NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline

Asthma: diagnosis, monitoring and chronic asthma management

Draft for consultation, October 2019

This guideline covers diagnosing, monitoring and managing asthma in adults, young people and children. It aims to improve the accuracy of diagnosis, help people to control their asthma and reduce the risk of asthma attacks. It does not cover managing severe asthma or acute asthma attacks.

Who is it for?

- GPs and practice nurses
- Healthcare professionals in secondary care and tertiary asthma services
- Commissioners and providers
- People with suspected or diagnosed asthma, their families and carers

This guideline will update NICE guideline NG80 (published November 2017).

We have reviewed the evidence on increasing the dose of inhaled corticosteroids within a self-management programme in children and young people with asthma. You are invited to comment on the new and updated recommendations. These are marked as **[2020]**.

You are also invited to comment on recommendations that NICE proposes to delete from the 2017 guideline.

We have not reviewed the evidence for the recommendations shaded in grey, and cannot accept comments on them. In some cases, we have made minor wording changes for clarification.

See update information for a full explanation of what is being updated.

This draft guideline contains:

- the draft recommendations
- recommendations for research
- rationale and impact sections that explain why the committee made the 2020 recommendations and how they might affect practice
- the guideline context.

Full details of the evidence and the committee's discussion on the 2020 recommendations are in the evidence review. Evidence for the 2017 recommendations is in the full version of the 2017 guideline.

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Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1.1 Initial clinical assessment

See also algorithm A for initial clinical assessment in adults, young people and children with suspected asthma.

Clinical history

1.1.1 Take a structured clinical history in people with suspected asthma. Specifically, check for:

- wheeze, cough or breathlessness, and any daily or seasonal variation in these symptoms
- any triggers that make symptoms worse
- a personal or family history of atopic disorders. **[2017]**

1.1.2 Do not use symptoms alone without an objective test to diagnose asthma. **[2017]**

1.1.3 Do not use a history of atopic disorders alone to diagnose asthma. **[2017]**

Physical examination

1.1.4 Examine people with suspected asthma to identify expiratory polyphonic wheeze and signs of other causes of respiratory symptoms, but be aware that even if examination results are normal the person may still have asthma. **[2017]**

Initial treatment and objective tests for acute symptoms at presentation

1.1.5 Treat people immediately if they are acutely unwell at presentation, and perform objective tests for asthma (for example, fractional exhaled nitric oxide [FeNO], spirometry and peak flow variability) if the equipment is available and testing will not compromise treatment of the acute episode. **[2017]**

1.1.6 If objective tests for asthma cannot be done immediately for people who are acutely unwell at presentation, carry them out when acute symptoms have been controlled, and advise people to contact their healthcare professional immediately if they become unwell while waiting to have objective tests. **[2017]**

1.1.7 Be aware that the results of spirometry and FeNO tests may be affected in people who have been treated empirically with inhaled corticosteroids. **[2017]**

Testing for asthma

1.1.8 Do not offer the following as diagnostic tests for asthma:

- skin prick tests to aeroallergens
- serum total and specific IgE
- peripheral blood eosinophil count
- exercise challenge (to adults aged 17 and over). **[2017]**

1.1.9 Use skin prick tests to aeroallergens or specific IgE tests to identify triggers after a formal diagnosis of asthma has been made. **[2017]**

Occupational asthma

1.1.10 Check for possible occupational asthma by asking employed people with suspected new-onset asthma, or established asthma that is poorly controlled:

- Are symptoms better on days away from work?

- Are symptoms better when on holiday[1]?

Make sure all answers are recorded for later review. **[2017]**

1.1.11 Refer people with suspected occupational asthma to an occupational asthma specialist. **[2017]**

1.2 Diagnosing asthma in young children

1.2.1 For children under 5 with suspected asthma, treat symptoms based on observation and clinical judgement, and review the child on a regular basis (see section 1.8). If they still have symptoms when they reach 5 years, carry out objective tests (see section 1.3 and algorithm B). **[2017]**

1.2.2 If a child is unable to perform objective tests when they are aged 5:

- continue to treat based on observation and clinical judgement
- try doing the tests again every 6 to 12 months until satisfactory results are obtained
- consider referral for specialist assessment if the child repeatedly cannot perform objective tests and is not responding to treatment. **[2017]**

1.3 Objective tests for diagnosing asthma in adults, young people and children aged 5 and over

See also table 1 for a summary of objective test threshold levels.

Diagnostic hubs

1.3.1 Those responsible for planning diagnostic service support to primary care (for example, clinical commissioning groups) should consider establishing asthma diagnostic hubs to achieve economies of scale and improve the practicality of implementing the recommendations in this guideline. **[2017]**

[1] 'Holiday' here means any longer time away from work than usual breaks at weekends or between shifts.

Airway inflammation measures

Fractional exhaled nitric oxide

1.3.2 Offer a FeNO test to adults (aged 17 and over) if a diagnosis of asthma is being considered. Regard a FeNO level of 40 parts per billion (ppb) or more as a positive test. **[2017]**

1.3.3 Consider a FeNO test in children and young people (aged 5 to 16)[2] if there is diagnostic uncertainty after initial assessment and they have either:

- normal spirometry **or**
- obstructive spirometry with a negative bronchodilator reversibility (BDR) test.

Regard a FeNO level of 35 ppb or more as a positive test. **[2017]**

1.3.4 Be aware that a person's current smoking status can lower FeNO levels both acutely and cumulatively. However, a high level remains useful in supporting a diagnosis of asthma. **[2017]**

Lung function tests

Spirometry

1.3.5 Offer spirometry to adults, young people and children aged 5 and over if a diagnosis of asthma is being considered. Regard a forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) ratio of less than 70% (or below the lower limit of normal if this value is available) as a positive test for obstructive airway disease (obstructive spirometry). **[2017]**

[2] Children at the lower end of the age range may not be able to do the FeNO test adequately. In these cases, apply the principles in recommendation 1.2.2.

Bronchodilator reversibility

1.3.6 Offer a BDR test to adults (aged 17 and over) with obstructive spirometry (FEV1/FVC ratio less than 70%). Regard an improvement in FEV1 of 12% or more, together with an increase in volume of 200 ml or more, as a positive test. **[2017]**

1.3.7 Consider a BDR test in children and young people (aged 5 to 16) with obstructive spirometry (FEV1/FVC ratio less than 70%). Regard an improvement in FEV1 of 12% or more as a positive test. **[2017]**

Peak expiratory flow variability

1.3.8 Monitor peak flow variability for 2 to 4 weeks in adults (aged 17 and over) if there is diagnostic uncertainty after initial assessment and a FeNO test and they have either:

- normal spirometry **or**
- obstructive spirometry, reversible airways obstruction (positive BDR) but a FeNO level of 39 ppb or less.

Regard a value of more than 20% variability as a positive test. **[2017]**

1.3.9 Consider monitoring peak flow variability for 2 to 4 weeks in adults (aged 17 and over) if there is diagnostic uncertainty after initial assessment and they have:

- obstructive spirometry **and**
- irreversible airways obstruction (negative BDR) **and**
- a FeNO level between 25 and 39 ppb.

Regard a value of more than 20% variability as a positive test. **[2017]**

1.3.10 Monitor peak flow variability for 2 to 4 weeks in children and young people (aged 5 to 16) if there is diagnostic uncertainty after initial assessment and a FeNO test and they have either:

- normal spirometry **or**
- obstructive spirometry, irreversible airways obstruction (negative BDR) and a FeNO level of 35 ppb or more.

Regard a value of more than 20% variability as a positive test. **[2017]**

Airway hyperreactivity measures

Direct bronchial challenge test with histamine or methacholine

1.3.11 Offer a direct bronchial challenge test with histamine or methacholine[3] to adults (aged 17 and over) if there is diagnostic uncertainty after a normal spirometry and either a:

- FeNO level of 40 ppb or more and no variability in peak flow readings **or**
- FeNO level of 39 ppb or less with variability in peak flow readings.

Regard a PC20 value of 8 mg/ml or less as a positive test. **[2017]**

1.3.12 Consider a direct bronchial challenge test with histamine or methacholine[3] in adults (aged 17 and over) with:

- obstructive spirometry without bronchodilator reversibility **and**
- a FeNO level between 25 and 39 ppb **and**
- no variability in peak flow readings (less than 20% variability over 2 to 4 weeks).

Regard a PC20 value of 8 mg/ml or less as a positive test. **[2017]**

1.3.13 If a direct bronchial challenge test with histamine or methacholine is unavailable, suspect asthma and review the diagnosis after treatment, or

[3] At the time of publication (November 2017), histamine and methacholine did not have UK marketing authorisation for this use. The healthcare professional should follow relevant professional guidance, taking full responsibility for the decision to use this test. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

refer to a centre with access to a histamine or methacholine challenge test. **[2017]**

Diagnosis in children and young people aged 5 to 16

See also algorithm B for objective tests in young people and children aged 5 to 16.

1.3.14 Diagnose asthma in children and young people (aged 5 to 16) if they have symptoms suggestive of asthma and:

- a FeNO level of 35 ppb or more and positive peak flow variability **or**
- obstructive spirometry and positive bronchodilator reversibility. **[2017]**

1.3.15 Suspect asthma in children and young people (aged 5 to 16) if they have symptoms suggestive of asthma and:

- a FeNO level of 35 ppb or more with normal spirometry and negative peak flow variability, **or**
- a FeNO level of 35 ppb or more with obstructive spirometry but negative bronchodilator reversibility and no variability in peak flow readings, **or**
- normal spirometry, a FeNO level of 34 ppb or less and positive peak flow variability.

Do not rule out other diagnoses if symptom control continues to remain poor after treatment. Review the diagnosis after 6 weeks by repeating any abnormal tests and reviewing symptoms. **[2017]**

1.3.16 Refer children and young people (aged 5 to 16) for specialist assessment if they have obstructive spirometry, negative bronchodilator reversibility and a FeNO level of 34 ppb or less. **[2017]**

1.3.17 Consider alternative diagnoses and referral for specialist assessment in children and young people (aged 5 to 16) if they have symptoms suggestive of asthma but normal spirometry, a FeNO level of 34 ppb or less and negative peak flow variability. **[2017]**

Diagnosis in adults aged 17 and over

See also algorithm C for objective tests in adults aged 17 and over.

1.3.18 Diagnose asthma in adults (aged 17 and over) if they have symptoms suggestive of asthma and:

- a FeNO level of 40 ppb or more with either positive bronchodilator reversibility or positive peak flow variability or bronchial hyperreactivity, **or**
- a FeNO level between 25 and 39 ppb and a positive bronchial challenge test, **or**
- positive bronchodilator reversibility and positive peak flow variability irrespective of FeNO level. **[2017]**

1.3.19 Suspect asthma in adults (aged 17 and over) with symptoms suggestive of asthma, obstructive spirometry and:

- negative bronchodilator reversibility, and either a FeNO level of 40 ppb or more, or a FeNO level between 25 and 39 ppb and positive peak flow variability, **or**
- positive bronchodilator reversibility, a FeNO level between 25 and 39 ppb and negative peak flow variability.

Do not rule out other diagnoses if symptom control continues to remain poor after treatment. Review the diagnosis after 6 to 10 weeks by repeating spirometry and objective measures of asthma control and reviewing symptoms. **[2017]**

1.3.20 Consider alternative diagnoses, or referral for a second opinion, in adults (aged 17 and over) with symptoms suggestive of asthma and:

- a FeNO level below 40 ppb, normal spirometry and positive peak flow variability, **or**
- a FeNO level of 40 ppb or more but normal spirometry, negative peak flow variability, and negative bronchial challenge test, **or**

- obstructive spirometry with bronchodilator reversibility, but a FeNO level below 25 ppb, and negative peak flow variability, **or**
- positive peak flow variability but normal spirometry, a FeNO level below 40 ppb, and a negative bronchial challenge test, **or**
- obstructive spirometry with negative bronchodilator reversibility, a FeNO level below 25 ppb, and negative peak flow variability (if measured). **[2017]**

Diagnosis in people who are unable to perform an objective test

For young children who cannot perform objective tests, see section 1.2.

1.3.21 If an adult, young person or child with symptoms suggestive of asthma cannot perform a particular test, try to perform at least 2 other objective tests. Diagnose suspected asthma based on symptoms and any positive objective test results. **[2017]**

Good clinical practice in asthma diagnosis

1.3.22 Record the basis for a diagnosis of asthma in a single entry in the person's medical records, alongside the coded diagnostic entry. **[2017]**

1.4 Diagnostic summary

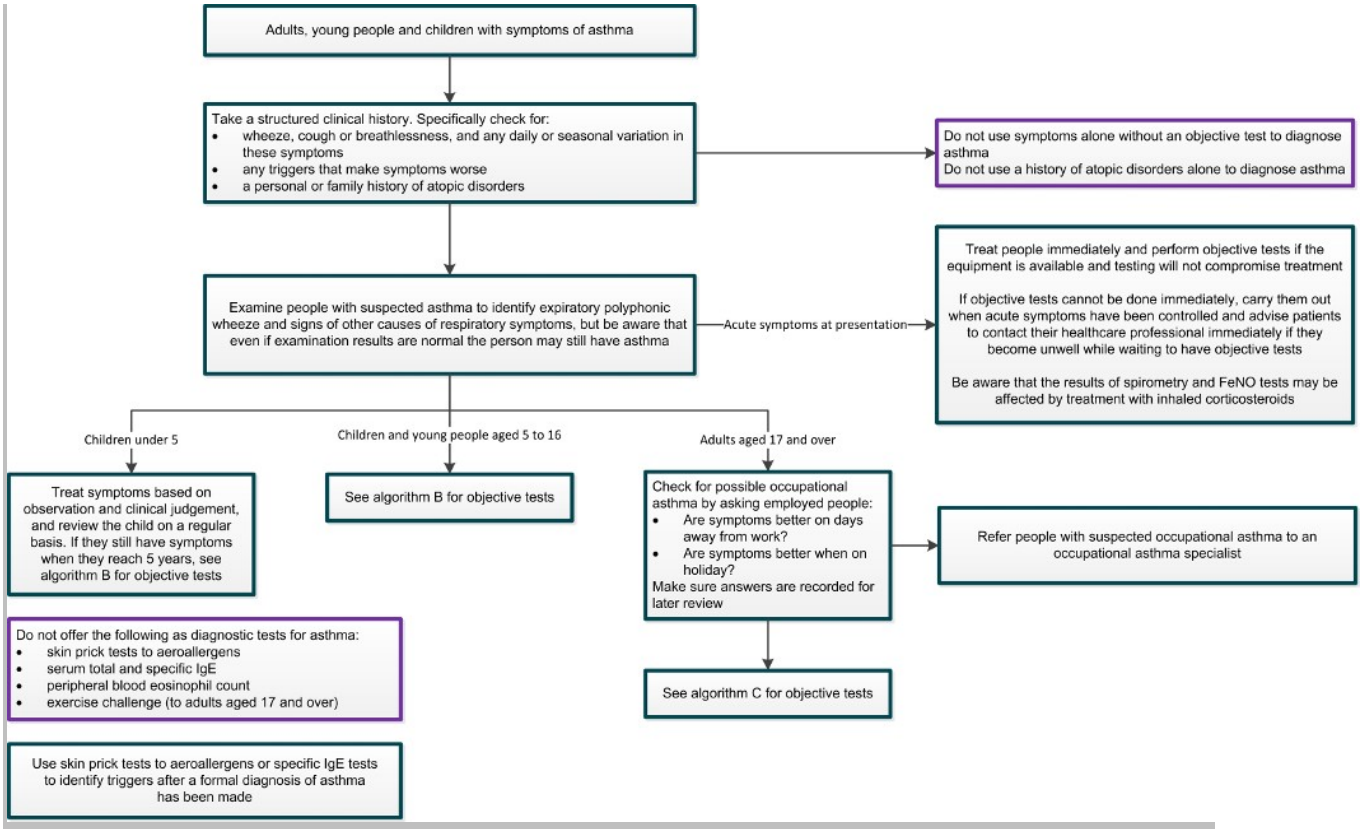
The following algorithms have been produced that summarise clinical assessment and objective testing for asthma. Table 1 summarises the objective test threshold levels.

Table 1 Positive test thresholds for objective tests for adults, young people and children (aged 5 and over)

Test	Population	Positive result
FeNO	Adults	40 ppb or more
	Children and young people	35 ppb or more
Obstructive spirometry	Adults, young people and children	FEV1/FVC ratio less than 70% (or below the lower limit of normal if this value is available)
Bronchodilator reversibility (BDR) test	Adults	Improvement in FEV1 of 12% or more and increase in volume of 200 ml or more
	Children and young people	Improvement in FEV1 of 12% or more
Peak flow variability	Adults, young people and children	Variability over 20%
Direct bronchial challenge test with histamine or methacholine	Adults	PC20 of 8 mg/ml or less
	Children and young people	n/a

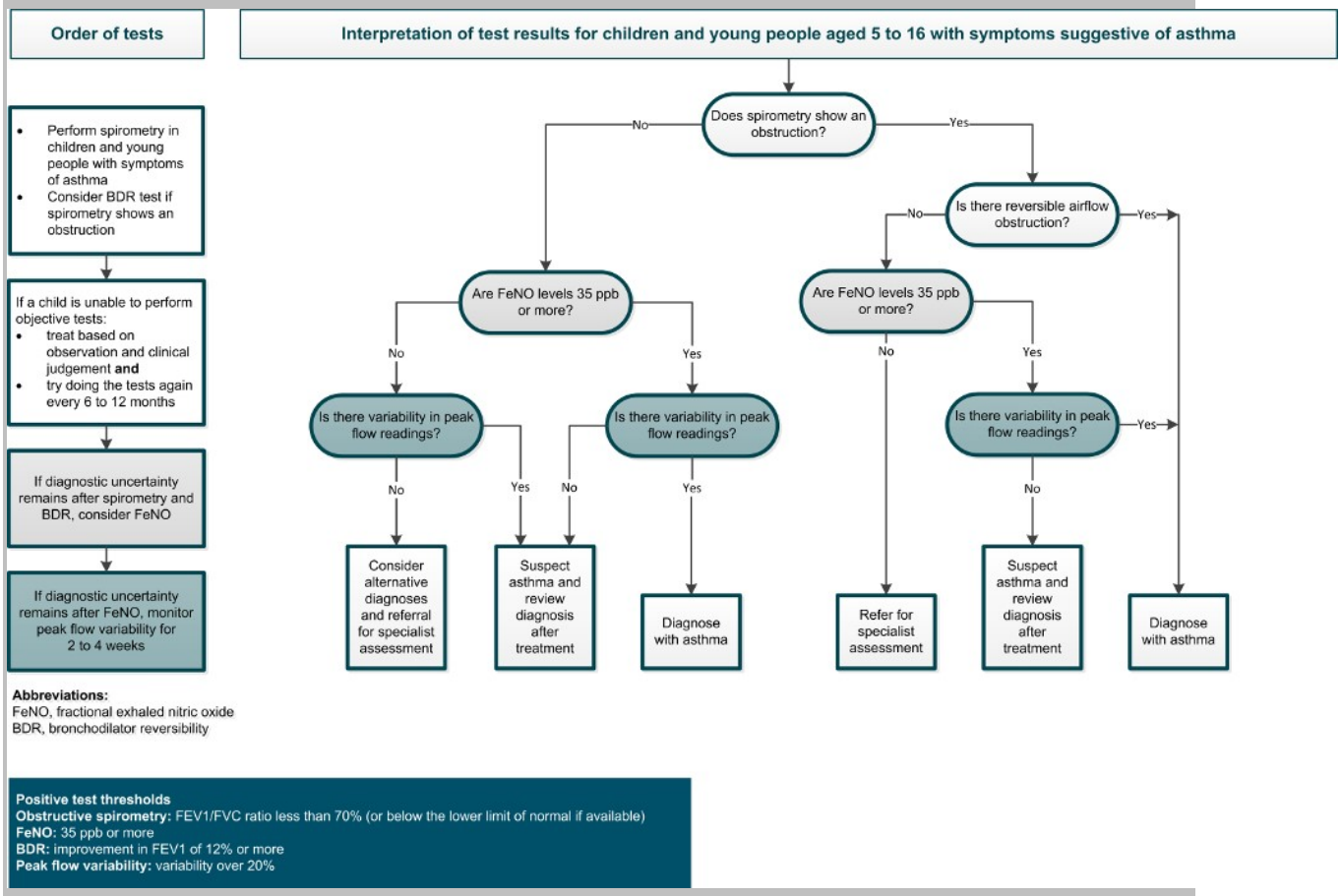
Abbreviations: FeNO, fractional exhaled nitric oxide; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; PC20, provocative concentration of methacholine causing a 20% fall in FEV1.

Algorithm A Initial clinical assessment for adults, young people and children with suspected asthma



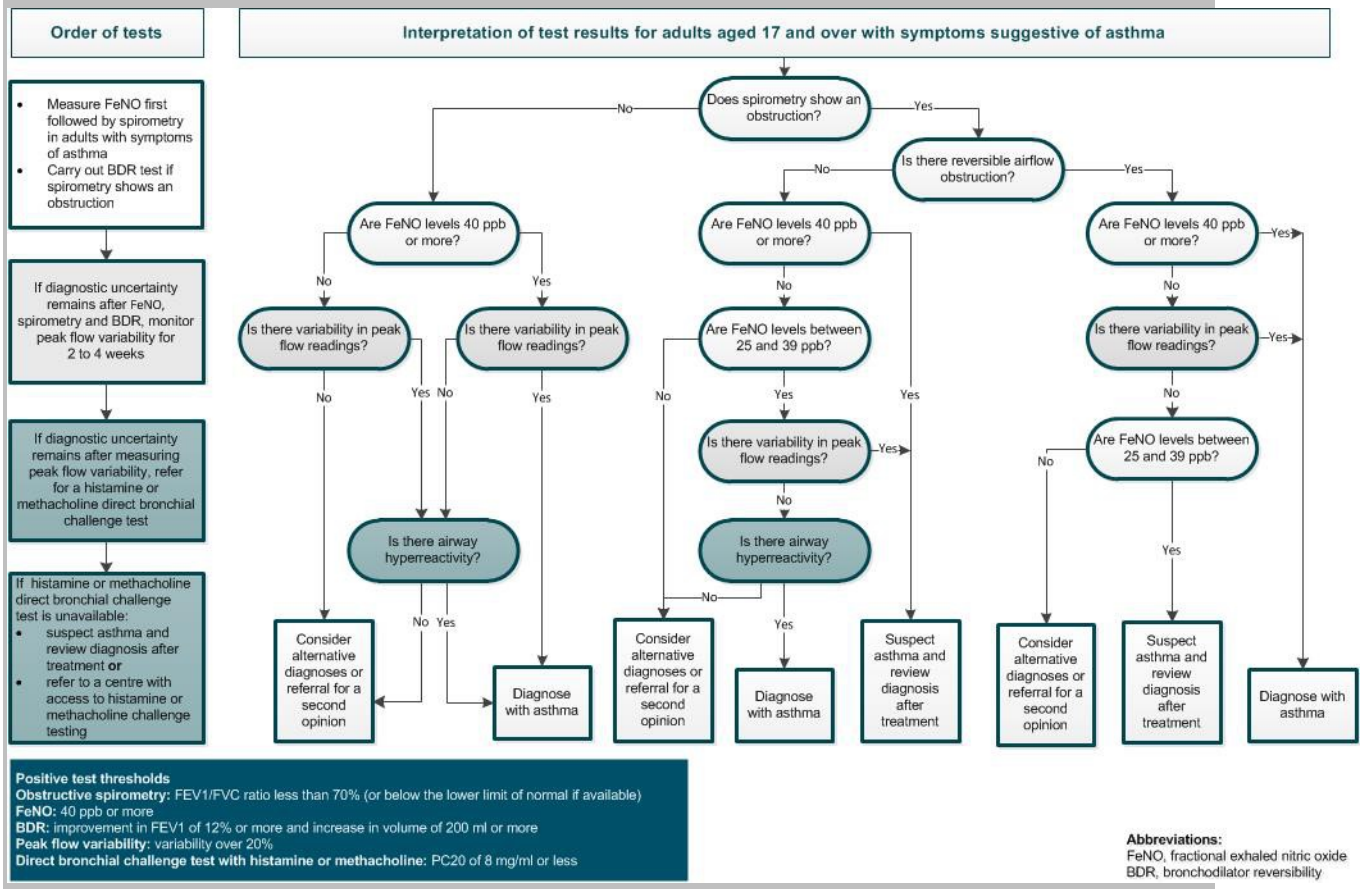
A full size downloadable PDF version is available in tools and resources

Algorithm B Objective tests for asthma in children and young people aged 5 to 16



A full size downloadable PDF version is available in tools and resources

Algorithm C Objective tests for asthma in adults aged 17 and over



A full size downloadable PDF version is available in tools and resources

1.5 Principles of pharmacological treatment

1.5.1 Take into account the possible reasons for uncontrolled asthma, before starting or adjusting medicines for asthma in adults, young people and children. These may include:

- alternative diagnoses
- lack of adherence
- suboptimal inhaler technique
- smoking (active or passive)
- occupational exposures
- psychosocial factors
- seasonal or environmental factors. **[2017]**

1.5.2 After starting or adjusting medicines for asthma, review the response to treatment in 4 to 8 weeks (see section 1.14 on monitoring asthma control). **[2017]**

1.5.3 If inhaled corticosteroid (ICS) maintenance therapy is needed, offer regular daily ICS rather than intermittent or 'when required' ICS therapy. **[2017]**

1.5.4 Adjust the dose of ICS maintenance therapy over time, aiming for the lowest dose required for effective asthma control. **[2017]**

1.5.5 Ensure that a person with asthma can use their inhaler device:

- at any asthma review, either routine or unscheduled
- whenever a new type of device is supplied. **[2017]**

1.6 Pharmacological treatment pathway for adults (aged 17 and over)

This section is for people with newly diagnosed asthma or asthma that is uncontrolled on their current treatment. Where the recommendations represent a change from traditional clinical practice, people whose asthma is well controlled on their current treatment should not have their treatment changed purely to follow this guidance.

1.6.1 Offer a short-acting beta$_2$ agonist (SABA) as reliever therapy to adults (aged 17 and over) with newly diagnosed asthma. **[2017]**

1.6.2 For adults (aged 17 and over) with asthma who have infrequent, short-lived wheeze and normal lung function, consider treatment with SABA reliever therapy alone. **[2017]**

1.6.3 Offer a low dose of an ICS as the first-line maintenance therapy to adults (aged 17 and over) with:

- symptoms at presentation that clearly indicate the need for maintenance therapy (for example, asthma-related symptoms 3 times a week or more, or causing waking at night) **or**
- asthma that is uncontrolled with a SABA alone. **[2017]**

1.6.4 If asthma is uncontrolled in adults (aged 17 and over) on a low dose of ICS as maintenance therapy, offer a leukotriene receptor antagonist (LTRA) in addition to the ICS and review the response to treatment in 4 to 8 weeks. **[2017]**

1.6.5 If asthma is uncontrolled in adults (aged 17 and over) on a low dose of ICS and an LTRA as maintenance therapy, offer a long-acting beta$_2$ agonist (LABA) in combination with the ICS, and review LTRA treatment as follows:

- discuss with the person whether or not to continue LTRA treatment
- take into account the degree of response to LTRA treatment. **[2017]**

1.6.6 If asthma is uncontrolled in adults (aged 17 and over) on a low dose of ICS and a LABA, with or without an LTRA, as maintenance therapy, offer to change the person's ICS and LABA maintenance therapy to a MART regimen with a low maintenance ICS dose. **[2017]**

1.6.7 If asthma is uncontrolled in adults (aged 17 and over) on a MART regimen with a low maintenance ICS dose, with or without an LTRA, consider increasing the ICS to a moderate maintenance dose (either continuing on a MART regimen or changing to a fixed-dose of an ICS and a LABA, with a SABA as a reliever therapy). **[2017]**

1.6.8 If asthma is uncontrolled in adults (aged 17 and over) on a moderate maintenance ICS dose with a LABA (either as MART or a fixed-dose regimen), with or without an LTRA, consider:

- increasing the ICS to a high maintenance dose (this should only be offered as part of a fixed-dose regimen, with a SABA used as a reliever therapy) **or**

- a trial of an additional drug (for example, a long-acting muscarinic receptor antagonist or theophylline) **or**
- seeking advice from a healthcare professional with expertise in asthma. **[2017]**

1.7 Pharmacological treatment pathway for children and young people aged 5 to 16

This section is for children and young people with newly diagnosed asthma or asthma that is uncontrolled on their current treatment. Where the recommendations represent a change from traditional clinical practice, children and young people whose asthma is well controlled on their current treatment should not have their treatment changed purely to follow guidance.

1.7.1 Offer a SABA as reliever therapy to children and young people (aged 5 to 16) with newly diagnosed asthma. **[2017]**

1.7.2 For children and young people (aged 5 to 16) with asthma who have infrequent, short-lived wheeze and normal lung function, consider treatment with SABA reliever therapy alone. **[2017]**

1.7.3 Offer a paediatric low dose of an ICS as the first-line maintenance therapy to children and young people (aged 5 to 16) with:

- symptoms at presentation that clearly indicate the need for maintenance therapy (for example, asthma-related symptoms 3 times a week or more, or causing waking at night) **or**
- asthma that is uncontrolled with a SABA alone. **[2017]**

1.7.4 If asthma is uncontrolled in children and young people (aged 5 to 16) on a paediatric low dose of ICS as maintenance therapy, consider an LTRA[4] in

[4] At the time of publication (November 2017), not all LTRAs have a UK marketing authorisation for use in children and young people aged under 18 for this indication.

addition to the ICS and review the response to treatment in 4 to 8 weeks. **[2017]**

1.7.5 If asthma is uncontrolled in children and young people (aged 5 to 16) on a paediatric low dose of ICS and an LTRA as maintenance therapy, consider stopping the LTRA and starting a LABA[5] in combination with the ICS. **[2017]**

1.7.6 If asthma is uncontrolled in children and young people (aged 5 to 16) on a paediatric low dose of ICS and a LABA as maintenance therapy, consider changing their ICS and LABA maintenance therapy to a MART regimen[6] with a paediatric low maintenance ICS dose. Ensure that the child or young person is able to understand and comply with the MART regimen. **[2017]**

1.7.7 If asthma is uncontrolled in children and young people (aged 5 to 16) on a MART regimen[6] with a paediatric low maintenance ICS dose, consider increasing the ICS to a paediatric moderate maintenance dose (either continuing on a MART regimen or changing to a fixed-dose of an ICS and a LABA, with a SABA as a reliever therapy). **[2017]**

1.7.8 If asthma is uncontrolled in children and young people (aged 5 to 16) on a paediatric moderate maintenance ICS dose with LABA (either as MART[6] or a fixed-dose regimen), consider seeking advice from a healthcare professional with expertise in asthma and consider either:

- increasing the ICS dose to paediatric high maintenance dose (only as part of a fixed-dose regimen, with a SABA used as a reliever therapy) **or**

[5] At the time of publication (November 2017), not all LABAs have a UK marketing authorisation for use in children and young people aged under 18 for this indication.
[6] At the time of publication (November 2017), MART regimens did not have a UK marketing authorisation for use in children and young people (aged under 12) for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

- a trial of an additional drug (for example, theophylline). **[2017]**

1.8 Pharmacological treatment pathway for children under 5

It can be difficult to confirm asthma diagnosis in young children, therefore these recommendations apply to children with suspected or confirmed asthma. Asthma diagnosis should be confirmed when the child is able to undergo objective tests (see section 1.2).

This section is for children under 5 with newly suspected or confirmed asthma, or with asthma symptoms that are uncontrolled on their current treatment. Where the recommendations represent a change from traditional clinical practice, children whose asthma is well controlled on their current treatment should not have their treatment changed purely to follow this guidance.

1.8.1 Offer a SABA as reliever therapy to children under 5 with suspected asthma. This should be used for symptom relief alongside all maintenance therapy. **[2017]**

1.8.2 Consider an 8-week trial of a paediatric moderate dose of an ICS in children under 5 with:

- symptoms at presentation that clearly indicate the need for maintenance therapy (for example, asthma-related symptoms 3 times a week or more, or causing waking at night) **or**
- suspected asthma that is uncontrolled with a SABA alone. **[2017]**

1.8.3 After 8 weeks, stop ICS treatment and continue to monitor the child's symptoms:

- if symptoms did not resolve during the trial period, review whether an alternative diagnosis is likely
- if symptoms resolved then reoccurred within 4 weeks of stopping ICS treatment, restart the ICS at a paediatric low dose as first-line maintenance therapy

- if symptoms resolved but reoccurred beyond 4 weeks after stopping ICS treatment, repeat the 8-week trial of a paediatric moderate dose of ICS. **[2017]**

1.8.4 If suspected asthma is uncontrolled in children under 5 on a paediatric low dose of ICS as maintenance therapy, consider an LTRA[7] in addition to the ICS. **[2017]**

1.8.5 If suspected asthma is uncontrolled in children under 5 on a paediatric low dose of ICS and an LTRA as maintenance therapy, stop the LTRA and refer the child to a healthcare professional with expertise in asthma for further investigation and management. **[2017]**

1.9 Adherence

1.9.1 For guidance on managing non-adherence to medicines in people with asthma, see the NICE guideline on medicines adherence. **[2017]**

1.10 Self-management

1.10.1 Offer an asthma self-management programme, comprising a written personalised action plan and education, to adults, young people and children aged 5 and over with a diagnosis of asthma (and their families or carers if appropriate). **[2017]**

1.10.2 Within a self-management programme, offer an increased dose of ICS for 7 days to adults (aged 17 and over) who are using an ICS in a single inhaler, when asthma control deteriorates. Clearly outline in the person's asthma action plan how and when to do this, and what to do if symptoms do not improve. When increasing ICS treatment:

- consider quadrupling the regular ICS dose
- do not exceed the maximum licensed daily dose. **[2017]**

[7] At the time of publication (November 2017), not all LTRAs have a UK marketing authorisation for use in children and young people aged under 18 for this indication.

1.10.3 For children and young people aged 5 to 16 with a diagnosis of asthma, include advice in their self-management plan on contacting a healthcare professional for a review, if their asthma control deteriorates (see also section 1.13 on monitoring asthma control). Encourage consistent ICS use to prevent deterioration and explain that there is no evidence of clinical benefit from increased doses of ICS. For people who have not maintained consistent ICS use, restarting ICS and taking it regularly may help them to regain control of their asthma. **[2020]**

1.10.4 Consider an asthma self-management programme, comprising a written personalised action plan and education, for the families or carers of children under 5 with suspected or confirmed asthma. **[2017]**

To find out why the committee made the 2020 recommendation on self-management and removed the 2017 recommendation on increasing ICS treatment within a self-management programme in children and young people and how this might affect practice, see rationale and impact.

1.11 Decreasing maintenance therapy

1.11.1 Consider decreasing maintenance therapy when a person's asthma has been controlled with their current maintenance therapy for at least 3 months. **[2017]**

1.11.2 Discuss with the person (or their family or carer if appropriate) the potential risks and benefits of decreasing maintenance therapy. **[2017]**

1.11.3 When reducing maintenance therapy:

- Stop or reduce dose of medicines in an order that takes into account the clinical effectiveness when introduced, side effects and the person's preference.
- Only consider stopping ICS treatment completely for people who are using low dose ICS alone as maintenance therapy and are symptom free. **[2017]**

1.11.4 Agree with the person (or their family or carer if appropriate) how the effects of decreasing maintenance therapy will be monitored and reviewed, including self-monitoring and a follow-up with a healthcare professional. **[2017]**

1.11.5 Review and update the person's asthma action plan when decreasing maintenance therapy. **[2017]**

1.12 Risk stratification

1.12.1 Consider using risk stratification to identify people with asthma who are at increased risk of poor outcomes, and use this information to optimise their care. Base risk stratification on factors such as non-adherence to asthma medicines, psychosocial problems and repeated episodes of unscheduled care for asthma. **[2017]**

1.13 Monitoring asthma control

1.13.1 Monitor asthma control at every review. If control is suboptimal:

- confirm the person's adherence to prescribed treatment in line with the recommendations on assessing adherence in the NICE guideline on medicines adherence
- review the person's inhaler technique
- review if treatment needs to be changed
- ask about occupational asthma (see recommendation 1.1.10) and/or other triggers, if relevant. **[2017]**

1.13.2 Consider using a validated questionnaire (for example, the Asthma Control Questionnaire or Asthma Control Test) to monitor asthma control in adults (aged 17 and over). **[2017]**

1.13.3 Monitor asthma control at each review in adults, young people and children aged 5 and over using either spirometry or peak flow variability testing. **[2017]**

1.13.4 Do not routinely use FeNO to monitor asthma control. **[2017]**

1.13.5 Consider FeNO measurement as an option to support asthma management in people who are symptomatic despite using inhaled corticosteroids. (This recommendation is from NICE's diagnostics guidance on measuring fractional exhaled nitric oxide concentration in asthma.) **[2017]**

1.13.6 Do not use challenge testing to monitor asthma control. **[2017]**

1.13.7 Observe and give advice on the person's inhaler technique:

- at every consultation relating to an asthma attack, in all care settings
- when there is deterioration in asthma control
- when the inhaler device is changed
- at every annual review
- if the person asks for it to be checked. **[2017]**

Terms used in this guideline

This section defines terms that have been used in a particular way for this guideline. For other definitions see the NICE glossary.

Expiratory polyphonic wheeze

A wheeze is a continuous, whistling sound produced in the airways during breathing. It is caused by narrowing or obstruction in the airways. An expiratory polyphonic wheeze has multiple pitches and tones heard over different areas of the lung when the person breathes out.

ICS doses

ICS doses and their pharmacological strengths vary across different formulations. In general, people with asthma should use the smallest doses of ICS that provide optimal control for their asthma, in order to reduce the risk of side effects.

For adults aged 17 and over:

- less than or equal to 400 micrograms budesonide or equivalent would be considered a low dose

- more than 400 micrograms to 800 micrograms budesonide or equivalent would be considered a moderate dose
- more than 800 micrograms budesonide or equivalent would be considered a high dose.

For children and young people aged 16 and under:

- less than or equal to 200 micrograms budesonide or equivalent would be considered a paediatric low dose
- more than 200 micrograms to 400 micrograms budesonide or equivalent would be considered a paediatric moderate dose
- more than 400 micrograms budesonide or equivalent would be considered a paediatric high dose.

MART

Maintenance and reliever therapy (MART) is a form of combined ICS and LABA treatment in which a single inhaler, containing both ICS and a fast-acting LABA, is used for both daily maintenance therapy and the relief of symptoms as required. MART is only available for ICS and LABA combinations in which the LABA has a fast-acting component (for example, formoterol).

Objective test to diagnose asthma

Tests carried out to help determine whether a person has asthma, the results of which are not based on the person's symptoms, for example, tests to measure lung function or evidence of inflammation. There is no single objective test to diagnose asthma.

Risk stratification

Risk stratification is a process of categorising a population by their relative likelihood of experiencing certain outcomes. In the context of this guideline, risk stratification involves categorising people with asthma by their relative likelihood of experiencing negative clinical outcomes (for example, severe exacerbations or hospitalisations). Factors including non-adherence to asthma medicines, psychosocial problems and repeated episodes of unscheduled care can be used to guide risk stratification.

Once the population is stratified, the delivery of care for the population can be targeted with the aim of improving the care of the strata with the highest risk.

Suspected asthma

Suspected asthma describes a potential diagnosis of asthma based on symptoms and response to treatment that has not yet been confirmed with objective tests.

Uncontrolled asthma

Uncontrolled asthma describes asthma that has an impact on a person's lifestyle or restricts their normal activities. Symptoms such as coughing, wheezing, shortness of breath and chest tightness associated with uncontrolled asthma can significantly decrease a person's quality of life and may lead to a medical emergency. Questionnaires are available that can be quantify this.

This guideline uses the following pragmatic thresholds to define uncontrolled asthma:

- 3 or more days a week with symptoms **or**
- 3 or more days a week with required use of a SABA for symptomatic relief **or**
- 1 or more nights a week with awakening due to asthma.

Putting this guideline into practice

NICE is recommending objective testing with spirometry and FeNO for most people with suspected asthma. This is a significant enhancement to current practice, which will take the NHS some time to implement, with additional infrastructure and training needed in primary care. New models of care, being developed locally, could offer the opportunity to implement these recommendations. This may involve establishing diagnostic hubs to make testing efficient and affordable. They will be able to draw on the positive experience of NICE's primary care pilot sites, which trialled the use of FeNO.

The investment and training required to implement the new guidance will take time. In the meantime, primary care services should implement what they can of the new

guidelines, using currently available approaches to diagnosis until the infrastructure for objective testing is in place.

NICE has produced tools and resources to help you put this guideline into practice.

- Adoption support resource
- Resource impact report
- Resource impact templates

Recommendations for research

The 2017 guideline committee made the following recommendations for research on diagnosing and monitoring asthma and for managing chronic asthma. The committee's full set of research recommendations is detailed in the 2017 full guideline on asthma: diagnosis and monitoring and the 2017 full guideline on chronic asthma management.

As part of the 2020 update, the guideline committee made 1 new research recommendation on managing asthma within a personalised asthma plan for children and young people.

Diagnosing and monitoring asthma

1 Diagnosing asthma in children and young people aged 5 to 16

What is the acceptability and diagnostic accuracy of objective tests that could be used to comprise a diagnostic pathway for asthma in children and young people aged 5 to 16 (for example, exercise challenge, direct bronchial challenge with histamine or methacholine, indirect bronchial challenge with mannitol and peripheral blood eosinophil count)? **[2017]**

Why this is important

Asthma is a common condition, diagnosed in nearly 1 in 10 children. There are no validated and reliable objective criteria for diagnosing asthma, so the vast majority of asthma diagnoses are currently based on symptoms and signs. However, symptoms and signs consistent with a diagnosis of asthma are not specific to the condition and can be present in other illnesses. This diagnostic uncertainty results in many children

being incorrectly diagnosed with asthma, and many children with asthma in whom the diagnosis is delayed or missed. A single objective measure, or set of objective measures, that can be performed easily in non-specialist clinical settings (although it is noted that challenge tests need to be performed in specialist settings) will help improve diagnostic certainty and reduce the proportion of children treated inappropriately for asthma. This would ensure that children with the condition are identified and treated early.

2 Diagnosing asthma in adults (aged 17 and over)

What is the clinical and cost effectiveness of using an indirect bronchial challenge test with mannitol to diagnose asthma in adults (aged 17 and over)? **[2017]**

Why this is important

Chronic airway inflammation is associated with bronchial hyper-responsiveness, which is integral to defining asthma. Bronchial challenge testing can help diagnose asthma and assess response to inhaled corticosteroid therapy. It can also be used to monitor asthma control, alongside assessing symptoms and lung function. It is increasingly used in asthma management, although currently most tests are performed only in specialised centres or research settings.

Indirect challenge tests with inhaled mannitol act via active inflammatory cells and mediators, whereas direct challenge tests with inhaled histamine or methacholine act directly on bronchial smooth muscle. Indirect challenge testing is more specific but less sensitive than direct challenges.

Direct challenge testing may not identify a person whose asthma will respond to inhaled corticosteroids. A positive result to an indirect challenge may reflect active airway inflammation that is likely to respond to inhaled corticosteroid therapy. Because a response to mannitol indicates active airway inflammation, identifying non-responsiveness in treated patients may help demonstrate good asthma control with inhaled corticosteroid therapy and identify people whose asthma is less likely to deteriorate after a dose reduction.

Mannitol bronchial challenge testing is quicker and simpler than current direct tests (which are generally confined to specialist respiratory centres), and uses a standardised inhaler device, so is potentially more useful in primary care.

3 Monitoring adherence to treatment

What is the clinical and cost effectiveness of using electronic alert systems designed to monitor and improve adherence with regular inhaled maintenance therapy in people with asthma? **[2017]**

Why this is important

Adherence with regular maintenance inhaled corticosteroids, on their own or in combination with long-acting beta agonists, is of paramount importance to achieve control of asthma and prevent asthma attacks. Published evidence in patients with severe asthma suggests that at least 30% of patients are partially or non-adherent with their prescribed medications, and the Royal College of Physicians' National Review of Asthma Deaths (NRAD) demonstrated that poor adherence was associated with 38% of asthma deaths.

4 Monitoring inhaler technique

What is the current frequency and the current method being used to check the inhaler technique of people with asthma? What is the optimal frequency and the best method of checking inhaler technique to improve clinical outcomes for people with asthma? **[2017]**

Why this is important

Knowing and understanding how to use an inhaler properly is the cornerstone of asthma management and symptom control. There has been an increase in the types of inhaler devices and the types of delivery system available. The various types of drugs for asthma control are also available in different inhaler devices on their own and in a combination of 2 drugs. It is therefore vital for patients to learn the proper inhaler technique for their device to ensure optimum drug delivery to the lungs for asthma control.

5 Monitoring asthma control using tele-healthcare

What is the long-term (more than 12 months) clinical and cost effectiveness of using tele-healthcare as a means to monitor asthma control in adults, young people and children? Methods of tele-healthcare can include telephone interview (with healthcare professional involvement) and internet or smartphone-based monitoring support (no healthcare professional involvement). **[2017]**

Why this is important

Asthma outcomes have not improved in the past 15 years, and the personal and economic costs of poor control are high. Computers and smartphones play an ever-greater role in modern life, with a growing proportion of people using them regularly for work, leisure, communication and information. The efficient use of distance monitoring systems and the integration of new technologies into healthcare are important for patients and for healthcare systems in terms of convenience, costs and outcomes.

Managing chronic asthma

1 Increasing the dose of ICS within a personalised asthma plan for children and young people

For children and young people with asthma that is managed in primary care, is there an advantage to increasing the ICS dose when asthma control has deteriorated compared with using the usual dose in a personalised asthma plan? **[2020]**

To find out why the committee made the research recommendation see rationale and impact.

2 Starting asthma treatment

In adults, young people and children with asthma who have not been treated previously, is it more clinically and cost effective to start treatment with a reliever alone (a short-acting beta$_2$ agonist [SABA]) or with a reliever (a SABA) and maintenance therapy (such as ICS)? Are there specific prognostic features that indicate that one of these treatment options may be more appropriate for some groups? **[2017]**

Why this is important

Recently best practice has shifted from starting people with asthma on a SABA as a reliever alone and starting maintenance therapy only if the person continues to have persistent asthma symptoms, to starting people on a low dose inhaled corticosteroid (ICS) as maintenance therapy alongside the SABA at the first instance. The committee agree with this shift and have included consensus-based recommendations in line with this pattern. However, the shift is not based on direct clinical evidence comparing these strategies for people with newly diagnosed asthma. There is also little evidence to support the particular groups in which one option or the other is more appropriate.

3 Second-line maintenance therapy in children and young people (under 16)

Is maintenance therapy more effective with a paediatric low dose of ICS plus a leukotriene receptor antagonist (LTRA) or with a paediatric low dose of ICS plus a long-acting beta$_2$ agonist (LABA) in the treatment of asthma in children and young people (under 16) who have uncontrolled asthma on a paediatric low dose of ICS alone? **[2017]**

Why this is important

There is a lack of evidence on managing asthma in children and young people under 16. Many of the recommendations for children and young people in this guideline were made using extrapolation from the adult evidence and the consensus of the guideline committee. The guideline committee would like to encourage more research in this age group. This particular question was prioritised because it affects the early stages of the treatment pathway and could have significant clinical and cost implications for managing asthma in this age group.

4 Additional maintenance therapy for asthma uncontrolled on a moderate dose of ICS plus LABA with or without LTRA

What is the clinical and cost effectiveness of offering additional maintenance therapy to adults, young people and children with asthma that is uncontrolled on a moderate dose of ICS plus LABA with or without LTRA? **[2017]**

Why this is important

The evidence is insufficient in quantity and quality to support strong recommendations for the use of additional maintenance therapy beyond moderate dose ICS plus LABA. The clinical evidence tends to favour the addition of a long-acting muscarinic antagonist (LAMA) but the guideline committee did not consider this to be conclusive, particularly because the addition of a LAMA is not cost effective compared with treatment with a placebo. In current practice, the alternative treatment options to adding a LAMA at this stage are increasing ICS dose to high, addition of theophyllines or a course of oral steroids. Therefore, to truly understand the cost effectiveness of LAMAs, a randomised controlled trial and health economic analysis taking into account the impact of LAMAs on oral steroid use and comparing the addition of LAMAs to any alternative strategy (as opposed to just placebo) is needed. The guideline committee felt the body of evidence, supported by consensus agreement and current practice, was sufficient to weakly recommend the options of ICS high dose plus LABA, addition of a LAMA or theophylline or seeking advice from a healthcare professional with expertise in asthma. However, a study comparing these various strategies would be critical for stronger recommendations or a more specific order of options.

5 Decreasing pharmacological treatment

In adults, young people and children with well-controlled asthma, what are the objective measurements and prognostic factors that indicate that a decrease in regular maintenance treatment is appropriate? **[2017]**

Why this is important

There is consensus within the guideline committee and across healthcare professionals managing asthma that people with well-controlled asthma should not remain on high dose or multiple preventer medicines for long periods of time. However, there is little evidence available about which people might benefit most from decreasing regular maintenance therapy. This guideline identified 3 studies attempting to answer this question but none of them included a sufficiently large population, with suitable decrease in treatment throughout and assessment of multiple prognostic markers.

6 Improving adherence to asthma medication

What are the most clinically and cost-effective strategies to improve medicines adherence in adults, young people and children with asthma who are non-adherent to prescribed medicines? **[2017]**

Why this is important

There is a consensus within the guideline committee and across healthcare professionals that medicines adherence is an important determinant of asthma control, and that non-adherence is a common problem. However, there is a lack of high-quality evidence on methods to improve adherence to asthma medicines. The guideline identified a number of studies focusing on this question, but there was not a strong body of evidence behind any specific intervention strategy. In addition, the guideline committee had concerns about the applicability of studies that did not report outcomes after a prolonged follow-up and studies that only used self-reported measures to assess adherence. The guideline committee felt further that higher-quality research is needed to recommend specific interventions for this common and significant problem.

Rationale and impact

These sections briefly explain why the committee made the recommendations and how they might affect practice. They link to details of the evidence and a full description of the committee's discussion.

Self-management

Recommendation 1.10.3

Why the committee changed the recommendations

The evidence for children and young people found that increasing the dose of inhaled corticosteroid (ICS) did not show any benefits or harms compared to the usual dose for reducing asthma exacerbations. It was limited to only 1 study with a small number of participants who had a personalised action plan. The committee also looked at studies in adults, but agreed that the evidence was not applicable because of the high average age of participants.

The 2017 guideline recommended that quadrupling the dose of ICS could be considered within a self-management plan for children and young people whose asthma is deteriorating. The guideline update committee agreed that this was based on limited evidence, mostly in adults, and that the new evidence did not support this. However, it also agreed that there wasn't any significant evidence to suggest that increasing the dose of ICS is harmful compared to the usual dose. The committee believe that increasing the dose of ICS within the licensed limit does not reduce child growth. This is supported by the evidence, which showed that increasing the dose in the short term did not result in a statistically significant decrease in child growth, even though the study exceeded the licensed limit.

Therefore, the committee decided to remove the 2017 recommendation rather than replacing it with a recommendation that prohibits increasing the dose of ICS.

The committee discussed the importance of a personalised action plan to guide children and young people if their asthma worsens and to reassure them that they are in control of their treatment. Children and young people who find that increasing their dose of ICS is helpful when their asthma control worsens should be able to continue to do this as an agreed strategy in their action plan. However, based on their experience the committee members agreed that it is important to review the child or young person's self-management plan if their asthma control is deteriorating. Reviews involve checking current medicines and inhaler technique, discussing any factors that may be triggering symptoms, discussing adherence and education needs, and reviewing their action plan. They should be carried out as needed, in addition to annual review.

The committee also discussed the importance of an individualised approach for children and young people, because they have varied and changing support needs at different ages. Studies have shown that most child asthma deaths involve children who have frequent but mild symptoms that are not responding to their personalised action plan. This recommendation should help to ensure that these children and young people receive the support that they need if they start to have problems with their asthma control.

The committee agreed that further research is needed to give clearer guidance on increasing the dose of ICS in children and young people within a self-management plan and made a research recommendation to promote further research and inform future practice.

How the recommendations might affect practice

The recommendation will lead to an increase in the review of self-management programmes for children and young people and reduce the variation in current practice for this. The increase in resources needed for this is likely to be offset by a reduction in the cost of treating asthma exacerbations.

Full details of the evidence and the committee's discussion are in evidence review: increasing ICS treatment within supported self-management for children and young people.

Return to recommendations

Context

Asthma is a chronic inflammatory respiratory disease. It can affect people of any age, but often starts in childhood. Asthma is a variable disease which can change throughout a person's life, throughout the year and from day to day. It is characterised by attacks (also known as exacerbations) of breathlessness and wheezing, with the severity and frequency of attacks varying from person to person. The attacks are associated with variable airflow obstruction and inflammation within the lungs, which if left untreated can be life-threatening, however with the appropriate treatment can be reversible.

In 2018 the Global Asthma report estimated that asthma affects 339 million people worldwide. It is the most common chronic condition to affect children, and in the UK approximately 5.4 million people (1.1 million children and 4.3 million adults) currently get treatment for asthma (Asthma UK).

The causes of asthma are not well understood. A number of risk factors are associated with the condition, often in combination. These influences can be genetic (the condition clusters in families) and/or environmental (such as inhalation of

allergens or chemical irritants). Occupational causes of asthma in adults are often under-recognised.

Diagnosis and monitoring

There is currently no gold standard test available to diagnose asthma; diagnosis is principally based on a thorough history taken by an experienced clinician. Studies of adults diagnosed with asthma suggest that up to 30% do not have clear evidence of asthma. Some may have had asthma in the past, but it is likely that many have been given an incorrect diagnosis. Conversely, other studies suggest that asthma may be underdiagnosed in some cases.

The diagnosis recommendations will improve patient outcomes and will be cost-effective to the NHS in the long-term; NICE's cost impact assessment projects a saving of approximately £12 million per year in England, before implementation costs.

Initial clinical assessment should include questions about symptoms (wheezing, cough, breathing and chest problems) and any personal or family history of allergies, atopic disorders or asthma. Various tests can be used to support a diagnosis, but there is no single test that can definitively diagnose asthma.

A number of methods and assessments are available to determine the likelihood of asthma. These include measuring airflow obstruction (spirometry and peak flow) and assessment of reversibility with bronchodilators, with both methods being widely used in current clinical practice. However, normal results do not exclude asthma and abnormal results do not always mean it is asthma, because they could be indicators of other respiratory diseases or spurious readings.

Testing for airway inflammation is increasingly used as a diagnostic strategy in clinical practice. This includes measuring fractional exhaled nitric oxide (FeNO).

Other diagnostic strategies include blood or skin prick tests to detect allergic reactions to environmental influences, exercise tests to detect evidence of bronchoconstriction, and measures of airway hyperreactivity such as histamine/methacholine or mannitol challenge tests. However, it is debatable which

test or measure, or combination of them, is the most effective to accurately diagnose asthma.

It is recognised that asthma control is suboptimal in many people with asthma. This has an impact on their quality of life, their use of healthcare services and the associated costs. Asthma control can be monitored by measuring airway obstruction or inflammation and by using validated questionnaires, but the most effective monitoring strategy is unclear.

Managing chronic asthma

The severity of asthma varies; some people have severe asthma that limits normal activities, whereas others are able to lead a relatively normal life. The illness fluctuates during the year and over time, so the level of treatment needs to be tailored to the person's current level of asthma severity. Many people with asthma, particularly children, seem to have fewer symptoms over time, and an important part of management is decreasing treatment if asthma is well controlled.

There is no cure for asthma, so management focuses on reducing exposure to known triggers if possible, relief of symptoms if there is airway narrowing, and reduction in airway inflammation by regular preventive treatment. Adherence to regular treatment reduces the risk of significant asthma attacks in most people with asthma. The focus of asthma management in recent years has been on supporting people with asthma and their healthcare professional to devise a personalised treatment plan that is effective and relatively easy to implement.

The aims of this guideline

The guideline covers children under 5, children and young people aged 5 to 16, and adults aged 17 and over with suspected or diagnosed asthma. The guideline applies to all primary, secondary and community care settings in which NHS-funded care is provided for people with asthma.

The sections on diagnosing and monitoring asthma (sections 1.1 to 1.4 and 1.14) aim to provide clear advice on effectively diagnosing people presenting with new symptoms of suspected asthma and monitoring to ensure optimum asthma control. It

is not intended to be used to re-diagnose people who already have an asthma diagnosis.

The sections on managing chronic asthma (sections 1.5 to 1.13) aim to provide clear advice for healthcare professionals and people with asthma to develop a personalised action plan. The plan should support self-management of asthma, and ensure that the person is receiving the best possible treatment for their current level of illness. It focuses on the pharmacological management of chronic asthma, in particular the treatment pathway for people with uncontrolled asthma. It also covers adherence to treatment, risk stratification and self-management.

The guideline does not cover severe, difficult-to-control asthma or the management of acute asthma attacks.

In 2018, new evidence was identified by the NICE surveillance team on increasing the dose of inhaled corticosteroids within a self-management programme in children and young people with asthma. Topic experts, including those who helped to develop the 2017 guideline, agreed that the new evidence could have an impact on the recommendations. This evidence has been reviewed and the recommendations in this area updated.

Finding more information and resources

To find out what NICE has said on topics related to this guideline, see our web page on asthma.

Update information

We have reviewed the evidence on increasing the dose of inhaled corticosteroids within a self-management programme in children and young people with asthma.

Recommendations are marked **[2020]** if the evidence has been reviewed.

Recommendations that have been deleted or changed

We propose to delete a recommendation from the **[2017]** guideline. Table 1 sets out this recommendation and includes details of replacement recommendations. If there

is no replacement recommendation, an explanation for the proposed deletion is given.

In recommendations shaded in grey and ending **[2017]**, we have not reviewed the evidence. In some cases minor changes have been made – for example, to update links, or bring the language and style up to date – without changing the intent of the recommendation.

See also the previous NICE guideline and supporting documents.

Table 1 Recommendations that have been deleted

Recommendation in [2017] guideline	Comment
Within a self-management programme, consider an increased dose of ICS for 7 days for children and young people (aged 5 to 16) who are using an ICS in a single inhaler, when asthma control deteriorates. Clearly outline in the person's asthma action plan how and when to do this, and what to do if symptoms do not improve. When increasing ICS treatment: • consider quadrupling the regular ICS dose • do not exceed the maximum licensed daily dose. (1.10.4)	Replaced by: For children and young people aged 5 to 16 with a diagnosis of asthma, include advice in their self-management plan on contacting a healthcare professional for a review, if their asthma control deteriorates (see also section 1.13 on monitoring asthma control). Encourage consistent ICS use to prevent deterioration and explain that there is no evidence of clinical benefit from increased doses of ICS. For people who have not maintained consistent ICS use, restarting ICS and taking it regularly may help them to regain control of their asthma. [2020] (1.10.3)

ISBN: