PCRS-UK briefing document

Asthma guidelines

November 2017

This briefing was prepared initially for the benefit of our members, who are healthcare professionals working primarily in primary and community care with an interest in respiratory disease. It was intended to outline the similarities and differences between asthma guidelines from different sources and to advise, from a primary care perspective, on how to proceed where there were discrepancies between guidelines.

It was finalised after extensive review and comment by clinical members of our Executive committee, and other core committees.

npj | Primary Care Respiratory Medicine *Official Journal of the PCRS-UK*

http://www.nature.com/npjpcrm/

The Primary Care Respiratory Society, is a registered charity; (Charity No: 1098117) and a company limited by guarantee registered in England (Company No: 4298947). VAT Registration Number: 866 1543 09. Registered offices: PCRS-UK, Miria House, 1683b High Street, Knowle, Solihull B93 0LL. Telephone: +44 (0)1675 477600. Email: info@pcrs-uk.org
Website: http://www.pcrs-uk.org Twitter: @pcrsuk Facebook: https://www.facebook.com/PCRSUK

The Primary Care Respiratory Society UK is grateful to its corporate supporters including AstraZeneca UK Ltd, Boehringer Ingelheim Ltd, Chiesi Ltd, Johnson & Johnson Ltd, Napp Pharmaceuticals, Novartis UK, Pfizer Ltd. and TEVA UK Limited for their financial support which supports the core activities of the Charity and allows PCRS-UK to make its services either freely available or at greatly reduced rates to its members. Click HERE for PCRS-UK statement on pharmaceutical funding

1. Background

The Scottish Intercollegiate Guidelines Network (SIGN) and British Thoracic Society (BTS) have been collaborating on producing and updating the British Asthma Guideline since 2003. These are therefore well established guidelines covering all aspects of asthma care. They have been updated on the basis of most recent evidence on a chapter by chapter basis, with partial updates every 2 years or so. This guideline was accredited by NICE in 2014 as a high quality guideline, following best practice in guideline development.

In 2013, NICE announced that it would be commencing work on a guideline on the diagnosis and monitoring of asthma. NICE also developed a quality standard for asthma that year, which consisted of a succinct set of quality statements to guide high quality asthma care. This was based on the BTS/SIGN guideline as there was no NICE guideline to follow. In 2015, NICE added to its work programme the development of a guideline on asthma management.

An important aspect of NICE guidelines is that they include a thorough health economic evaluation, which other guidelines do not. This can lead to differences in recommendations where clinical evidence indicates that there is no clinical difference between two interventions. Limited funds are a reality in the NHS and it is responsible practice to look at the most cost-effective options.

Publication of the Asthma diagnosis and monitoring guideline was delayed due to a 12-month evaluation and field test of the draft recommendations, following concerns about the feasibility of implementation. We believe that the feasibility work highlighted significant concerns about the practicalities of implementing the guideline. Both NICE guidelines will now be published as a single guideline on November 29, 2017.

The Global Initiative for Asthma (GINA) has also been developing asthma guidance for many years, and is the most well recognised international guidance for asthma. GINA has been operating since 1993 and the most recent report was published in 2017, the 'Global strategy for asthma management and prevention report'. However, there is little awareness of GINA in mainstream general practice in the UK, and it has little impact on asthma care.

The purpose of this briefing paper is:

- To set out PCRS-UK position on asthma diagnosis, monitoring and management for a primary care audience in the UK based on its assessment of and taking account of the guidelines from BTS/SIGN and NICE
- To comment on the differences between the BTS/SIGN asthma guideline and the NICE asthma guideline on diagnosis and monitoring, and chronic management
- To confirm PCRS-UK's response to the new NICE guideline

2. Multiple guidelines

We believe that multiple guidelines are unhelpful as they create uncertainty for clinicians about the most appropriate approach to take, and may lead to inconsistencies in the care of individual patients, if clinicians follow different guidelines.

We have strongly recommended that NICE collaborates with BTS and SIGN in line with their memorandum of understanding - 'by working together they can draw on the strength of their organisations and enhance the contribution that they each make towards improving the quality of care for the benefit of patients' - to develop a single guideline ensuring clarity and consistency. We have asked that the two groups get together to seek consensus on discrepancies or to explain the rationale for any differences, and believe they did meet in early 2017, but in the absence of such consensus, PCRS-UK is producing guidance for primary care.

3. PCRS-UK recommendations

3.1 Diagnosing asthma - PCRS-UK recommendation

3.1.1 We support the BTS/SIGN approach to diagnosis which assesses the probability of asthma as high, intermediate or low and emphasises a structured clinical assessment as the first step.

3.1.2 The diagnosis of asthma is a clinical one. It is not possible to rely on any single clinical feature or test result and patients seen when they are well may have no symptoms, no abnormal physical signs and no physiological abnormalities. What is required is careful integration of evidence from a wide variety of sources – the clinical history, examination, physiological tests of airways obstruction and other supporting tests and investigations where available. The basis for the decision that a patient has asthma should be documented carefully, and the diagnosis of asthma revisited and checked regularly.

3.1.3 This integration of information about an individual over time is best done in primary care, where the majority of asthma diagnoses are currently made. Because of the variable nature of asthma, it is likely that at least some of these assessments will need to be repeated over time and to assess objective response to trials of treatment, before a confident diagnosis can be made. We see our patients when their asthma is not troublesome, and weeks or months later when their symptoms are triggered by a viral infection or the hay fever season. A diagnostic algorithm based on repeated clinical assessments, peak flow monitoring and trials of initiating and discontinuing therapy, supported by objective clinical tests and with referral to specialist services in cases of doubt or difficulty, is a practical way forward.

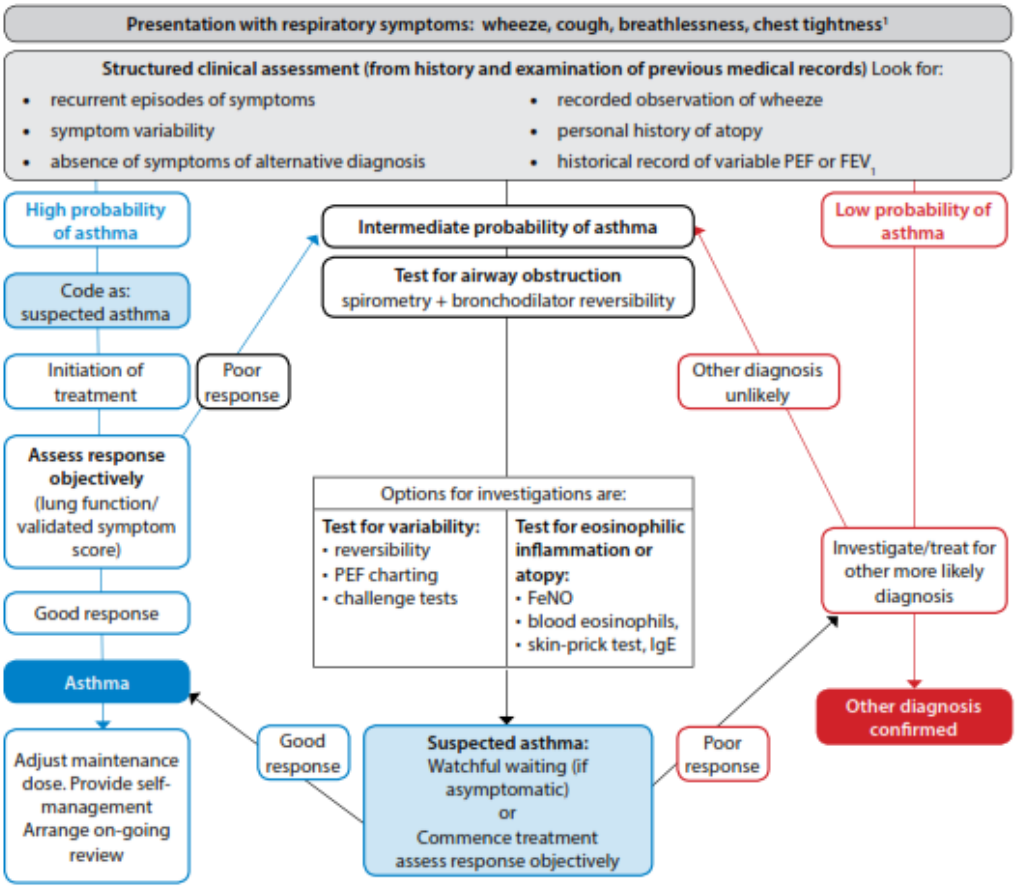
3.1.4 Objective tests – in all patients old enough to perform them - should be done as part of initial diagnostic assessment to support a confident diagnosis of asthma, and these tests need to be repeated over time to demonstrate convincingly variable airways obstruction. We support the move to more widespread objective testing, and peak flow measurement and monitoring is a key initial objective test. Further work is needed to explore how to achieve the greatest value from including Fractional Exhaled Nitric Oxide (FeNO) and spirometry in the diagnostic pathway, but it is important that the initiation of treatment should not be delayed while waiting for a confirmation of asthma using these tests. However, we have significant concerns about an approach that recommends greater reliance on objective testing at a single point in time, as that risks not detecting asthma if the patient is asymptomatic at the time of testing. The majority of people with asthma will have normal spirometry when it is tested; these false negatives mean it is not possible to rule out asthma with spirometry, so a normal spirometry result does not exclude asthma. There are both false positives and false negatives with FeNO, and it may not detect asthma in a patient with a chest infection or in patients who smoke.

3.1.5 BTS/SIGN recommend the use of lower limit of normal (LLN) for FEV_1/FVC ratio (instead of the fixed ratio of 70%) in order to avoid the substantial under diagnosis in children and over diagnosis of obstruction in older people. On a practical level, the use of spirometry is not well established in children in primary care and additional training may be needed to ensure accurate results.

3.1.6 The role of FeNO in diagnosis advocated by NICE and BTS/SIGN is very different, and GINA considers that FeNO is not helpful in ruling in or ruling out an asthma diagnosis. NICE advocates a central role for FeNO in diagnosis, which we do not support given the limitations mentioned above. We do however see a positive role for FeNO in line with BTS/SIGN guidance, which acknowledges that a positive FeNO test indicates the presence of eosinophilic inflammation and increases the probability of asthma, where the structured clinical assessment suggests an intermediate probability.

3.1.7 We are concerned that NICE's recommendation to use FeNO in all people with suspected asthma as a primary investigation raises significant and additional implementation challenges and could have a number of unintended consequences. We recognise that FeNO is not widely available in primary care, is an additional cost - both in terms of initial investment and ongoing cost of consumables - and is therefore unlikely to be considered a viable option for an individual practice, but may be more realistically provided as part of a locality based diagnostic service. A perceived mandatory requirement for FeNO testing may increase referrals into secondary care. This risks deskilling primary care, and overloading secondary care services.

Figure 1: BTS/SIGN Diagnostic algorithm (2016)



[1] In children under 5 years and others unable to undertake spirometry in whom there is a high or intermediate probability of asthma, the options are monitored initiation of treatment or watchful waiting according to the assessed probabilityof asthma.

Diagnosis in children

3.1.8 The diagnosis of asthma in children aged under 5 yrs is based on establishing the probability of asthma after an initial structured clinical assessment, and if appropriate, followed by an 8 week trial of ICS 400mcg/day. Where diagnostic doubt persists referral for specialist assessment should be considered.

3.1.9 Confirmation by objective demonstration of peak flow or spirometry reversibility is desirable in children old enough to perform these tests.

All ages

3.1.10 While investigating asthma and until diagnosis is confirmed, use code 'Suspected asthma' – and once the diagnosis is confirmed, record the basis for a diagnosis of asthma in a single entry in the person's medical records, alongside the coded diagnostic entry.

NICE comments on implementation

3.1.11 We are pleased to see that NICE recommends a 'phased implementation'. However, this does not address the more fundamental concerns we have about the weaknesses of testing at a single point in time. Although NICE talks of allowing time for the investment and training required to implement the new guidance, it gives no guidance on the approach to or pace of implementation at a local level, nor how it will be funded. Balanced against other priorities within respiratory care and more broadly in the NHS, we do not see the widespread implementation of FeNO testing for all as a high priority but localities should begin to address where and at what scale it can add value.

3.2 Asthma management - PCRS-UK recommendation

3.2.1 PCRS-UK recommends a patient centred approach, where supporting self-management and partnership with the patient are central to asthma management.

3.2.2 We recommend promoting non-pharmacological approaches regardless of the medication patients are on – addressing tobacco dependency, weight control, activity/exercise, promoting use of spacers to increase efficacy of MDIs

3.2.3 Before any change is made to medication if control is inadequate – check for (and address) the following common causes of poor control:

- Incorrect – or additional, co-morbid - diagnosis
- Lack of adherence
- Check number of SABAs vs ICS being used
- Inappropriate inhaler technique
- Smoking (active or passive)
- Occupational exposures
- Psychosocial factors
- Seasonal or environmental factors

3.2.4 We recommend that prescriptions for inhalers are written by their brand names and device to ensure that patients receive the inhaler that the prescriber intends for them. Writing the generic name or not specifying the device may result in a patient receiving an inhaler they have not been taught to use.

3.2.5 PCRS-UK regards ICS as the bedrock of asthma treatment and therefore supports the use of regular low dose ICS with SABA on a prn basis, as first line maintenance treatment in most adults with asthma.

3.2.6 We advocate close monitoring of the use of SABA to ensure no more than 12 a year. (The National Review of Asthma Deaths identified this as a risk for fatal asthma.) There is a range of opinion on the right threshold for prompt clinical review of patients who over-use SABA with some believing that 12 is too high, and that the threshold for 'poor control' should be as low as 6 per year, or somewhere between 6 and 12.

3.2.7 NICE and SIGN/BTS have different advice on the choice of first-line add-on treatment to low dose ICS. Clinicians have a choice between adding an LTRA or adding a LABA for patients not controlled on low dose ICS. Clinicians are currently confident and in the habit of adding in LABA at this stage in line with BTS/SIGN recommendations, however based on the evidence review undertaken by NICE there is little to choose between LABA and LTRA.

3.2.7.1 LABA are marginally more effective than LTRA in controlling exacerbations. In addition, they are given as combination inhalers so that non-adherence with ICS is prevented.

3.2.7.2 LTRA are substantially cheaper than LABA. Cost is a key consideration for the NHS and thus unless there is good reason to the contrary, PCRS-UK recommends trying LTRA as first line add on therapy to ICS. It is important to withdraw the LTRA if it is ineffective (adding LABA to the LTRA would obviate the cost advantage of this approach).

3.2.7.3 LTRA are oral, while LABA are inhaled which may be an advantage for some people, and LTRA are also effective in allergic rhinitis.

3.2.7.4 Factors such as patient preference, compliance, concomitant diseases (e.g. rhinitis), risk of exacerbation are important factors for the clinician to consider when deciding the best option for an individual patient. Ultimately the decision should be made after discussion between the clinician and patient.

3.2.7.5 It is inappropriate to switch a patient whose symptoms are well controlled on current treatment, so there is no need to change the medication of patients who are well controlled on LABA/ICS.

3.2.8 PCRS-UK supports the use of a paediatric low dose ICS with LTRA, as first line add on treatment in children with asthma. If this combination is ineffective, switch the LTRA for a LABA.

3.3 Monitoring asthma – PCRS-UK recommendation

3.3.1 Monitor asthma control at every review, using peak flow and/or spirometry. If control is suboptimal, check:

- The diagnosis (are the symptoms due to asthma?)
- Adherence to treatment
- Inhaler technique
- Review suitability of current treatment
- Ask about occupational triggers
- Ideas and concerns about asthma and its treatment

- Ask about other triggers, especially smoking tobacco or other substances, and use an exhaled carbon monoxide meter to monitor

3.3.2 Use a validated questionnaire to assess control – Asthma Control Questionnaire or Asthma Control Test. RCP3Qs are a useful screening test for poor control (any positive answers should trigger a more in-depth assessment of control).

3.3.3 There is insufficient evidence from real-life primary care to support using FeNO routinely to monitor asthma control. However, it may be an option to support asthma management in people who are symptomatic despite using ICS as it can help detect poor adherence.

3.3.4 Observe and give advice on inhaler technique :

- at every consultation
- when there is deterioration in control
- when the inhaler device is changed
- if the patient requests a check

3.3.5 Record in the notes symptomatic asthma control, lung function, asthma attacks, oral corticosteroid use, and time off work/school.

3.3.6 Support the patient in self managing their condition and promote the use of an action plan.

November 2017

Appendices - Differences between BTS/SIGN and NICE guidelines

4. Differences between BTS/SIGN and NICE guidelines

4.1 Diagnosing asthma

4.1.1 BTS/SIGN guidance

The BTS/SIGN guideline sets out some clear principles about diagnosing asthma:

- The diagnosis of asthma is a clinical one. They recommend a structured clinical assessment to assess the initial probability of asthma.
- Central to all definitions is the presence of symptoms (more than one of wheeze, breathlessness, chest tightness, cough) and of variable airflow obstruction, airway hyperresponsiveness and/or inflammation.
- Tests influence the probability of asthma but do not prove a diagnosis. Spirometry is the investigation of choice, using the lower limit of normal, together with bronchodilator reversibility testing. However BTS/SIGN stress that a normal spirogram does not exclude asthma, since it may indicate that the patient is asymptomatic at that point in time.
- Asthma status and the outcome of diagnostic tests for asthma vary over time. Therefore they recommend comparing the outcome of tests when the patient is symptomatic and asymptomatic to determine whether there is variation.

Referral for challenge testing or FeNO if there is still diagnostic uncertainty is recommended, along with peak flow testing. FeNO Is regarded as providing supportive but not conclusive evidence for an asthma diagnosis. They point out that there are some important confounders so that FeNO will not always detect asthma.

4.1.2 NICE guidance

- NICE advocates a great reliance on objective testing, and recommends that asthma is not diagnosed on symptoms alone. As well as taking a structured clinical history, and examination, it is recommended that tests - FeNO and spirometry - are undertaken at the first presentation if possible.
- Occupational asthma should always be checked for in adults.
- In children and young people, spirometry is the first line recommended test, and if obstruction is found, then bronchodilator reversibility testing. Peak flow monitoring is only recommended after FeNO testing in cases of diagnostic uncertainty.
- In adults, FeNO testing and spirometry are the first tests recommended. If obstruction is found, then bronchodilator reversibility testing. Peak flow monitoring is advised for 2-4 weeks to check on variability. If there is still uncertainty, then referral for histamine/methacholine challenge testing is recommended.
- NICE recommends that diagnostic hubs are considered by those responsible for service provision – and specifically mentions CCGs in England. This appears to have been included in the most recent draft guideline in order to address the objections raised to the first draft, such as the issue of lack of availability and cost of FeNO testing in primary care, and insufficient numbers of trained staff in spirometry. They suggest that diagnostic hubs may achieve economies of scale and improve the practicality of implementing the guidelines. No evidence is offered to support the recommendation for diagnostic hubs.

- In the feasibility testing of the initial draft guideline (2015) -
    - 59% of patients with suspected asthma remained of uncertain diagnostic status at the end of the study period (25% had asthma)
    - Spirometry was normal in 73 % of those diagnosed with asthma
    - Diagnostic value of FeNO testing in the study is not reported
    - Fourteen (10%) of the patients with suspected asthma reached the point in the algorithm of requiring bronchial provocation testing – which was in effect not available – no patient had undergone this test by the time the project closed

4.2 Monitoring asthma

4.2.1 BTS/SIGN guideline

BTS SIGN gives a thorough overview of tools/questionnaires for monitoring asthma and recommends their use in order that consistent and specific information about the impact of asthma on daily life is collected systematically.

It also gives clear recommendations for what should be monitored and recorded in annual reviews. It stresses recording symptomatic asthma control, lung function, asthma attacks, oral corticosteroid use, and time off work/school.

It is strong in recommending the role of a self-management plan and on having discussions about self-management with the patient.

4.2.2 NICE guideline

This section of the guideline was succinct and relatively uncontentious. It underplays the importance of monitoring smoking behaviour compared to BTS/SIGN, as well as the role of supporting self-management.

It does not recommend FeNO testing for routine monitoring of asthma, but does recommend it for people not controlled on ICS. Since ICS are now recommended as the mainstay of treatment, this is somewhat confusing.

4.3 Managing asthma

4.3.1 BTS/SIGN guideline

- BTS/SIGN recently removed the numbering of steps in favour of verbal descriptions of treatment stages. It describes more clearly the sequence of treatments to be used if standard doses of ICS are not effective in controlling symptoms.
- In all but those with infrequent shortlived wheeze, regular low dose ICS with SABA as required is the recommended first line treatment.
- The first line add-on to low dose ICS is LABA. If this proves inadequate in controlling symptoms, there are three possibilities at the next step (additional add-on therapies). LTRAs only feature if an increased dose of ICS, with or without continued LABA, is insufficient to control asthma symptoms.
- There is a clear intention to defer the use of high dose ICS, and to step down from high dose ICS once control has been regained.
- Referral to a specialist is recommended for patients requiring high dose ICS.
- BTS/SIGN covers non-pharmacological approaches comprehensively - such as tobacco dependency, weight control, activity/exercise, complementary therapies
- There is a significant section on the importance of supported self-management.

4.3.2 NICE guideline

- The most significant difference between the NICE guideline and the BTS/SIGN British asthma guideline is the recommendation of the first-line add-on treatment to low dose inhaled corticosteroids (ICS) in adults when asthma is not sufficiently controlled. NICE recommends a leukotriene receptor antagonist (LTRA) whereas BTS/SIGN recommends a long-acting beta agonist (LABA).
- This recommendation is based explicitly on its health economic analysis which found that it would be much more cost effective for LTRAs to be used rather than LABAs as first-line add-on to ICS. They estimate that there could be significant savings to the NHS by deferring the use of LABAs in favour of LTRAs.
- There are some significant omissions from the NICE guideline, so that the guideline does not cover all aspects of asthma management (no section on emergency treatment, nor guidance on management of severe or brittle asthma, nor non-pharmacological treatments such as tobacco dependency, weight control, activity/exercise, complementary therapies). The final guideline has therefore been called Chronic asthma management
    - It is unclear on when patients should be referred for an expert opinion
    - The central importance of inhaler technique is not mentioned, nor is the use of spacers to enhance the delivery of medication from a metered dose inhaler