Asthma: Diagnosis and Monitoring

Consultation on draft guideline - stakeholder comments

Comments to be submitted to Asthma@nice.nhs.uk

before 5pm on 11 March 2015.

Please note:		Please fill in both the 'stakeholder organisation' and 'name of commentator' fields. We cannot accept forms with attachments such as research articles, letters or leaflets. Forms that are not correctly submitted as requested may be returned to you. NICE has developed a list of possible areas of interest in the draft guideline for your information.		
Stakeholder organisation(s) (if you are responding as an individual rather than a registered stakeholder please state name here):		Asthma UK		
Name of commentator (if you are responding as an individual rather than a registered stakeholder please leave blank):		Sophie Cramb		
Comment number	Document Indicate if you are referring to the full version,	Page number Indicate number or 'general' if your comment	Line number Indicate number or 'general' if your comment	Comments Please insert each comment in a new row. Please do not paste other tables into this table, because your comments could get lost – type directly into this table.

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	NICE version or the appendices	relates to the whole document	relates to the whole document	
Example	Full	16	45	We are concerned that this recommendation may imply that ……..
1	Full & NICE	General	General	We welcome NICE's continued work to improve the quality of asthma care through clinical guidelines and standards, and welcome the opportunity this guideline will present to improve the lives of people with asthma. The most important factor to consider when developing a diagnosis and monitoring guideline is that people with asthma receive the timely diagnosis and treatment they need as early as possible, and that their condition is effectively monitored throughout their life to ensure that they receive the right treatment at the right time to reduce their risk of asthma attacks.
2	Full & NICE	General	General	Overall, we welcome the attempt to capture the best research available and translate this into a more systematic approach to the asthma diagnostic process. Over the next five to ten years, we should see advances in this area and this guideline is a good start until more evidence and tests are identified. However, although this guideline takes us some way to improving the asthma diagnosis pathway, it is clear that the evidence remains limited and that **there is still no definitive diagnostic test(s): even when using this 'gold standard' approach it will still not be possible to confirm someone definitely has, or does not have, asthma due to its variability, especially in relation to seasonal triggers such as pollen and colds.** The impact of a complex, lengthy diagnostic process on people with asthma must therefore be considered in light of the fact that a definitive diagnosis of asthma will still not be possible because the condition may change throughout the seasons or indeed throughout someone's life. **Patients must be fully aware of the limitations of the diagnostic tests which only reflect symptoms at one point in time and do not reflect variability such as seasonality.** **The monitoring aspect of the guideline should therefore be considered as an integral part of diagnosis**, until

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				more diagnostic evidence is available. **Continuous monitoring after initial diagnosis, and then later through an annual asthma review, presents the only effective way of confirming diagnosis throughout the seasons, collecting a body of evidence to understand more about a person's asthma so that they only take asthma medication when they need it.** Such initial monitoring must then be followed up with a 'world class' annual asthma review to monitor ongoing symptoms, control, triggers and adherence. This is especially the case for children and young people, or elderly people, whose symptoms may be more likely to change over the long term, putting them at higher risk of an asthma attack. The guideline should therefore reflect the significance of monitoring in enhancing diagnosis and contributing to risk reduction, more than it currently does**.** **The guidance should also not prevent reviews from being delivered more dynamically, against the desire and needs of both patients and health care professionals (for example, using informatics to transmit monitoring information remotely, communicating with patients via telephone and video conferencing). If specific tests must be performed at each review, regardless of whether patients are at low or high risk, then this could be a potential barrier to a digital shift in care.** To reduce risk of asthma attacks, monitoring should also be focused towards identifying those patients who are at highest risk (for example, children, those who smoke, those recently hospitalised, and those who over-use blue inhalers), and alternative mechanisms should be in place for those at lower risk and less engaged. Effective monitoring will result in better prevention of asthma attacks, in line with the vision described in the Five Year Forward View. In summary: • Although asthma diagnosis is important, the current diagnostic tests available will only ever provide a snap shot view of symptoms which will change throughout the seasons, for example during pollen or cold and flu seasons. • Patients must therefore be fully informed that there is no diagnostic process which can definitely diagnose

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				asthma. • In this context, it is vital that initial monitoring is conducted as part of the broader diagnosis, to continually track symptoms, triggers, control and adherence, and that this monitoring then evolves into an appropriate annual asthma review. • Annual asthma reviews are currently not being delivered as frequently as they should be, and do not always include the right basic elements, despite incentives and national focus. As such, the challenges of implementing a new diagnostic pathway with new tests and equipment should not be underestimated. When identifying priority areas for implementation, emphasis should firstly be placed on effective monitoring. Only secondly should it be placed on confirming diagnosis, and only then in those who asthma may vary most: children and young people in the first instance. • The monitoring process should not be designed in a way which prohibits a more dynamic, digital approach to monitoring and reviews using technology.
3	Full & NICE	General - Diagnosis	General - Diagnosis	The importance of balancing the specificity of tests (identifying those who don't have asthma), and sensitivity (identifying those who do) is well articulated. However, due to the repeated emphasis on an estimated over diagnosis of asthma which was cited in the scope, there is a risk that the approach cited may be biased towards specificity, leading to premature exclusions of asthma which could put patients at risk. Over-diagnosis is frequently referenced in the documents (for example, Full Guideline, pp. 25, 27, 51, 164 etc.). However, there is no reference to the methodology used to come to this conclusion and how the 30% over diagnosis figure was taken as the most important factor in diagnosis (in contrast to other papers which cite under diagnosis). For example, calculations in the Full Guideline are made on direct bronchial challenge testing on p. 164 using a figure from one paper (Aaron et al), which estimated that a third of people currently diagnosed are misdiagnosed (of which a 35% had to seek help for their asthma or had to restart asthma medication in a six month follow up period). It is unclear why this paper alone was used to complete this calculation and why over diagnosis was considered a priority above the risks associated with under diagnosis.

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				As such, the guideline may overlook the wealth of evidence which suggests that there is also a significant problem of under diagnosis in asthma (for example, within various different groups including children, adolescents and the elderly). There is a risk that in the recommended approach, normal results could lead to a misplaced decision to exclude asthma: just because all of the test results are normal it does not mean that someone does not have asthma.
4	Full & NICE	General - Diagnosis	General - Diagnosis	The algorithms for diagnosing asthma are very helpful, however, they could include further considerations about the impact on the patient in the following ways: • Comprehension: most importantly, patients should be informed that it is not possible to get a definitive diagnosis of asthma using current tests available. Patients should also be informed and able to understand which tests are being performed and why. All patients should be informed as to why some distressing tests are being performed and also understand why they may not be able to perform all of the manoeuvres required. • Partnership approach: consideration should be given as to whether it is reasonable to expect patients to attend multiple appointments at multiple locations for multiple tests. Impact on travel, costs, and time out from work / school must be considered, as well as the fact that a definitive diagnosis may still not be reached. A discussion should be had with the patient to understand their needs. • Are there risks associated with a single patient having multiple tests performed by multiple professionals, at different locations, with potentially with varying levels of skills? Inconsistencies and errors may occur and considerations should be given to the value of having consistent testing performed, and access and availability of trained staff should be considered. • What is the risk to patients in delaying treatment until a diagnosis is confirmed if the diagnostic process takes a long time? The guidelines must be clear in stating that treatment should commence and continue as a way to reduce the risk of asthma attacks, even when diagnosis remains unclear. Treatment itself is a valuable part of the diagnostic process in that it is possible to trial treatments and assess response. • In light of all of the above, the term ‘consider’ rather than ‘offer’ should be used for all diagnostic testing recommendation. • Refer to the development of a written asthma action plan once diagnosis is ‘confirmed’.

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5	Full & NICE	General - diagnosis	General - diagnosis	As mentioned in the scope, the diagnosis aspect of the guideline relates to patients who are currently being investigated for suspected asthma. However, this could easily be overlooked within the document resulting in two adverse effects. Firstly, that patients with asthma are unfairly scrutinised and made to feel deceptive because they may not currently be experiencing symptoms (either due to good symptom control or an absence of triggers). Secondly, precious resources could be spent investigating existing patients when their asthma has already been diagnosed. This guideline should not instigate a review of every single asthma patient's diagnosis, and the documents should be more explicit in this regard. People with asthma are often telling us about their experience when their diagnosis is questioned. One person told us: "I once had a doctor tell me I didn't have asthma (I was diagnosed at 2 and this incident was when I was about 17) he stopped all my inhalers and told me I would be fine...2 days later I was rushed to hospital with a severe attack".
6	Full & NICE	General - diagnosis	General - diagnosis	The algorithms are very helpful but may also be considered complex. The logic behind how each test was prioritised and ordered could be clearer, and the value of each test in isolation is overlooked. For example, if clinicians only have access to some tests, or a patient only wants to go for one or two tests, it is difficult to know how a clinician would prioritise tests. Consideration should also be given as to how quality assurance will be given as to the quality of testing being performed. There is potential risk to patients if an unknowingly incompetent healthcare professional revoke diagnosis of asthma and removes treatment due to negative results, leading to the patient having an asthma attack.
7	Full & NICE	General-diagnosis	General - diagnosis	We were surprised that diagnosis through trial of medication was not considered as a potential method for diagnosis as this issue can be contentious and a review of the evidence would be helpful. It is currently recognised as one of the more common diagnostic techniques practiced. For example, in a survey we conducted on GPs and Practice Nurses in 2015, 67% said they currently use this method to diagnose asthma. However, we are aware that the evidence in this area is limited and an evaluation would be very useful. This especially the case for children who may be unable to complete diagnostic tests: it is vitally important that parents understand that diagnosis is not definitive and are aware of the importance of adherence within this context.
8	Full & NICE	General-monitoring	General - monitoring	People with asthma and health care professionals both tell us that the traditional asthma review model will need to evolve in order to be fit for purpose for all people with asthma, for example, using apps, and telephone / video communications.

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				By recommending that spirometry and / or peak flow monitoring should occur at each review, the guideline may limit the potential for asthma reviews to occur more remotely for those who are at lower risk, and less engaged.
9	Full (& NICE)	51	8-12	We welcome the acknowledgement that asthma is complex and highly variable, as this is what makes it so much harder to diagnose than other lung conditions. However, it would be helpful to see this reiterated more frequently and clearly throughout the documents, in conjunction with the fact that no single or group of tests can either confirm or disprove asthma diagnosis.
10	Full (& NICE)	84-85	Box 10.6	The guideline recommends that occupational asthma should be checked in those newly diagnosed and in those with established asthma which is poorly controlled. This recommendation should be referred to in the monitoring section in addition to, or instead of, the diagnosis section. It may also be helpful to note incident airway disease in these sections also.
11	Full (& NICE)	103	Quality of Evidence	We were interested to note the inclusion of BDR and while we welcome it, believe that more detail could emphasise the importance of taking the time to conduct the test properly to ensure patients are not put at risk.
12	Full (& NICE)	110-111	Entire box	Due to the fact that peak flow variability offers the potential to track lung function over time, is simple, and non-invasive for patients, we were surprised to see it lower down in the algorithm. As the only test which can offer more than a single snapshot of lung function, addressing potential seasonal variability, it can be very helpful in diagnosing asthma when conducted sequentially by an engaged and appropriately trained patient. Its value as an accessible, cost effective, comfortable test for people with asthma (rather than a rule in test) should not be overlooked without proper consideration.
13	Full (& NICE)	142-143	Other considerations	As FeNO levels can be altered by smoking, previous smoking history, diet and oral CS, this should be addressed in both the recommendation and the algorithms.
14	Full (& NICE)	212-213	Box	It would be helpful to specify that spirometry only ever provides a single snapshot view and that even if spirometry results remain consistent across reviews, it does not eliminate the possibility that asthma symptoms are present at other times. There are also challenges in terms of availability of the correct equipment for children and young people in primary care settings, in addition to the quality of training which makes its implementation challenging.

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				Spirometry services run by an appropriately trained staff (as opposed to spirometry/spirometers) should be referred to as a potentially successful model of delivery to address accessibility and training concerns to ensure the person performing the tests and interpreting the result is adequately trained. This may help to address access and training challenges. As mentioned above, if spirometry is mandatory at each review, this could limit the potential for ongoing monitoring and reviews to be delivered more dynamically, using digital technology.
15	Full (& NICE)	227, 233	Boxes	We welcome the use of FeNO as a test for monitoring inflammation, as this could provide an indication of adherence, which is an extremely important area to address as early as possible.
16	Full (& NICE)	252-5	Box	We welcome the high priority research recommendation on adherence monitoring mechanisms.
17	Full (& NICE)	263	Box	We welcome the emphasis placed on the importance of checking inhaler technique, and would also like reference made about the positive value of spacers.
18	NICE	General	General	In recommendation 1.1.3 it is stated that 'even if examination results are normal the person may still have asthma'. This should be reiterated for each of the recommendations which refer to specific diagnostic tests.
19	NICE	General	General	Where peak flow variability is mentioned, this should be defined as one or more spikes or dips in readings with specific values and variations.
20	NICE	General	General	Reference should be made somewhere to indicate that treatment should be initiated, even prior to diagnosis (or all diagnostic tests in the algorithm being completed). It would pose a significant risk to patients if treatment was withheld until all tests are completed, as this could take some time and the symptoms would still persist, putting patients at risk of an asthma attack.
21	NICE	General	General	We were surprised that no reference is made to creating and amending written asthma action plans within both the diagnosis and the monitoring sections as there is substantial evidence for their effectiveness.
22	NICE	3	Introduction, Para. 1	The introduction should explicitly state the variable nature of asthma and that it can change throughout someone's life, throughout the year and from day to day.
23	NICE	3	Introducti	Can you please confirm the source of the statistic, 'in the UK, 4.1million people get treatment for asthma': according to

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			on, Para. 2	our latest figures this is nearer 5.4 million.
24	NICE	3	Introduction, Para. 3	In this section, it should be acknowledged that under diagnosis exists in addition to over diagnosis. It is irresponsible to focus only on over diagnosis as it may put patients at risk.
25	NICE	3	Introduction, general	This section should place an emphasis on the fact that there is not enough research completed to identify a definitive test for asthma due to its variable nature, and that monitoring is the most effective way to confirm that a person is on the correct medication at the correct time. Asthma diagnostic tests simply indicate that monitoring should commence, rather than confirming that asthma is present. This should also be reflected on p. 4.
26	NICE	4		It should be emphasised that while diagnostic tests are important for those being newly diagnosed with asthma, monitoring is highly important for the 5.4 million people in the UK who are already being treated with asthma as a way to identify and reduce risk of asthma attacks, and to ensure they are on the correct medication when they need it. Both diagnosis and monitoring should be noted as a means of identifying high risk patients and reducing exposure to unnecessary and expensive treatments in order to step up or step down treatment as required. The second paragraph from the bottom should be amended to either reflect that other aspects of management were excluded because a new guideline is in development which will address this, or because diagnosis and monitoring is seen as the first priority. Reference to over diagnosis should be removed as it implies that management is not important, and suggests that it is more important to identify people who do not have asthma than to treat those who do effectively.
27	NICE	5	Patient-centred care	It should be noted that the ability of patients to make informed decisions about their care is especially important for asthma, where several complex and intrusive tests may be offered which may still not result in a definitive diagnosis of asthma. They must aware that, even after completing all of the tests, their diagnosis may change throughout the seasons or years. In the last paragraph, the final sentence should be revised to say 'Monitoring and management should be reviewed' for two reasons: firstly, because if monitoring is completed successfully then the right treatment will be provided at the right

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				time to the right people in the right way (diagnosis decisions will therefore not be relevant), and secondly because it may initiate a repeat of diagnostic tests at the transition stage which may not be clinically necessary, may be distressing for the patient, and may not be cost effective.
28	NICE	14	Recommendations	1.1.1 Should include 'tight chest', and should state that only one, some, or all, of these symptoms may be present. It should be stated somewhere that (as in 1.1.2), one should not use an objective test alone to diagnose asthma. A reference could also be made to evaluating through trial of medication, and how to assess response.
29	NICE	17	1.1.9	'Offer' should be changed to 'consider' due to the distressing nature of a bronchial challenge test with histamine or methacholine, the risk this test may pose to patients and the demands on the patients in travelling to receive this test in secondary care, as in 1.1.9.
30	NICE	18	1.2	Reference should be made to the fact that there is not enough evidence to suggest that a single test or combination of tests can definitively rule in or rule out asthma.
31	NICE	21	1.3.3	Reference should be made to the fact that completing peak flow or spirometry tests for monitoring should not prevent the development of a digital approach to asthma monitoring and reviews.
32	NICE	21-22	1.3.7	Add other scenarios: 'when requested by the patient', 'when poor adherence is suspected' and 'when a new device is provided'. Reference should also be made to the fact that adherence should be constantly reviewed, even if the guideline is not able to recommend specific tests.

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Comments on implementation (please see chapter 2 in NICE version)				
Do you agree with the areas that have been identified as having a big impact on practice or challenging to implement? Let us know if you would give priority to other areas and why. What would help users overcome these challenges? (For example, you could signpost us to examples of good practice or provide details of educational materials or other relevant resources that you have found useful). Please note that we will not formally respond to your comments on this section as we view these as an information gathering exercise.				
Comment	Document	Page	Line	

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Number	There is no need to indicate this as the implementation section is only featured in the NICE version	Number Not applicable	Number Not applicable	Comments
1				We know that asthma reviews currently vary in the frequency of delivery and the quality of the content. 2014 QOF data showed that over a million people are missing out on their asthma reviews, and a survey conducted by Asthma UK in 2014 showed that only a quarter of people received they key elements of an asthma review: an asthma action plan, and an inhaler technique check. If national, incentivised asthma reviews are not being provided to all people with asthma in the correct way, we must be realistic about what can be achieved in redesigning the diagnostic process and prioritise accordingly. Rather than investing in rolling out complex tests which will not provide a definitive asthma diagnosis, attention should be paid to getting the monitoring right to confirm patients are on the right medication at the right time and adherent. If priority must be placed on diagnosis, it should be focussed on providing a more detailed diagnosis for those groups most at risk of high variability: children and young people.
2				The priorities indicated will indeed have a big impact on implementation. Access to tests from primary care overall is going to be a key factor in the implementation of these guidelines. In a recent Asthma UK survey, spirometry and bronchial reversibility testing were the two most common diagnostic tests currently used, with more than 95% of these tests carried out in primary care. In contrast, only 5% of people who responded to our survey currently use FeNO testing to diagnose asthma, and only 30% of those who do so perform the test in primary care. It may be beneficial to examine successful initiatives to introduce new testing within the community: for example,

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				moving anticoagulation testing was successful and lessons could be learned to inform the introduction of some asthma diagnostic tests. Mobile / networked spirometry services have also proven to be very successful (for example, in Tower Hamlets). The impact on primary care patients (in terms of waiting times and travel to receive the tests) must be considered, as well as broader impact on patients, if tests are not accessible in primary care. For example, whether increased primary care referrals for bronchial challenge testing negatively impacts on waiting times for patients who have been referred to secondary or tertiary care who are waiting for the same tests. In the current guideline, length of time needed to complete the tests at both diagnosis and during reviews will need to be considered as it may extend current appointment times, and increase number of appointments. Training in all of the tests proposed will need to be initiated
3				People with asthma and health care professionals tell us that they want asthma monitoring to become more dynamic to reflect the views of the individual. They want to transmit monitoring information electronically, and want to communicate remotely, in order to identify whether a full, face to face asthma review is required (for high risk patients). If every patient must have spirometry at each asthma review, the guideline could be a barrier to this digital vision, preventing online and telephone based asthma reviews. There is a risk that such unintended consequences prevent engagement with disengaged patients, putting them at risk. It could also impact on the development of more dynamic models of care, outlined in the Five Year Forward View.
4				It could be difficult to successfully incentivise and report against the recommendations, despite the importance of monitoring the impact of this new guideline. As so many tests are recommended which may be inappropriate for different reasons (for example patient age, contraindications such as stroke in the last six months, patient refuses to take distressing test), so will be challenging to monitor targets and reporting measures.
5				The complexity of the algorithms may also be another factor, as well as clinicians understanding how and when to diverge from them. The role of health care professionals in effectively informing the patients of which tests are required, when, and why, should also not be underestimated. Without full understanding about the diagnostic process, it will be challenging for the patient to 'buy in' to the process and this could result in absence from remaining tests or poor adherence.
6				Differences between this guideline, the GINA guideline, and the BTS/SIGN guideline could also pose a challenge for

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				implementation. It is important that, where possible, the guidelines complement each other and are complemented by future guidelines, such as the NICE Asthma Management Guideline.
7				There may be challenges associated with implementing this guideline for children 5-16: for example, if they are unable to perform spirometry, will they be treated the same as the under 5 group? What if they have special needs, or do not have parental support who can assist with recording sequential peak flow (assuming the test can be completed)? What if they have complex needs which are prioritised over their asthma symptoms? Is there a risk in delay in treatment for this group? This is just one example of other vulnerable groups who need to be considered in the implementation of the guideline.

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