is followed by spirometry and reversibility, and peak flow variability as in the adult algorithm. Blood eosinophil count and skin prick testing are to be considered at the end of the algorithm instead of bronchial challenge testing in adults if peak flow variability does not provide a diagnosis.

The rationale for the stepwise approach to diagnostic tests is that asthma is a variable disease and no one single test can reliably diagnose asthma. The test with the highest sensitivity and specificity is actually bronchial challenge with methacholine or histamine. However, this is not available in primary care and is limited even in secondary care. The test is time consuming and can be unpleasant for patients, so it is placed right at the end of the diagnostic algorithm. In certain parts of Europe, bronchial challenge testing is the standard for asthma diagnosis.

FeNO has the advantage that inflammation often exists in the absence of respiratory symptoms and normal lung function.² The guidelines acknowledge that, although FeNO and eosinophil counts may have low sensitivity but high specificity,^{3,4} they should be easily available to the primary care clinician. So, in the presence of a suggestive history, if there is a raised FeNO or high eosinophil count, then a quick and reliable diagnosis of asthma can be made. If these tests are not positive or not available, then the algorithm progresses to either spirometry with bronchodilator

reversibility (BDR) or looking for peak expiratory flow (PEF) variability in both adults and children. Again, both tests have low sensitivity but good specificity for asthma.^{5,6}

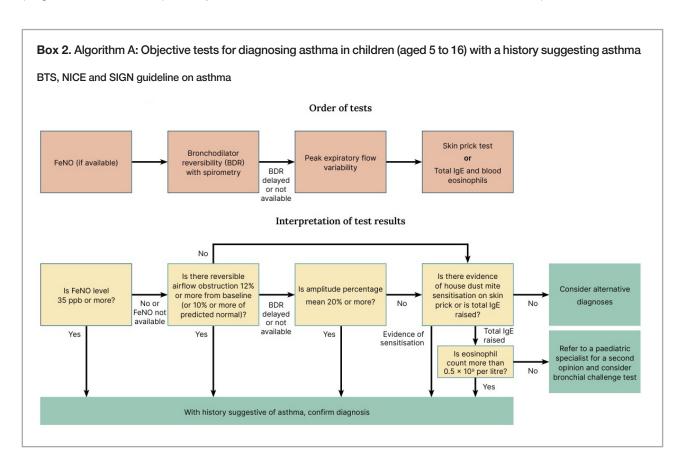
Key issues

Clinical history and assessment

The new guidelines are very different from the 2019 BTS/SIGN asthma guidance where clinical assessment and likelihood of asthma diagnosis along with response to treatment were the primary focus. Now that there is an emphasis on objective tests, there is a risk that the importance of history and clinical examination may be lost. Good history taking is an art, and clinicians need to be trained to make good clinical assessments rather than just rely on simple tests like diabetes and HbA1c. The PCRS Fit to Care document supports an expert level of training for clinicians making a new diagnosis of respiratory disease.

FeNO

The new guidelines do not acknowledge a few problems that may hinder its widespread adoption, the most obvious being that FeNO is currently not widely available in primary care. It is estimated that only 53% of PCNs in England had access to FeNO in March 2023.⁷ The guidelines recommend that FeNO should be undertaken as soon as possible after an acute



presentation. However, where this is available in primary care (delivered by Respiratory Diagnostic Hubs (RDHs) or CDCs/CIHs), there may be a long wait for the test, reducing its sensitivity. Sometimes these diagnostic hubs/centres are not close to the patients' homes so are difficult to access. If a referral to secondary care is needed, this can be even longer (many months) and even more inaccessible for the patient.

Very few primary care practices possess their own FeNO device currently. The devices themselves are costly to buy outright, and there is a cost per test due to consumables. However, although the cost of consumables can be reduced per test if a lot of tests are performed, this is unlikely for an individual practice, so centralising to an RDH helps to reduce costs. If a device is owned, there are training implications in both conducting and interpreting the test, although the test itself is fairly easy to do for both adults and children. The companies who make the devices offer good training programmes and materials and, compared with spirometry, there is no accreditation and registration required. Practitioners will need to be aware of other causes of a raised FeNO that may give rise to a false positive result, and that current smoking and inhaled or oral steroid use may suppress a reading.

The ideal situation is if a practice uses FeNO for both the diagnosis and the monitoring of asthma control to adjust medication. This would mean that FeNO becomes everyday practice, and clinicians are more comfortable and experienced at interpreting the result and fine-tuning asthma therapy. As more tests are done, the cost of consumables is reduced.

However FeNO is delivered, the costs will be borne by the ICB/health board who will be expected to commission further delivery models, especially as the new 2025 Quality and Outcomes Framework (QoF) Indicator for asthma will require confirmation of the diagnosis with at least one objective test. In a time where funding in the NHS is challenging, the ICB and health board may not see asthma as a priority. In areas with RDHs and CDCs, FeNO is usually done as part of the diagnostic process along with spirometry and BDR if indicated. Each appointment has time allocated for all of these tests to be done (30–45 min) and costed accordingly. It may not be cost effective for RDHs to offer just FeNO alone without spirometry. Any reduction in funding to the RDHs may make them economically unviable.

Eosinophil count

Although it is attractive to imagine that looking at a blood result will help diagnose asthma like an HbA1c in diabetes, this is far

from simple. Raised eosinophils at some stage may imply an atopic phenotype. However, they can be raised for reasons other than asthma (eg, some drug, allergies, helminthic infections, etc). The guidelines do not really give a cut-off for a positive result (other than higher than your local reference range), nor the timing of the test. The guidelines are not advocating performing a blood count at the time of symptoms (which may actually be the most useful), but rather to look at historical results. However, they do not give an indication of how long ago a raised eosinophil account is acceptable. Without more specific guidance, this may lead to overdiagnosis of asthma. This emphasises the importance of using an eosinophil count in the setting of clinical assessment and examination that suggests a diagnosis of asthma.

Non-atopic asthma

Placing tests for eosinophilic inflammation as the first step in asthma diagnosis emphasises the atopic nature of asthma, those with the Th2-high phenotype. However, the Th2-high phenotype only accounts for about 50% of patients with asthmatic symptoms. Therefore, half of all patients with asthma may not be detected by FeNO and eosinophil counts which may account for their low sensitivity. Spirometry and BDR, if available, also have only 30% sensitivity. So the initial steps of the algorithm may leave many patients with a potential diagnosis of asthma unconfirmed.

Pragmatic approach

So where does this leave us? If most patients with asthma symptoms do not have raised eosinophils and may have to wait a long time for FeNO or spirometry, then what can we do with a symptomatic patient? Previously, if we had a high suspicion for asthma we could treat and observe the response to treatment to make the diagnosis. It is very unlikely that we would leave a patient with a high suspicion of asthma untreated pending investigations. The pragmatic approach could be to treat the patient if symptomatic and progress to the third step of peak flow monitoring whilst awaiting FeNO and spirometry. The patient can be asked to keep a record of PEF for a week or two prior to treatment, and then for a further 2 weeks after initiation of treatment (with low-dose ICS/formoterol as maintenance and reliever therapy (MART)). This gives the advantage of not only being able to detect variation in airflow before treatment, but also response to treatment.

PEF monitoring is easily available and already part of primary care practice. As long as the patient can demonstrate good technique with the device and record the best of three blows, then it is relatively reliable. In addition, acquainting a patient in the use of the peak flow meter may help in assessing disease control in the future and used in a personalised asthma action plan, and starting the process of patient-initiated management. Encouraging primary care to use peak flow monitoring more may address some of the stumbling blocks faced by ICBs and health boards, with potentially increased costs funding FeNO at a time when they are expected to cut costs.

PCRS position

The placing of FeNO testing so early in the diagnostic algorithm for asthma will cause concern for many clinicians caring for patients with respiratory symptoms in primary care. In addition, the availability of FeNO in primary care settings is variable, and many centres do not have clinicians with the training to undertake FeNO assessments or the funding to provide them.

The PCRS Fit to Care document sensibly suggests that clinicians should be adequately trained before making a new diagnosis of asthma and that this training should be maintained. It therefore seems sensible that, whilst the use of FeNO should be encouraged and increased, a pragmatic approach is used to reduce the costs and training implications of the 2024 BTS/NICE/SIGN asthma guideline by making more use of PEF monitoring.

ICBs and health boards may wish to investigate novel ways of funding access to FeNO. Health Innovation Networks have access to funding and Pharma companies are offering support for access to FeNO. Whilst these options are attractive, ICBs and health boards will have to address internal conflicts of interest and establish longer term funding to achieve the guideline recommendations, and commission availability across their health community.

Where RDHs and CDCs are available – a referral pathway for asthma diagnosis could be implemented with prompt and easy access for primary care. There will be costs associated with this approach and ICBs and health boards will need to manage proactively.

PCNs should be encouraged to pool resources and expertise and establish RDHs, ensuring patients are seen:

- in a centre close to their own home;
- by a clinician with access to FeNO, spirometry and other diagnostic testing as required;
- with suitable training and expertise to undertake a clinical history, arrange investigations and interpret in light of the findings.

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