# Asthma: diagnosis and monitoring

2

3

4

1

# NICE guideline: short version

# **Draft for second consultation, July 2017**

**This guideline covers** assessing, diagnosing and monitoring suspected or confirmed asthma in adults, young people and children. It includes initial clinical assessment for people with suspected asthma, objective tests for diagnosis, and monitoring asthma control, adherence and inhaler technique.

#### 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

For this second consultation we have taken into account stakeholders views and the results of field testing work.

This version of the guideline contains the draft recommendations, context and recommendations for research. Information about how the guideline was developed is on the <u>guideline's page</u> on the NICE website. This includes the guideline committee's discussion and the evidence reviews (in the <u>full guideline</u>), the scope, and details of the committee and any declarations of interest.

# Contents

2	Recom	mendations	3
3	1.1	Initial clinical assessment	3
4	1.2	Diagnosing asthma and initial treatment for young children	4
5	1.3	Objective tests for diagnosing asthma in adults, young people and child	ren
6	aged	I 5 and over	5
7	1.4	Summary of objective test results for adults, young people and children	
8	(ove	r 5)	10
9	1.5	Monitoring asthma control	13
10	Diagno	stic algorithms	15
11	Putting	this guideline into practice	18
12	Contex	rt	20
13	Recom	mendations for research	22
14			
15			

#### 1 Recommendations

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

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.

#### 2 1.1 Initial clinical assessment

#### 3 Clinical history

- 4 1.1.1 Take a structured clinical history in people with suspected asthma.
- 5 Specifically, check for:
- wheeze, cough or breathlessness, and any daily or seasonal variation
   in these symptoms
- 7 in these symptoms
- a personal or family history of atopic disorders, and record any triggers
   that make symptoms worse.
- 10 1.1.2 Do not use symptoms alone without an objective test to diagnose asthma.
- 11 1.1.3 Do not use either an isolated clinical history of symptoms after exercise or 12 a history of atopic disorders to diagnose asthma.

#### Physical examination

- 14 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
- 17 asthma.

13

18

#### Initial treatment at presentation

19 1.1.5 Treat people immediately if they are acutely unwell at presentation. If possible, perform objective tests (including fractional exhaled nitric oxide

Asthma: diagnosis and monitoring: NICE guideline DRAFT (July 2017) Page 3 of 25

1		[FeNO] and spirometry) at the time of presentation. If objective tests
2		cannot be done immediately, they should be done when acute symptoms
3		have been controlled.
4	Testing	for asthma
5	1.1.6	Do not offer the following as diagnostic tests for asthma:
6		skin prick tests to aeroallergens
7		serum total and specific lgE
8		<ul> <li>peripheral blood eosinophil count</li> </ul>
9		exercise challenge (to adults aged 17 and over).
10	1.1.7	If indicated, use skin prick tests to aeroallergens or specific IgE tests to
11		identify triggers after a formal diagnosis of asthma has been made.
12	Occupat	tional asthma
13	1.1.8	Check for suspected occupational asthma by asking employed people
14		with newly diagnosed asthma, or established asthma that is poorly
15		controlled:
16		are symptoms better on days away from work?
17		<ul> <li>are symptoms better when on holiday¹?</li> </ul>
18		Make sure all answers are recorded for later review.
19	1.1.9	Refer people with suspected occupational asthma to an occupational
20		asthma specialist.
21	1.2	Diagnosing asthma and initial treatment for young children
22	1.2.1	For children under 5 with suspected asthma, treat symptoms based on
23		observation and clinical judgement, and review the child on a regular
24		basis <sup>2</sup> . If they still have symptoms when they reach 5 years, carry out
25		objective tests (see section 1.3 and algorithm B).

<sup>1</sup> 'Holiday' here means any longer time away from work than usual breaks at weekends or between shifts.

-

<sup>&</sup>lt;sup>2</sup> NICE is developing a guideline on <u>chronic asthma management</u>; publication expected October 2017.

1 2 3 4	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, and try doing the tests again every 6 to 12 months until satisfactory results are obtained.
5	1.3	Objective tests for diagnosing asthma in adults, young
6		people and children aged 5 and over
7	Diagnos	tic hubs
8 9 10 11	1.3.1	Those responsible for planning diagnostic service support to primary care should consider establishing asthma diagnostic hubs to achieve economies of scale and improve the practicality of implementing the recommendations in this guideline.
12	Airway i	nflammation measures
13	Fraction	al exhaled nitric oxide
14 15 16	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.
17 18 19	1.3.3	Consider a FeNO <sup>3</sup> test in children and young people (aged 5 to 16) if there is diagnostic uncertainty after initial assessment and they have either:
20 21 22		<ul> <li>normal spirometry or</li> <li>obstructive spirometry with a negative bronchodilator reversibility (BDR) test.</li> </ul>
23		Regard a FeNO level of 35 ppb or more as a positive test.
24 25	1.3.4	Be aware that a person's current smoking status can lower FeNO levels both acutely and cumulatively.

 $^3$  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.

Asthma: diagnosis and monitoring: NICE guideline DRAFT (July 2017) Page 5 of 25

# 1 Lung function tests

2	Spirome	try
3	1.3.5	Offer spirometry to adults, young people and children aged 5 and over.
4		Regard a forced expiratory volume in 1 second/forced vital capacity
5		(FEV1/FVC) ratio of less than 70% <sup>4</sup> as a positive test for obstructive
6		airway disease (obstructive spirometry).
7	Broncho	dilator reversibility
8	1.3.6	Offer a BDR test to adults (aged 17 and over) with obstructive spirometry
9		(FEV1/FVC ratio less than 70%). Regard an improvement in FEV1 of 12%
10		or more, together with an increase in volume of 200 ml or more, as a
11		positive test.
12	1.3.7	Consider a BDR test in children and young people (aged 5 to 16) with
13		obstructive spirometry (FEV1/FVC ratio less than 70%). Regard an
14		improvement in FEV1 of 12% <sup>2</sup> or more as a positive test.
15	Peak exp	piratory flow variability
16	1.3.8	Monitor peak flow variability for 2 to 4 weeks in adults (aged 17 and over)
17		if there is diagnostic uncertainty after initial assessment and they have
18		either:
19		<ul> <li>normal spirometry and the results of a FeNO test or</li> </ul>
20		obstructive spirometry, reversible airways obstruction (positive BDR)
21		and a FeNO level of 39 ppb or less.
22		Regard a value of more than 20% variability as a positive test.
23	1.3.9	Consider monitoring peak flow variability for 2 to 4 weeks in adults (aged
24		17 and over) if there is diagnostic uncertainty after initial assessment and
25		they have:
26		obstructive spirometry and
27		<ul> <li>irreversible airways obstruction (negative BDR) and</li> </ul>

<sup>4</sup> Or the lower limit of normal if the calculation is available for children aged 5 to 16 years.

Asthma: diagnosis and monitoring: NICE guideline DRAFT (July 2017) Page 6 of 25

ı		a FeNO level between 25 and 39 ppb.
2		Regard a value of more than 20% variability as a positive test.
3 4 5	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 they have either:
6 7 8		<ul> <li>normal spirometry and the results of a FeNO test or</li> <li>obstructive spirometry, irreversible airways obstruction (negative BDR) and a FeNO level of 35 ppb or more.</li> </ul>
9		Regard a value of more than 20% variability as a positive test.
10	Airway h	yper-reactivity measures
11	Direct br	onchial challenge test with histamine or methacholine
12 13 14	1.3.11	Offer a direct bronchial challenge test with histamine or methacholine <sup>5</sup> to adults (aged 17 and over) if there is diagnostic uncertainty after a normal spirometry and either a:
5  6  7		<ul> <li>FeNO level of 40 ppb or more and no variability in peak flow readings or</li> <li>FeNO level of 39 ppb or less with variability in peak flow readings.</li> </ul>
18		Regard a PC20 value of 8 mg/ml or less as a positive test.
19 20	1.3.12	Consider a direct bronchial challenge test with histamine or methacholine <sup>6</sup> in adults (aged 17 and over) with:
21		obstructive spirometry and

<sup>5</sup> At the time of consultation (July 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 <a href="Prescribing guidance: prescribing unlicensed medicines">Prescribing guidance: prescribing unlicensed medicines</a> for further information.

Asthma: diagnosis and monitoring: NICE guideline DRAFT (July 2017) Page 7 of 25

<sup>&</sup>lt;sup>6</sup> At the time of consultation (July 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 <u>Prescribing guidance: prescribing unlicensed medicines</u> for further information.

1		<ul> <li>a FeNO level between 25 and 39 ppb and</li> </ul>
2		<ul> <li>no variability in peak flow readings (less than 20% variability over 2 to</li> </ul>
3		4 weeks).
4		Regard a PC20 value of 8 mg/ml or less as a positive test.
5	1.3.13	If a histamine or methacholine challenge test is unavailable, suspect
6		asthma and review the diagnosis after treatment, or refer to a centre with
7		access to a histamine or methacholine challenge test.
8	Children	and young people aged 5 to 16 (algorithm B)
9	1.3.14	Diagnose asthma in children and young people (aged 5 to 16) if they have
10		symptoms suggestive of asthma and:
11		<ul> <li>a FeNO level of 35 ppb or more and positive peak flow variability or</li> </ul>
12		obstructive spirometry and positive bronchodilator reversibility.
13	1.3.15	Suspect asthma in children and young people (aged 5 to 16) if they have
14		symptoms suggestive of asthma and:
15		a FeNO level of 35 ppb or more with normal spirometry and negative
16		peak flow variability <b>or</b>
17		<ul> <li>a FeNO level of 35 ppb or more with obstructive spirometry but</li> </ul>
18		negative bronchodilator reversibility and no variability in peak flow
19		readings <b>or</b>
20		<ul> <li>normal spirometry, a FeNO level of 34 ppb or less and positive peak</li> </ul>
21		flow variability.
22		Do not rule out other diagnoses if symptom control continues to remain
23		poor after treatment. Review the diagnosis after 6 weeks by repeating any
24		abnormal tests and reviewing symptoms.
25	1.3.16	Refer children and young people (aged 5 to 16) for specialist assessment
26		if they have obstructive spirometry, negative bronchodilator reversibility
7		and a FeNO level of 34 pph or less

1	1.3.17	Consider alternative diagnoses and referral for specialist assessment in
2		children and young people (aged 5 to 16) if they have symptoms
3		suggestive of asthma but normal spirometry, a FeNO level of 34 ppb or
4		less and negative peak flow variability.
5	Adults a	ged 17 and over (algorithm C)
6	1.3.18	Diagnose asthma in adults (aged 17 and over) if they have symptoms
7		suggestive of asthma and:
8		FeNO level of 40 ppb or more with either positive bronchodilator
9		reversibility or positive peak flow variability, or
10 11		<ul> <li>FeNO level between 25 and 39 ppb and a positive bronchial challenge test, or</li> </ul>
12		<ul> <li>positive bronchodilator reversibility and positive peak flow variability</li> </ul>
13		irrespective of FeNO level.
14	1.3.19	Suspect asthma in adults (aged 17 and over) with symptoms suggestive
15		of asthma, obstructive spirometry but negative bronchodilator reversibility,
16		and:
17		a FeNO level of 40 ppb or more or
18		<ul> <li>a FeNO level between 25 and 39 ppb and positive peak flow variability.</li> </ul>
19		Do not rule out other diagnoses if symptom control continues to remain
20		poor after treatment. Review the diagnosis after 6 to 10 weeks by
21		repeating spirometry and objective measures of asthma control and
22		reviewing symptoms.
23	1.3.20	Consider alternative diagnoses, or referral for a second opinion, in adults
24		(aged 17 and over) with symptoms suggestive of asthma, and:
25		FeNO level of 40 ppb or more but normal spirometry, negative peak
26		flow variability, and negative bronchial challenge test, <b>or</b>
27		• obstructive spirometry with bronchodilator reversibility, but FeNO below
28		40 ppb, negative peak flow variability and a negative bronchial
29		challenge test (if measured), <b>or</b>

Asthma: diagnosis and monitoring: NICE guideline DRAFT (July 2017) Page 9 of 25

1		<ul> <li>positive peak flow variability but normal spirometry, FeNO below</li> </ul>
2		40 ppb, and a negative bronchial challenge test, <b>or</b>
3		obstructive spirometry with negative bronchodilator reversibility, FeNO
4		below 40 ppb, and negative peak flow variability (if measured).
5	Good cl	inical practice in asthma diagnosis
6	1.3.21	Do not diagnose asthma based on a single test.
7	1.3.22	Record the basis for a diagnosis of asthma in a single entry in the
8		person's medical records, alongside the coded diagnostic entry.
9	1.4	Summary of objective test results for adults, young people
10		and children (over 5)
11	Algorithn	ns have been produced that summarise objective testing for asthma in
12	adults, y	oung people and children (over 5).
13	Interpre	ting objective test results
14	1.4.1	For adults (aged 17 and over), use the thresholds in table 1 and the
15		summary of test results in table 2 to interpret objective test results.
16	1.4.2	For children and young people (aged 5 to 16), use the thresholds in table
17		1 and the summary of test results in table 3 to interpret objective test
18		results.

# 1 Table 1 Positive test thresholds for objective tests for adults, young people

### 2 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, children and young people	FEV1/FVC ratio less than 70% <sup>7</sup>
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, children and young people	Variability over 20%
Direct bronchial challenge	Adults	PC20 of 8 mg/ml or less
test with histamine or methacholine	Children and young people	

<sup>&</sup>lt;sup>7</sup> Or the lower limit of normal if the calculation is available for children aged 5 to 16 years.

# 1 Table 2 Summary of test results for diagnosing asthma in adults aged 17 and

# 2 over

Spirometry	FeNO	BDR	Peak flow	Direct challenge	Interpretation
+	+	+	N/A	N/A	Diagnose asthma
+	+	-	N/A	N/A	Suspect asthma
+	- (<25)	-	N/A	N/A	Consider alternative diagnosis
Initial objecti	ive tests and p	eak flow res	ults		
Spirometry	FeNO	BDR	Peak flow	Direct challenge	Interpretation
+	-	+	+	N/A	Diagnose
-	+	N/A	+	N/A	asthma
+	- (25-39)	-	+	N/A	Suspect asthma
+	- (<25)	+	-	N/A	Consider alternative diagnosis or referral
Initial objecti	ive tests, peak	flow and dire	ect challenge to	est results	•
Spirometry	FeNO	BDR	Peak flow	Direct challenge	Interpretation
+	- (25-39)	+	-	+	Diagnose
+	- (25-39)	-	-	+	asthma
-	+	N/A	-	+	7
-	-	N/A	+	+	7
+	- (25-39)	+	-	-	Consider
-	-	N/A	+	_	alternative
		N/A			diagnosis

#### 1 Table 3 Summary of test results for diagnosing asthma in children and young

#### 2 people aged 5 to 16

Spirometry	BDR	FeNO	Peak flow variability	Interpretation
+	+	N/A	N/A	Diagnose asthma
Initial objectiv	e tests and FeNC	) results		
Spirometry	BDR	FeNO	Peak flow variability	Interpretation
+	-	-	N/A	Refer to a specialist
Initial objectiv	e tests, FeNO an	d peak flow varia	bility results	
0				
Spirometry	BDR	FeNO	Peak flow variability	Interpretation
Spirometry +	BDR -	FeNO +		Interpretation  Diagnose
	BDR - N/A		variability	
	-	+	variability +	Diagnose asthma Suspect
+	-	+ +	variability +	Diagnose asthma
+ - +	- N/A -	+ + + +	variability +	Diagnose asthma Suspect

3

4

10

### 1.5 Monitoring asthma control

- 5 1.5.1 Monitor asthma control at every review. If control is suboptimal:
- confirm the person's adherence to prescribed treatment in line with the
   recommendations on <u>assessing adherence</u> 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 <u>recommendation 1.1.8</u>) and/or
   other triggers, if relevant.
- 13 1.5.2 Consider using a validated questionnaire (the Asthma Control
   14 Questionnaire or Asthma Control Test) to monitor asthma control in adults
   15 (aged 17 and over).

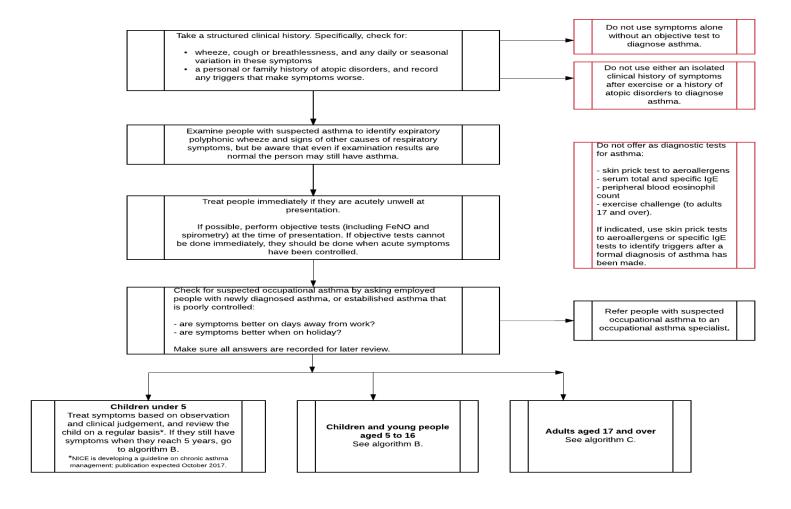
1	1.5.3	Monitor asthma control at each review in adults, young people and
2		children aged 5 and over using either spirometry or peak flow variability
3		testing.
4	1.5.4	Do not routinely use FeNO to monitor asthma control.
5	1.5.5	Consider FeNO measurement as an option to support asthma
6		management in people who are symptomatic despite using inhaled
7		corticosteroids. (This recommendation is from NICE's diagnostics
8		guidance on measuring fractional exhaled nitric oxide concentration in
9		asthma.)
10	1.5.6	Do not use challenge testing to monitor asthma control.
11	1.5.7	Observe and give advice on the person's inhaler technique:
12		at every consultation relating to an asthma attack, in all care settings
13		when there is deterioration in asthma control
14		when the inhaler device is changed
15		at every annual review
16		if the person asks for it to be checked.

17

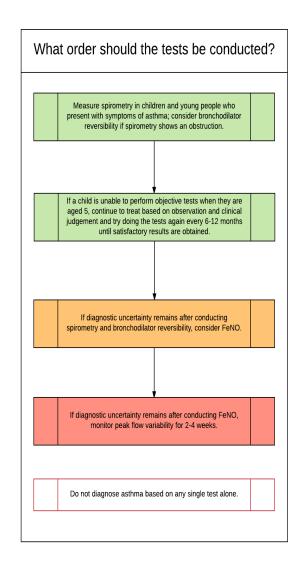
Asthma: diagnosis and monitoring: NICE guideline DRAFT (July 2017) Page 14 of 25

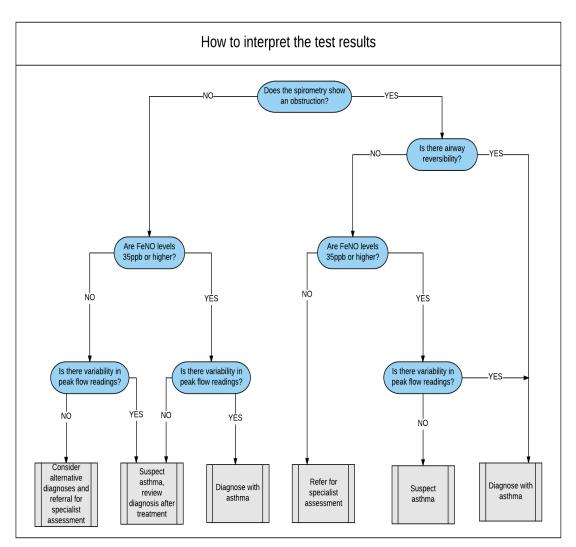
# Diagnostic algorithms

#### 2 Algorithm A Initial clinical assessment

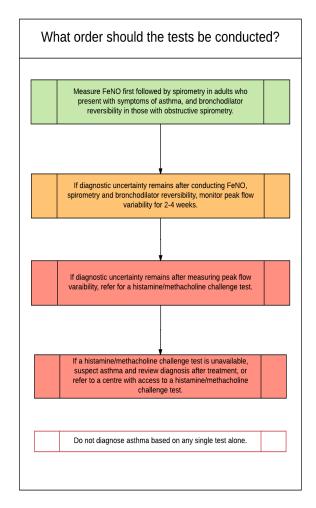


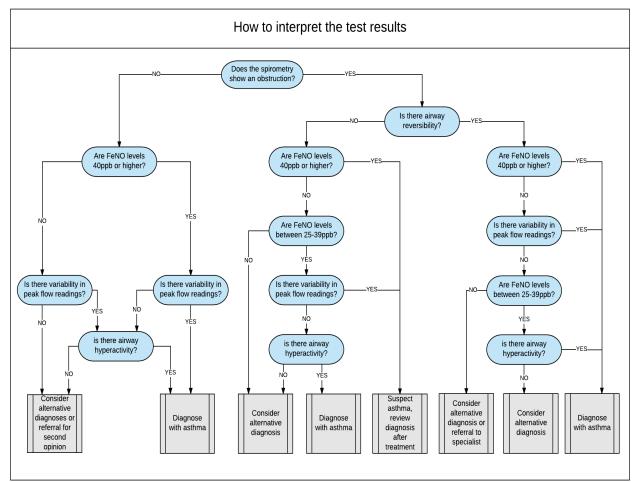
#### Algorithm B: Objective tests for children and young people aged 5 to 16





#### Algorithm C: Objective tests for adults aged 17 and over





# 1 Putting this guideline into practice

- 2 [This section will be finalised after consultation]
- 3 NICE has produced tools and resources [link to tools and resources tab] to help you
- 4 put this guideline into practice.
- 5 Some issues were highlighted that might need specific thought when implementing
- 6 the recommendations. These were raised during the development of this guideline.
- 7 They are:
- 8 effective spirometry use in asthma diagnosis
- availability of FeNO testing
- availability of direct bronchial challenge testing.
- 11 Putting recommendations into practice can take time. How long may vary from
- 12 guideline to guideline, and depends on how much change in practice or services is
- 13 needed. Implementing change is most effective when aligned with local priorities.
- 14 Changes recommended for clinical practice that can be done quickly like changes
- in prescribing practice should be shared quickly. This is because healthcare
- professionals should use guidelines to guide their work as is required by
- 17 professional regulating bodies such as the General Medical and Nursing and
- 18 Midwifery Councils.
- 19 Changes should be implemented as soon as possible, unless there is a good reason
- 20 for not doing so (for example, if it would be better value for money if a package of
- 21 recommendations were all implemented at once).
- 22 Different organisations may need different approaches to implementation, depending
- 23 on their size and function. Sometimes individual practitioners may be able to respond
- 24 to recommendations to improve their practice more quickly than large organisations.
- 25 Here are some pointers to help organisations put NICE guidelines into practice:
- 26 1. Raise awareness through routine communication channels, such as email or
- 27 newsletters, regular meetings, internal staff briefings and other communications with

- 1 all relevant partner organisations. Identify things staff can include in their own
- 2 practice straight away.
- 3 2. **Identify a lead** with an interest in the topic to champion the guideline and motivate
- 4 others to support its use and make service changes, and to find out any significant
- 5 issues locally.
- 6 3. Carry out a baseline assessment against the recommendations to find out
- 7 whether there are gaps in current service provision.
- 8 4. Think about what data you need to measure improvement and plan how you
- 9 will collect it. You may want to work with other health and social care organisations
- and specialist groups to compare current practice with the recommendations. This
- may also help identify local issues that will slow or prevent implementation.
- 12 5. **Develop an action plan**, with the steps needed to put the guideline into practice,
- and make sure it is ready as soon as possible. Big, complex changes may take
- longer to implement, but some may be quick and easy to do. An action plan will help
- in both cases.
- 16 6. For very big changes include milestones and a business case, which will set out
- 17 additional costs, savings and possible areas for disinvestment. A small project group
- 18 could develop the action plan. The group might include the guideline champion, a
- 19 senior organisational sponsor, staff involved in the associated services, finance and
- 20 information professionals.
- 7. **Implement the action plan** with oversight from the lead and the project group.
- 22 Big projects may also need project management support.
- 23 8. **Review and monitor** how well the guideline is being implemented through the
- 24 project group. Share progress with those involved in making improvements, as well
- as relevant boards and local partners.
- 26 NICE provides a comprehensive programme of support and resources to maximise
- 27 uptake and use of evidence and guidance. See our into practice pages for more
- 28 information.

- 1 Also see Leng G, Moore V, Abraham S, editors (2014) Achieving high quality care –
- 2 practical experience from NICE. Chichester: Wiley.

#### 3 Context

- 4 Asthma is a chronic inflammatory respiratory disease. It can affect people of any
- 5 age, but often starts in childhood. Asthma is a variable disease which can change
- 6 throughout a person's life, throughout the year and from day to day. It is
- 7 characterised by attacks (also known as exacerbations) of breathlessness and
- 8 wheezing, with the severity and frequency of attacks varying from person to person.
- 9 The attacks are associated with variable airflow obstruction and inflammation within
- the lungs, which if left untreated can be life-threatening, however with the
- 11 appropriate treatment can be reversible.
- 12 In 2013, the World Health Organization estimated that 235 million people had
- 13 asthma 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)
- 15 currently get treatment for asthma (Asthma UK).
- 16 The causes of asthma are not well understood. A number of risk factors are
- 17 associated with the condition, often in combination. These influences can be genetic
- 18 (the condition clusters in families) and/or environmental (such as inhalation of
- 19 allergens or chemical irritants). Occupational causes of asthma in adults are often
- 20 under-recognised.
- 21 There is currently no gold standard test available to diagnose asthma; diagnosis is
- 22 principally based on a thorough history taken by an experienced clinician. Studies of
- 23 adults diagnosed with asthma suggest that up to 30% do not have clear evidence of
- 24 asthma. Some may have had asthma in the past, but it is likely that many have been
- 25 given an incorrect diagnosis. Conversely, other studies suggest that asthma may be
- 26 underdiagnosed in some cases. One study found that only 79% of people with
- 27 objective airflow obstruction presenting with respiratory symptoms in primary care
- were recorded as having asthma. This indicates an underdiagnosis by GPs in 21%
- 29 of cases.

- 1 The typical wheeze found in a person with asthma is a continuous, polyphonic
- 2 whistling sound produced in the airways during expiration and is related to
- 3 obstruction of the airways on breathing out. Expiratory polyphonic wheeze is a
- 4 characteristic clinical symptom and sign in people with asthma or other obstructive
- 5 airways diseases.
- 6 Initial clinical assessment should include questions about symptoms (wheezing,
- 7 cough, breathing and chest problems) and any personal or family history of allergies,
- 8 atopic disorders or asthma. Various tests can be used to support a diagnosis, but
- 9 there is no single test that can definitively diagnose asthma.
- 10 A number of methods and assessments are available to determine the likelihood of
- 11 asthma. These include measuring airflow obstruction (spirometry and peak flow) and
- 12 assessment of reversibility with bronchodilators, with both methods being widely
- 13 used in current clinical practice. However, normal results do not exclude asthma and
- abnormal results do not always mean it is asthma, as they could be indicators of
- 15 other respiratory diseases or spurious readings.
- 16 Testing for airway inflammation is increasingly used as a diagnostic strategy in
- 17 clinical practice. This includes measuring fractional exhaled nitric oxide (FeNO).
- However, there is some uncertainty about both the sensitivity and specificity of
- 19 FeNO, particularly as to whether it can distinguish individuals with allergen-induced
- airways inflammation without airways hyperreactivity from individuals with asthma.
- 21 Other diagnostic strategies include blood or skin prick tests to detect allergic
- 22 reactions to environmental influences, exercise tests to detect evidence of
- bronchoconstriction, and measures of airway hyper-reactivity such as
- 24 histamine/methacholine or mannitol challenge tests. However, it is debatable which
- 25 test or measure, or combination of them, is the most effective to accurately diagnose
- 26 asthma.
- 27 It is recognised that asthma control is suboptimal in many people with asthma. This
- 28 has an impact on their quality of life, their use of healthcare services and the
- 29 associated costs. Asthma control can be monitored by measuring airway obstruction
- or inflammation and by using validated questionnaires, but the most effective
- 31 monitoring strategy is unclear.

Asthma: diagnosis and monitoring: NICE guideline DRAFT (July 2017) Page 21 of 25

- 1 The aim of this guideline is to provide clear advice on effectively diagnosing people
- 2 presenting with new symptoms of suspected asthma and monitoring to ensure
- 3 optimum asthma control. It does not cover severe, difficult to control asthma or any
- 4 other aspects of management. It is not intended to be used to re-diagnose people
- 5 who already have an asthma diagnosis.
- 6 The guideline covers children under 5, children and young people aged 5 to 16, and
- 7 adults aged 17 and over who are being investigated for suspected asthma, or who
- 8 have been diagnosed with asthma and are having their condition monitored. The
- 9 guideline applies to all primary, secondary and community care settings in which
- 10 NHS-funded care is provided for people with asthma.

#### 11 **More information**

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

12

13

22

#### **Recommendations for research**

- 14 The guideline committee has made the following recommendations for research. The
- 15 committee's full set of research recommendations is detailed in the <u>full guideline</u>.

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

- 17 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
- 20 histamine or methacholine, indirect bronchial challenge with mannitol and peripheral
- 21 blood eosinophil count)?

#### Why this is important

- 23 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
- 27 can be present in other illnesses. This diagnostic uncertainty results in many children

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

#### 8 2 Diagnosing asthma in adults (aged 17 and over)

- 9 What is the clinical and cost effectiveness of using an indirect bronchial challenge
- 10 test with mannitol to diagnose asthma in adults (aged 17 and over)?

#### 11 Why this is important

- 12 Chronic airway inflammation is associated with bronchial hyper-responsiveness,
- which is integral to defining asthma. Bronchial challenge testing can help diagnose
- 14 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
- 17 performed only in specialised centres or research settings.
- 18 Indirect challenge tests with inhaled mannitol act via active inflammatory cells and
- mediators, whereas direct challenge tests with inhaled histamine or methacholine act
- 20 directly on bronchial smooth muscle. Indirect challenge testing is more specific but
- 21 less sensitive than direct challenges.
- 22 Direct challenge testing may not identify a person who will respond to inhaled
- 23 corticosteroids. A positive result to an indirect challenge may reflect active airway
- 24 inflammation that is likely to respond to inhaled corticosteroid therapy. Because a
- 25 response to mannitol indicates active airway inflammation, identifying non-
- 26 responsiveness in treated patients may help demonstrate good asthma control with
- 27 inhaled corticosteroid therapy and identify people less likely to deteriorate after a
- 28 dose reduction.

Asthma: diagnosis and monitoring: NICE guideline DRAFT (July 2017) Page 23 of 25

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

#### 4 3 Monitoring adherence to treatment

- 5 What is the clinical and cost effectiveness of using electronic alert systems designed
- 6 to monitor and improve adherence with regular inhaled maintenance therapy in
- 7 people with asthma?

#### 8 Why this is important

- 9 Adherence with regular maintenance inhaled corticosteroids, on their own or in
- 10 combination with long-acting beta agonists, is of paramount importance to achieve
- 11 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
- 14 Review of Asthma Deaths (NRAD)<sup>8</sup> demonstrated that poor adherence was
- 15 associated with 38% of asthma deaths.

## 16 4 Monitoring inhaler technique

- 17 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
- 20 asthma?

21

#### Why this is important

- 22 Knowing and understanding how to use an inhaler properly is the cornerstone of
- 23 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
- 25 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
- 28 asthma control.

-

Asthma: diagnosis and monitoring: NICE guideline DRAFT (July 2017) Page 24 of 25

<sup>&</sup>lt;sup>8</sup> Royal College of Physicians' National Review of Asthma Deaths (May 2014).

#### 1 5 Monitoring asthma control using tele-healthcare

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

#### 7 Why this is important

- 8 Asthma outcomes have not improved in the past 15 years, and the personal and
- 9 economic costs of poor control are high. Computers and smartphones play an ever-
- 10 greater role in modern life, with a growing proportion of people using them regularly
- 11 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
- 14 outcomes.
- 15 **ISBN**:

Asthma: diagnosis and monitoring: NICE guideline DRAFT (July 2017) Page 25 of 25