

**NATIONAL INSTITUTE FOR HEALTH AND
CARE EXCELLENCE**

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Asthma

Date of quality standards advisory committee post-consultation meeting:

20th June 2018

2 Introduction

The draft quality standard for asthma was made available on the NICE website for a 4-week public consultation period between 20th April and 29th May 2018. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 17 organisations, which included national organisations, professional bodies, patient groups and others.

This report provides the quality standards advisory committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the committee as part of the final meeting where the committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the committee should read this summary alongside the full set of consultation comments, which are provided in appendix 1.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?
2. Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be to be for these to be put in place?
3. Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

Stakeholders were also invited to respond to the following statement specific questions:

4. For draft quality statement 2: Which specific components of the written personalised action plan are most important? Would it be helpful to focus on ensuring specific components are included in the written personalised action plan?
5. For draft quality statement 5: We have suggested using the European Respiratory Society/American Thoracic Society definition of severe asthma in line with NHS

England's [specification for adult specialised respiratory services for severe asthma](#).

Is this reasonable and will it be possible to identify this population in practice?

6. Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please submit your example to the [NICE local practice collection](#) on the NICE website. Examples of using NICE quality standards can also be submitted.

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- There was some support for the updated quality standard and acknowledgement that it now reflects the NICE guideline.
- Stakeholders suggested, however, that it is not clear why the number of statements has been reduced to 5 and it was felt that the other original statements should still be highlighted as national priorities for improvement. There was a particular focus on inhaler technique but other statements such as treatment of acute asthma with oral or intravenous steroids within 1 hour, annual review and specialist review before discharge following an asthma attack were also still felt to be important by several stakeholders.
- More emphasis needed on recognising and addressing poor adherence.
- More emphasis needed on ensuring all treatment options are communicated at the appropriate point in the patient pathway.

Consultation comments on data collection

- Stakeholders suggested that although some data is available it is likely to be more limited in secondary care and requires better coding.
- It was suggested that the collection and auditing of data will require additional resources.

Consultation comments on resource impact

- There were some concerns about the resources available to achieve the statements, however, it was suggested that there could be significant resource savings by reducing incorrect diagnosis and optimising medication and self-care.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People aged 5 and over with suspected asthma have objective tests to support diagnosis. [2013, updated 2018]

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- General
 - There were some concerns about the resource impact of this statement due to a lack of resources such as FeNO testing, and the need to improve the quality of spirometry and staff training.
- Statement
 - Whilst there was support for the statement it was acknowledged that it will not ensure implementation of the NICE diagnostic algorithm.
 - Should acknowledge that it will be some time before objective testing becomes routine.
 - Should highlight the importance of clinical history and examination alongside objective tests to support diagnosis.
- Measures
 - Additional measures suggested:
 - ◇ A measure to ensure access to the full range of objective tests
 - ◇ Ensuring healthcare professionals have the skills to interpret test results accurately
 - Structure measure b) should not be limited to primary care.
 - Structure measure c) should include a record of symptoms, treatment and efficacy along with objective tests.
 - The QOF data is not a valid data source to identify prevalence of correctly diagnosed asthma.
- Audience descriptors

- Should highlight the need to provide information about asthma or to refer people to sources of advice and support.
- Should specify the need for up to date records of training, policies and procedures in relation to objective testing.
- Healthcare professionals should include pharmacists.
- Definitions
 - It should be clearer what an objective test is and when and how they are used.
- Equality and diversity considerations
 - Should acknowledge that not all over 5's, including some adults, are able to perform objective tests.
 - Should include people who immigrate to the UK with a diagnosis of asthma.

5.2 *Draft statement 2*

People aged 5 and over with asthma have a written personalised action plan. [2013]

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- General
 - It was suggested that this statement should be easy to achieve as validated action plans are readily available. It will require staff to be trained and sufficient time will be needed in reviews so that the action plan can be discussed in detail.
- Statement
 - Should emphasise the education and involvement of the person in developing the personalised action plan.
- Measures
 - Process measure a) should specify that people have a written personalised action plan that is 'documented within their records'.
 - Consider including a patient reported process measure.
 - Should include identifying people admitted to hospital (including A&E) who do not have an action plan so that one can be developed.
 - Outcomes should include use of SABA inhalers and prednisolone prescribing.
- Audience descriptors
 - Should include annual review of personalised action plans rather than just review following an asthma attack.
 - Should specify that written action plans are up to date.
 - Community pharmacists could check action plans during Medicines Use Reviews.
 - A digital version of the action plan should be available to improve access.
 - Should signpost to educational and supportive materials/services to help people self-manage their condition.
 - Should include training of healthcare professionals.
- Equality and diversity considerations

- Action plans should be accessible to people who cannot access IT and to people who cannot read English.
- Should specify that action plans meet the NHS standards for written information.

Consultation question 4

Which specific components of the written personalised action plan are most important? Would it be helpful to focus on ensuring specific components are included in the written personalised action plan?

Stakeholders made the following comments in relation to consultation question 4:

- There was some agreement that it would be helpful to identify the components of a good quality action plan but not to prioritise specific components over others.
- It was suggested that the Asthma UK action plan should be referenced.
- Key components were identified as:
 - maintenance treatment – preventers and relievers and avoiding triggers
 - recognising deterioration of symptoms
 - escalation plan – how to manage an asthma attack including when to seek medical advice
 - returning to maintenance treatment following an asthma attack
 - review dates.

5.3 *Draft statement 3*

People with asthma have their asthma control monitored at every review. [2013, updated 2018]

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Statement
 - Should be more specific about what is included in monitoring asthma control i.e. symptom questionnaires and objective measures.
 - There was concern that measurement at a single point in time is insufficient and it was suggested that other signs of poor asthma control including extra use of reliever medication, oral steroids and asthma attacks should be included.
 - Should include a check on inhaler technique.
 - Should specify frequency of review, for example, at least annually.
 - Should specify that it is a structured asthma review rather than any health-related review.
- Rationale
 - Specify that monitoring asthma control may lead to an assessment of possible reasons for poorly controlled asthma including adherence, inhaler technique, triggers and co-morbidities.
- Measures
 - Should include training/skills of healthcare professionals.
 - Should include asthma reviews being carried out to monitor asthma control.
 - Reduce the number of SABA reliever inhalers included in outcome a) to 6.
 - Prescribing data for outcome a) may not be accurate because inhalers supplied in an emergency/out of hours may not be included.
 - The Department of Health community pharmacy quality payments scheme ([Community Pharmacy in 2016/17 and Beyond](#)) is a potential data source for outcome a).
 - Include an additional outcome measure ‘proportion of people with asthma that are not collecting the expected number of inhaled corticosteroids (ICS) for their dose within the past 12 months.’

- Audience descriptors
 - Should suggest monitoring of signs of poor asthma control such as extra use of reliever medication, lower than expected use of inhaled corticosteroids and asthma attacks to identify people who may be at risk and therefore who should be reviewed.
 - Should specify the actions to follow when poor adherence, inhaler technique or risk factors are identified.
- Definitions
 - Should include RCP 3 questions.
 - Should include person with asthma keeping a 2 week symptom diary to reinforce self-care.

5.4 Draft statement 4

People who receive hospital treatment for an asthma attack are followed up by their GP practice within 2 working days of discharge. [2013, updated 2018]

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- General
 - Statement will be very difficult to achieve in some areas due to the current pressure on primary care and may require additional resources.
- Statement
 - The timescale is unrealistic due to the time taken to share information between secondary and primary care in some areas - 5 days suggested as an alternative.
 - Alternative focus suggested on a brief review of asthma management by the organisation providing treatment for the asthma attack.
 - Alternative focus suggested on secondary care advising people attending A&E to make an appointment with their GP to support patient choice.
 - A focus only on A&E was suggested as follow-up likely to be less relevant post admission.
- Rationale
 - Should specify that follow-up is needed to ensure the asthma attack is responding to treatment and that the person is given support and advice on what to do next.
 - Purpose of follow-up needs to be better defined to avoid it becoming a tick box exercise.
- Measures
 - In structure b) acute care providers could arrange the GP follow up appointment directly rather than having a notification system.
- Audience descriptors
 - Should emphasise the need for timely notification to the GP practice so that the 48 hour timescale can be met.

- Healthcare professionals should include pharmacists and nurses and doctors should be a specialist in asthma.
- Should suggest that initial follow-up could be by telephone/digitally.
- Should suggest commissioners set up a local incentive/quality improvement scheme to encourage the pathway to be established.
- Definitions
 - Should define follow-up so that content is clear e.g. review of current maintenance therapy, adherence, inhaler technique and personalised action plan.

5.5 Draft statement 5

People with severe asthma are referred to a specialist severe asthma service for assessment. [2013, updated 2018]

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- General
 - There were concerns about potential resource impact as many people with suspected severe asthma are not currently referred to a specialist. It was suggested that there may need to be an increase in the capacity of severe asthma clinics and increased resources to identify people who should be referred.
- Statement
 - Should focus on people with ‘suspected’ severe asthma as diagnosis is not feasible in primary care.
 - It is inappropriate to generalise adult referral criteria to children.
- Rationale
 - Include consideration of alternative treatment options including pharmacological and non-pharmacological treatments.
- Measures
 - Include referral criteria in structure measure b).
 - Outcome b) does not match the ERS/ATS definition of severe asthma which suggests 2 rather than 3 courses of high-dose oral corticosteroids.
- Audience descriptors
 - There were different opinions on the requirement to address adherence and comorbidities before referral. Some stakeholders suggested this should be emphasised and a checklist should be available with information sent electronically with the referral. Others suggested this should not be a requirement because primary care may not have the skills and tests available to further improve outcomes.
 - Commissioners should ensure referral pathways are in place, with proactive identification of suspected severe asthma so that a referral can be made.

- People being referred should be given advice on what to expect.
- Definitions
 - Needs to be clearer what a specialist adult and paediatric severe asthma service is e.g. does it include referral of children and young people to a general paediatrician, is it just referral from secondary to tertiary care?

Consultation question 5

We have suggested using the European Respiratory Society/American Thoracic Society definition of severe asthma in line with NHS England's [specification for adult specialised respiratory services for severe asthma](#). Is this reasonable and will it be possible to identify this population in practice?

Stakeholders made the following comments in relation to consultation question 5:

- There is broad agreement with the ERS/ATS definition of severe asthma although some stakeholders felt the definition needs to be clearer.
- It was questioned why the BTS/SIGN definition was not used.
- It was suggested that the definition of severe asthma should be distinguished from the definition of 'difficult to control' asthma.
- There was agreement that it is possible to identify people that should be referred from GP records as all the criteria are coded. Airflow limitation, is however, frequently badly performed and coded.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Review of inhaler technique
- Treatment of exacerbations - BTS Acute Asthma Care Bundle and Royal College of Emergency Medicine standards of care.
- Difficult to control asthma

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Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments ¹
1	Asthma UK	General	<p>Key messages:</p> <p>Asthma is a variable condition. Continual monitoring is essential. Patient education, advice and support including a written asthma action plan can help a patient to self-monitor and has been shown to prevent hospital admissions. Asthma needs to be more accurately coded across settings to ensure we can track referrals, and identify at-risk patients</p> <p>Patients and health care professionals need to co-create personalised asthma action plans to ensure patients are engaged and understand how to manage their asthma effectively.</p> <p>Severe asthma diagnosis is currently not feasible in primary care due to the short appointments, lack of expertise and diagnostics tools. The quality standard should emphasise the referral of patients (with suspected severe asthma) to specialists instead of requiring a severe asthma diagnosis to be confirmed in primary care.</p> <p>We need to scale-up best practice and learn from colleagues excelling in asthma care for example, the North-West London asthma dashboard that “red-flags” at-risk patients</p> <p>Some of the statements from 2013 quality standard for asthma that are no longer considered national priorities for improvement are problems that still need to be addressed.</p> <p>A number of the proposed changes overlook key issues in terms of implementation and measurement of the quality standards. These changes will not ensure that people with asthma all receive a high standard of care. We have highlighted some of the key problems below.</p>
2	Asthma UK	General	The variance in asthma care across the country, offers the opportunity for health care professionals to learn best practice from their colleagues in other parts of the country.

¹PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement number	Comments ¹
			<div data-bbox="1084 300 1861 756" style="border: 1px solid black; padding: 10px;"> <p data-bbox="1115 331 1711 354"><i>Case Study: North-West London Whole Systems Integrated Care Programme</i></p> <ul data-bbox="1182 421 1850 750" style="list-style-type: none"> <li data-bbox="1182 421 1850 469">• <i>This system facilitates patient follow-up and collects the data to see if the follow-up happened.</i> <li data-bbox="1182 475 1850 523">• <i>It also addresses the issue of excessive reliever-use, as prescribing data is used to track the risk indicator.</i> <li data-bbox="1182 529 1850 603">• <i>They have linked patient data across 8 CCGs, including hospitals, GP practices, community and mental health trusts and adult social care, to allow integrated care through a shared dashboard.</i> <li data-bbox="1182 609 1850 683">• <i>An asthma dashboard has been developed that quickly provides a view of key risk indicators and classifies asthma risk into “red flag” status to help clinicians quickly identify people with asthma that are at high risk.</i> <li data-bbox="1182 689 1850 750">• <i>This can be used to allow patients to be prioritised for review and resources to be targeted to those in most need. A printout of risk factors can also be provided to patients to help them understand their asthma better.</i> </div>
3	Asthma UK	General	<p data-bbox="797 772 1989 826"><u>Statements from 2013 quality standard for asthma that are no longer considered national priorities for improvement</u></p> <p data-bbox="797 833 1883 858">These statements still require attention and are fundamental to improving asthma outcomes:</p> <p data-bbox="797 893 2145 954">1. People with asthma are given specific training and assessment in inhaler technique before starting any new inhaler treatment.</p> <p data-bbox="797 986 2123 1075">This is essential and should be extended to checking inhaler adherence and technique at every opportunity. This is especially important where there is evidence of poor asthma control which is caused by untreated airway inflammation and is a risk factor for life threatening asthma attacks and hospitalisation.</p> <p data-bbox="797 1110 2141 1168">This fits with the NHS Outcomes Framework indicators “Ensuring people feel supported to manage their condition” and “Reducing time spent in hospital with LTCs”</p> <p data-bbox="797 1203 2123 1289">Poor inhaler technique is more likely to cause harm due to side effects and are less likely to be cost-effective – leading to wasted resources for the NHS and symptoms/risk that are not fully addressed – putting patients at risk of life threatening asthma attacks</p>

ID	Stakeholder	Statement number	Comments ¹
			<p>2. People with asthma receive a structured review at least annually.</p> <p>The Asthma UK annual review shows this is not happening routinely. All patients with asthma should get an annual review. Ideally providing some structure to it will encourage better levels of care. It should include measures of asthma control and objective measures of lung function or inflammation. Because the quality of asthma care varies so tremendously it is crucial that asthma reviews are carried out by someone with appropriate knowledge, experience and skills.</p> <p>Having an annual asthma review is essential (especially with QOF being phased out) to monitoring asthma control and reducing risk. It is also essential to fulfil the NHS Outcomes Framework indicators “Ensuring people feel supported to manage their condition” and “Reducing time spent in hospital with LTCs”.</p> <p>Not having an annual review is associated with an increased risk of mortality from asthma (NRAD 2014).</p> <p>An annual review would help address NHS Outcomes Framework and NHS Public Health Outcomes Framework targets on preventable and premature mortality rates as well as unscheduled hospitalisation.</p> <p>3. People with asthma who present with an exacerbation of their symptoms receive an objective measurement of severity at the time of presentation.</p> <p>This is a critical Quality Standard that should not be removed. NRAD (2014) demonstrated that 46% of the 195 patient deaths could have been avoided but they were not treated in line with the asthma guidelines.</p> <p>Acute episodes provide an important and life-saving opportunity in the journeys of people with asthma and should be managed consistently across the NHS and across all healthcare locations.</p> <p>A structured assessment and treatment plan aligned with BTS Acute Asthma Care Bundle and Royal College of Emergency Medicine standards of care . This would help address the NHS Outcomes Framework and NHS Public Health Outcomes Framework targets on preventable and premature mortality rates as well as unscheduled hospitalisation.</p> <p>4. People aged 5 years or older presenting to a healthcare professional with a severe or life-threatening acute exacerbation of asthma receive oral or intravenous steroids within 1 hour of presentation.</p> <p>See Quality statement 1 (page 2).</p>

ID	Stakeholder	Statement number	Comments ¹
			<p>5. People admitted to hospital with an acute exacerbation of asthma have a structured review by a member of a specialist respiratory team before discharge.</p> <p>An acute exacerbation of asthma should not be the end of the patient journey. It is an important signal that the treatment and/or self-care may have been insufficient to adequately manage the asthma. Additional follow up and support is required to ensure full resolution of the exacerbation and to prevent future exacerbations. The BTS Asthma Care Bundle is an evidence based and easily implementable/measurable aspect of care.</p> <p>By including assessment by someone from the expert team the moment of crisis can be harnessed to adjust treatments and influence behaviours to help address NHS Outcomes Framework and NHS Public Health Outcomes Framework targets on preventable and premature mortality rates as well as unscheduled hospitalisation.</p>
4	AstraZeneca UK	General	<p>References</p> <ol style="list-style-type: none"> 1. Foster JM et al, Inhaler reminders improve adherence with controller treatment in primary care patients with asthma, J Allergy Clin Immunol, December 2014, volume 134, Issue 6, Pages 1260–1268.e3 2. O’Byrne PM et al, The paradoxes of asthma management: time for a new approach? Eur Respir J 2017; 50: 1701103 3. Laforest L et al, Prescribed therapy for asthma: therapeutic ratios and outcomes. BMC Fam Pract 2015; 16: 49 4. Royal College of Physicians. Why Asthma Still Kills. The National Review of Asthma Deaths (NRAD). Published May 2014. https://www.rcplondon.ac.uk/projects/outputs/why-asthma-still-kills 5. British Thoracic Society Scottish / Intercollegiate Guidelines Network. SIGN 153 British guideline on the management of asthma. Edinburgh. Revised edition published September 2016. Available at URL: https://www.brit-thoracic.org.uk/document-library/clinical-information/asthma/btssign-asthma-guideline-2016/ 6. National Institute of Health and Care Excellence. Asthma: diagnosis, monitoring and chronic asthma management (NG80) Published November 2017. Available from https://www.nice.org.uk/guidance/ng80 All rights reserved. Subject to Notice of rights.
5	Boston Scientific	General	<p>We are pleased to see NICE is reviewing the quality standards for Asthma. As part of these quality standards we would like to ask NICE to reinforce the need for all patients with asthma to receive the most appropriate treatment depending on the severity of the disease, and to highlight how important it is that patients receive the right treatment at the right time. Currently, some patients wait too long before having access to certain therapies and for this reason we ask NICE to highlight through these quality standards the need to ensure all treatment options are communicated at the correct time and also to provide specific guidance as to the optimal patient pathway based</p>

ID	Stakeholder	Statement number	Comments ¹
			on the latest evidence available. This optimal patient pathway could be informed by examining the data in the difficult asthma registry.
6	British Thoracic Society	General	It is not clear why the statements have been reduced from 11 to 5 Some important standards have been lost (consideration of occupational asthma, early treatment with systemic steroid in exacerbation). However the 5 standards chosen are reasonable when set against the NICE guidelines which prioritise these areas.
7	Department of Health and Social Care	General	Thank you for the opportunity to comment on the above quality standard update. I wish to confirm that the Department of Health and Social Care has no substantive comments to make, regarding this consultation.
8	National Paediatric Respiratory and Allergy Nurse Group (NPRANG)	General	Yes the key areas for quality improvement are included in the standards
9	NHS England	General	The QS now reflects the new NICE guideline. The statements are all reasonable but obviously limited in scope by the nature of the QS.
10	NHS England Specialised Commissioning	General	Inhaler technique remains essential when changing inhalers. This should be included as part of a quality standard.
11	NHS England Specialised Commissioning	General	<p>Withdrawn statements</p> <p>People with asthma are given specific training and assessment in inhaler technique before starting any new inhaler treatment.</p> <p>It would be preferable to keep this in and change to people with asthma are given specific training in inhaler technique before starting any new inhaler treatment and that this is reviewed at all further asthma review appointments. (increasing evidence of poorer outcomes if patient can't use inhaler including: Molimard M, Raheison C, Lignot S, Balestra A, Lamarque S, Chartier A, et al. Chronic obstructive pulmonary disease exacerbation and inhaler device handling: real-life assessment of 2935 patients. Eur Respir J. 2017;49(2).)</p> <p>People aged 5 years or older presenting to a healthcare professional with a severe or life-threatening acute exacerbation of asthma receive oral or intravenous steroids within 1 hour of presentation.</p> <p>It would be preferable for this to remain in having explored the death of two children in the last 18 months in our region. In both, one via minor injury unit, the other via telephone triage - the initiation of corticosteroid was considerably delayed and in one this could potentially have been life saving.</p>

ID	Stakeholder	Statement number	Comments ¹
			<p>People with asthma are given specific training and assessment in inhaler technique before starting any new inhaler treatment.</p> <p>2013 QS 4: assessment of inhaler technique - this is a key component of every asthma review. It is unclear why this has been removed.</p> <p>2013 QS9: specialist review pre discharge – the wording of this statement was problematic as there is not 24/7 specialist respiratory cover in most Trusts. However, a structured review pre discharge is very important, and the lack of specialist respiratory cover has driven upskilling of nursing and medical teams who look after patients with acute asthma attacks.</p> <p>Annual assessment has been removed. The purpose of this review was poorly defined and greater clarity about the annual assessment would have been preferable to removing it.</p> <p>It is disappointing that the inhaler technique standard is no longer included as we still need to ensure this happens, for children and adults alike.</p> <p>2013 statements removed.</p> <p>Inhaler training vital, especially on children. It does get a mention in statement 3. Use of oral/IV steroids within 1 hour for life threatening exacerbation also critical</p>
12	NHS England Specialised Commissioning	General	<p>It is disappointing that no mention of adherence is mentioned in any of the Qs. Recognising and addressing poor adherence is likely to have a greater impact on asthma management and outcomes than any of the other Qs. This is the largest factor behind poor asthma control, frequent exacerbations and admissions. Primary care should annually review prescribing of inhaled steroids and bronchodilators, hospital care should request this data from GPs also. If 50% inhaled steroids are collected then we know patient not taking them. If large amounts bronchodilators used this is a risk factor for asthma deaths.</p>
13	Novartis Pharmaceuticals UK Ltd	General	<p>Thank you for the opportunity to comment on this draft Quality Standard. We agree with all of the quality statements that are included in the draft consultation document with one suggested addition to statement 3 (as described in our second comment below).</p>
14	Royal College of General Practitioners	General	<p>Statements 2-5 seem appropriate. However it should be made clear that people attending A/E should be advised by secondary care to make an appointment to be seen in general practice.</p> <p>Statement 1 refers to objective tests for asthma and we refer to our response to the NICE guidelines on Asthma and testing.</p>

ID	Stakeholder	Statement number	Comments ¹
15	Royal College of Nursing	General	The RCN supports the development of these Standards, however we do not think you should have taken the inhaler review out of the standards as this is fundamental to patient care.
16	Royal College of Paediatrics and Child Health	General	Please note that the RCPCH have no comments to make on this consultation.
17	Royal College of Physicians	General	The RCP is grateful for the opportunity to respond to the above consultation. In doing so we would like to endorse the response submitted by the British Thoracic Society (BTS). We have also liaised with our National Asthma and COPD Audit Programme (NACAP) and our Joint Committee on Clinical Immunology & Allergy and would like to make the following comments.
18	UK Inhaler Group	General	<p>In the current version of the quality standard, inhaler technique features as a quality statement in its own right, which highlights the importance of patients knowing how to use their inhalers if they are to receive maximum benefit from them.</p> <p><i>'People with asthma are given specific training and assessment in inhaler technique before starting any new inhaler treatment.'</i></p> <p>It is disappointing that this has not been carried through into the revised version of the draft QS, as the importance of patients using inhalers properly has not in any way diminished since 2013.</p> <p>Indeed – the data that NICE has collated on the extent to which patients are receiving guidance on inhaler technique has not improved since 2013. This means that 20% of patients or more are not getting full benefit from their inhalers if they have not been getting help on how to use them.</p> <p>https://www.nice.org.uk/guidance/QS25/uptake</p> <p>Given the overall cost of inhalers to the NHS, this represents significant wastage of resource if patients do not get the benefit they should from their prescribed medication.</p> <p>There are 106 inhalers on the market in the UK, and 19 different inhaler devices. This is a situation that can cause confusion for prescribers, dispensers and patients alike and highlights that careful selection of the most appropriate inhaler for a patient can be undermined by poor technique, if the patient is not shown how to use it.</p>
19	UK Inhaler Group	General	<p>We note that you have incorporated checking inhaler technique into the detailed text that underpins Quality statement 3 -<i>Statement 3 People with asthma have their asthma control monitored at every review.</i> [2013, updated 2018]</p> <p>While it is pleasing to see that you have incorporated a specific quality measure referring to inhaler technique – <i>b) Proportion of people with asthma who had a review of their inhaler technique within the past 12 months,</i> we feel that downgrading inhaler technique checks from having a quality statement in its own right will give out the wrong message to clinicians, managers and patients, and imply that it is a less important intervention or that the clinical community has 'sorted it'..</p>

ID	Stakeholder	Statement number	Comments ¹
			As the QS is not mandated and there are no checks in the system to see that it is being implemented, the reality is that the QS will not be a lever to drive improved inhaler technique if it is not a headline issue with a Quality statement of its own.
20	Association of Respiratory Nurse Specialists (ARNS)	Question 1	No all of the areas now considered to be addressed at local level still need to be at a national level, particularly those such as inhaler technique.
21	Asthma UK	Question 1	<p>No, more work is needed in the following areas:</p> <ul style="list-style-type: none"> • Ensuring all patients have personalised asthma care plans • Using appropriate and realistic quality measures for standards of asthma care. • Ensuring that health care professionals (in all care settings) have adequate access to and the appropriate training to use asthma diagnostic tools as recommended. • Clarity on the need to refer patients with suspected severe asthma to specialist care because confirming a diagnosis in primary care is very difficult due to the lack of tools, time and expertise. • Ensuring that the necessary systems and structures are in place for patient follow-up after an A&E attendance or hospital admittance.
22	Royal Pharmaceutical Society	Question 1	<p>The NICE Quality standards and indicators Briefing paper show that stakeholders have identified inhaler technique and the importance of a structured annual review as areas for quality improvement. The removal of quality statements 4 and 5 from the 2013 NICE quality standards is of concern.</p> <p>Poor inhaler technique can result in poor asthma outcomes, therefore it is important that people with asthma are given training and review of inhaler technique.</p> <ul style="list-style-type: none"> • NICE NG80 mentions that it is <i>'vital for patients to learn the proper inhaler technique for their device to ensure optimum drug delivery to the lungs for asthma control.'</i> • The briefing paper (page 14) states that an Asthma UK survey found that 76.3% of respondents said that their doctor/nurse helped to make sure they could use all their inhalers correctly before starting to use them, which was a decline from 2015 (79.3%), and as such we believe that this should remain in the standards. • The British Thoracic Society has stated in a press release that <i>'A new innovative tracking device has revealed that the majority of people with chronic lung disease are not using their inhalers correctly'</i>: https://www.brit-thoracic.org.uk/pressmedia/2016/two-thirds-of-people-with-chronic-lung-disease-use-inhalers-incorrectly/). <p>Removing statement 5 that people with asthma receive a structured review at least annually may impact on the number of patients that receive a review. The lack of review may mean poor asthma control and opportunities to check inhaler technique are missed. Particularly as the Asthma UK annual survey 2017 indicated a decline in the</p>

ID	Stakeholder	Statement number	Comments ¹
			number of people that reported receiving a review in 2017 (point 4.3.3 on page 23 of the briefing paper), despite this recommendation by National Review of Asthma Deaths report in 2014 (https://www.asthma.org.uk/globalassets/campaigns/nrad-executive-summary.pdf).
23	UK Inhaler Group	Question 1	<i>Does this draft quality standard accurately reflect the key areas for quality improvement?</i> No – we believe that systematic checking of inhaler technique should have a much higher profile since poor inhaler technique leads to poor control of asthma and to wastage of NHS resources.
24	Association of Respiratory Nurse Specialists (ARNS)	Question 2	Data can be extracted from primary care level but is very limited at secondary care level. Systems are not currently in place to collect data in ED.
25	Asthma UK	Question 2	Yes, but the data may not be of good enough quality to rely on. Better coding of asthma care is required. Also, the data in many instances is merely a proxy for quality. It will not tell you about the quality of the asthma review, the quality of the tests being performed or their interpretation, or the quality of the completion of an asthma action plan.
26	Royal College of Physicians	Question 2	Our experts expressed doubt as to whether there are local systems to collect the patient data.
27	Association of Respiratory Nurse Specialists (ARNS)	Question 3	No these statements are not currently achievable due to lack of time allowed for routine reviews (to incorporate a PAAP), lack of resources (FeNO), lack of clinic availability (follow up 48 hrs after an acute episode).
28	Asthma UK	Question 3	There is a large unmet need for people with suspected severe asthma. Many are treated in primary care without being considered for referral. Severe asthma clinics will need to have the capacity to deal with these extra numbers. There is a significant resource required to provide the training and equipment for primary care to deliver these quality standards. It has been well documented about the concerns of primary care to deliver the NICE Asthma diagnosis and monitoring guidelines especially in relation to FeNO testing. There are wider concerns about the quality of spirometry delivery and interpretation and the level of clinical understanding of the diagnosis and management of respiratory conditions more generally. In the long term, there are significant resource gains to be had by improving respiratory care generally and asthma care specifically. By reducing incorrect diagnoses, optimising medication (and having less people on medicines that they do not need), optimising self-care and providing access to skilled respiratory clinicians there can be significant impacts made on scheduled and unscheduled care costs.
29	Association of Respiratory Nurse Specialists (ARNS)	Question 6	No examples.
30	Association of Respiratory Nurse Specialists (ARNS)	Statement 1	Structure measure b - Needs to include secondary care as some asthmatics are initially diagnosed in this setting.

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31	Asthma UK	Statement 1	We welcome the monitoring of training in asthma of primary HCPs and the documentation of the basis of diagnosis as this will ensure that objective testing was only used on newly diagnosed patients.
32	Asthma UK	Statement 1	<p><u>Accurate and appropriate diagnosis of asthma</u> We are calling for objective tests to help diagnose asthma to be available in primary care. However, not all over 5's (nor some adults) are able to perform these objective tests. Quality statement 1 should highlight the importance of clinical history and examination alongside objective tests to support diagnosis. Tests can give normal results and so cannot be solely relied on for diagnosis. These tests should be repeated if there is clinical suspicion based on medical history and examination. People with asthma/ suspected asthma also require information about their condition and the procedures they will need to undergo to confirm the diagnosis. Information about asthma is an essential part of effective self-management. A correct diagnosis process should also include provision or referral to sources of advice and support.</p>
33	Asthma UK	Statement 1	<p><u>Healthcare professional training and access to diagnostic tools</u> The Quality Statement should emphasise the need to ensure there is access to a full range of objective diagnostic tests, the skills required to perform those tests competently and the skills required to interpret the results accurately. The Quality Statement should also ensure that staff have the ability to refer to a local service performed by clinicians with appropriate competence and appropriate skills to interpret the results accurately. This should not only be limited to primary care. Quality of care in secondary care, tertiary care and community care/ by external providers must also be assured. By not monitoring access to diagnostic tools, we are ignoring an opportunity to reduce the number of newly-diagnosed patients with asthma who have a record of objective tests to support their diagnosis. For healthcare professionals, there should be up-to-date records of training, policies and procedures in any organisation responsible for organising and/or performing objective testing. Commissioners could also consider providing adequate resource from primary or secondary care to provide objective test services in place of local diagnostic hubs for asthma that would optimise the investment in equipment and staff training.</p>
34	Asthma UK	Statement 1	<p><u>Measuring the prevalence of asthma</u> The Quality and Outcomes Framework Indicator AST001 is not a valid data source to identify the prevalence of correctly diagnosed asthma. A time limited AST001 will only identify the people with new diagnoses of asthma. It would need to be cross referenced with a Read code or documentary evidence for the reason for the new</p>

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			<p>diagnosis/objective measurements. It would not necessarily tell you anything about the accuracy of those tests or interpretation.</p> <p>Use purely of AST001 would also miss a significant number of people who are incorrectly NOT given a diagnosis of asthma. Additional searches could be done to identify people who are for example given an inhaler or oral steroids for intermittent symptoms but who may have underlying asthma.</p>
35	AstraZeneca UK	Statement 1	<p>(Quality measures, data source, section b)</p> <p>Ensuring the standardisation of training for Primary Care HCP across the UK can be difficult to achieve. There are differences across the country regarding resources, HCPs baseline training, capacity and competencies (especially within the primary care setting), and clear asthma pathways are not well established in every locality. In addition, training of HCPs may result in further expenses and time constraint for the NHS at local level.</p>
36	British Thoracic Society	Statement 1	<p>Delivery of more objective testing is a laudable target and commissioners are already looking at how this can realistically be delivered in different settings such as through the development of diagnostic hubs in PHC. It will, however, be some time before this will become mainstream and measuring it at this early stage seems harsh.</p>
37	Circassia Plc	Statement 1	<p>Circassia welcome this statement to provide and routinely perform objective tests for asthma diagnosis in primary care.</p> <p>How is this directive enforced and monitored in primary care?</p> <p>We have found extensive evidence within primary care in England that practitioners refuse to provide routine FeNO testing as outlined in the diagnostic algorithms in NG80 (both adult and paediatrics). Many CCG's and Health Boards are considering NICE NG80 respiratory HUBS but need to be supported with NICE implementation team activity to develop the need, value and impetus to enhance the priority of the service development.</p> <p>Therefore Circassia poses the question: How is routine FeNO testing actively encouraged and directed by NICE to CCGs and primary care practices? How will routine FeNO testing be documented in order to fulfil the Quality measures associated with Quality statement 1: a) Evidence of local arrangements or referral pathways to diagnostic hubs to ensure that people aged 5 and over with suspected asthma have objective tests to support diagnosis. .</p> <p>b) Evidence of local arrangements to ensure that healthcare professionals in primary care are trained and competent to carry out objective tests to support diagnosis of asthma. c) Evidence of local processes to ensure that the basis for a diagnosis of asthma is documented.</p>
38	National Paediatric Respiratory and Allergy Nurse Group (NPRANG)	Statement 1	<p>This statement may be hard to measure because objective measurements are not routinely done in primary care and therefore unlikely to be achievable.</p> <p>Objective measurements need to be carried out by a practitioner with the knowledge and skills to provide the test. In paediatrics they will need to be carried out by a practitioner who has been specifically trained.</p>

ID	Stakeholder	Statement number	Comments ¹
			<p>While objective tests can support a diagnosis of asthma these should be done along with a good history taken by a HCP trained in asthma diagnosis and management. Normal spirometry does not exclude the diagnosis of asthma and could lead to misdiagnosis. Many children have normal spirometry however this would not exclude a diagnosis of asthma.</p> <p>Yes mostly It is feasible keep a record of objective measurements taken to support diagnosis on electronic data basis and this information will need to include a record of symptoms, treatment and efficacy not just objective tests. It is unclear who will collect and audit the data and this will require additional resources to fund.</p> <p>Resources would need to be available to ensure the objective testing / investigations can be performed by appropriately trained / competent practitioners. Practitioners working with children will need the relevant skills to help children perform such testing.</p>
39	NHS England	Statement 1	This statement may be hard to measure because FeNO testing is not routinely available in the primary care.
40	NHS England	Statement 1	Equality and diversity consideration do not include considerations for children from ethnic minority backgrounds (where parents may not be able to speak English) or considerations for patients who immigrate to the UK with diagnosis of Asthma.
41	NHS England Specialised Commissioning	Statement 1	<p>Diagnosis There has already been a great deal of discussion on diagnosis following the publication of the NICE guideline on diagnosis and management. Documentation of objective tests (as suggested by the quality statement) will be much more achievable than diagnosis according to the NICE guideline (included in the explanatory notes). Evidence of objective testing is welcomed but implementation of the NICE diagnostic algorithm will be difficult to achieve.</p> <p>Accurate and appropriate diagnosis of asthma We are calling for objective tests to help diagnose asthma to be available in primary care. However, not all over 5's (nor some adults) are able to perform these objective tests. Quality statement 1 should highlight the importance of clinical history and examination alongside objective tests to support diagnosis. Tests can give normal results and so cannot be solely relied on for diagnosis. These tests should be repeated if there is clinical suspicion based on medical history and examination. People with asthma/ suspected asthma also require information about their condition and the procedures they will need to undergo to confirm the diagnosis. Information about asthma is an essential part of effective self-management A correct diagnosis process should also include provision or referral to sources of advice and support.</p> <p>Healthcare professional training and access to diagnostic tools</p>

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			<p>The Quality Statement should emphasise the need to ensure there is access to a full range of objective diagnostic tests, the skills required to perform those tests competently and the skills required to interpret the results accurately. The Quality Statement should also ensure that staff have the ability to refer to a local service performed by clinicians with appropriate competence and appropriate skills to interpret the results accurately. This should not only be limited to primary care. Quality of care in secondary care, tertiary care and community care/ by external providers must also be assured.</p> <p>By not monitoring access to diagnostic tools, we are ignoring an opportunity to reduce the number of newly-diagnosed patients with asthma who have a record of objective tests to support their diagnosis.</p> <p>For healthcare professionals, there should be up-to-date records of training, policies and procedures in any organisation responsible for organising and/or performing objective testing.</p> <p>Commissioners could also consider providing adequate resource from primary or secondary care to provide objective test services in place of local diagnostic hubs for asthma that would optimise the investment in equipment and staff training.</p> <p>Measuring the prevalence of asthma</p> <ul style="list-style-type: none"> - The Quality and Outcomes Framework Indicator AST001 is not a valid data source to identify the prevalence of correctly diagnosed asthma. A time limited AST001 will only identify the people with new diagnoses of asthma. It would need to be cross referenced with a Read code or documentary evidence for the reason for the new diagnosis/objective measurements. It would not necessarily tell you anything about the accuracy of those tests or interpretation. - Use purely of AST001 would also miss a significant number of people who are incorrectly NOT given a diagnosis of asthma. Additional searches could be done to identify people who are for example given an inhaler or oral steroids for intermittent symptoms but who may have underlying asthma.
42	Primary Care Respiratory Society UK	Statement 1	<p>Statement 1 People aged 5 and over with suspected asthma have objective tests to support diagnosis. [2013, updated 2018]</p> <p>The underpinning text for this statement presents an opportunity to reinforce the useful role of repeated peak expiratory flow (PEF) measurements over time, as the most useful objective test in 5s-8s since undertaking spirometry is very difficult in this age group. Many staff are untrained in performing spirometry on children and the equipment may not allow accurate spirometry in children, as they don't report the appropriate information.</p>

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			<p>We support objective testing in principle but believe that single measurements of airway obstruction in asthma in a GP/nurse surgery is of limited value – as would be a single HbA1C in a diabetic. This is a condition characterised by variation over time. The value of PEF measurement and monitoring lies in its ability for patients to undertake an objective test on a repeated basis over time at home, rather than a single point in time spirometry conducted by a healthcare professional in a surgery.</p> <p>So objective testing is good in principle but no substitute for good history taking, examination, trial of treatment, and careful follow up e.g.</p> <p>It is disappointing that the NICE guideline does not make sufficient reference to repeated PEF as a useful and valid objective test, and on this point we support the content of the British asthma guideline from BTS/SIGN. NICE does recognise the value of PEF but includes this in their recommendations for use in cases of difficulty. We believe that this should be a first line objective test in primary care.</p>
43	Royal College of Physicians	Statement 1	<p>Comment 1: This is an opportunity to reinforce useful role of repeated PEF measurements as most useful objective test in all primary care patients but particularly in 5s-8s as spirometry very hard in this age group, and many staff untrained in delivering spirometry to children and equipment may not allow accurate spirometry in children. Single point in time objective testing in asthma is unhelpful. Specifically mentioning peak diaries would be ideal.</p> <p>Comment 2: The type of test needs to be specified.</p>
44	Royal Pharmaceutical Society	Statement 1	<p>What the quality statement means for different audiences</p> <p>Healthcare professionals (such as doctors and nurses) – should include pharmacists in this statement as pharmacists prescribers are involved in the diagnosis of asthma, for example in GP practices.</p>
45	Sanofi	Statement 1	<p>Sanofi supports the intent of Statement 1 - <i>People aged 5 and over with suspected asthma have objective tests to support diagnosis</i> – but would support the development of more detailed guidance for healthcare professionals on what an ‘objective test’ is and when and how these are used. In our opinion these should involve a combination of lung function tests, FeNO and assessment of clinical and family history.</p>
46	Association of Respiratory Nurse Specialists (ARNS)	Statement 2	<p>When you have written “Healthcare professionals review and update written personalised action plans with the person following an asthma attack to prevent further asthma attacks.” It should include on an annual basis also and not just after an “attack”.</p>
47	Asthma UK	Statement 2	<p>We agree with the proposal to an audit of patient health records to determine the proportion of people with asthma (PWA) who have an up to date action plan. It would provide more value if this audit was of patients upon discharge from hospital. If patients that are seen in A&E or admitted to hospital for asthma do not have action plans they could then be identified then and given one.</p>

ID	Stakeholder	Statement number	Comments ¹
			<p>Action plans are fundamental to improving outcomes for people with asthma. As we mentioned in our stakeholder engagement response, the quality measure should emphasise the education and involvement of the patient in creating a personalised action plan, that falls in line with the NICE Guidelines recommendation 1.10.</p> <p>Asthma is a variable and often unpredictable condition. A great deal of responsibility falls upon the patient and their carers to keep doing the basics of self-care. They must also respond to a changing environment, symptoms and tailor their behaviours and treatment accordingly. A written asthma action plan helps support people with asthma to stay well and so that they know what to do when symptoms change.</p> <p>A written asthma action plan would support the NHS Outcomes Framework indicators “Ensuring people feel supported to manage their condition” and “Reducing time spent in hospital with LTCs”. Having a written asthma action plan reduces risk of hospitalisation due to asthma by 4 times. It is not sufficient to give a patient a written asthma action plan, they should be completed with the patient.</p> <p>A digitised action plan may be more likely to be carried by the patient (on a mobile device), be more readily shared with other people responsible for care (other health providers, care agencies, schools) and could be shared in the patient record and patient-held record when the data-sharing technology becomes available.</p> <p>The international clinical and research consensus is that the Asthma UK written asthma action plan is the benchmark by which all action plans are tested. The Asthma UK plans are developed based on evidence about what comprises an effective action plan. They have recently been updated in line with NICE Asthma diagnosis and monitoring guidelines.</p> <p><u>Quality measures</u></p> <p>The quality measure “Proportion of people aged 5 and over with asthma who have a written personalised action plan” should be amended to read “Proportion of people aged 5 and over with asthma who have a written personalised action plan documented within their records, not just a Read Code)”. Regarding measured outcomes, the amount of prednisolone prescribing in asthma and/or use of SABA inhalers should be measured in addition to the rate of hospital attendance or admission for an asthma attack. Prescribing data can be used as a data source for the rate of prednisolone and/or SABA use.</p>
48	Asthma UK	Statement 2	<p><u>Recommendations for service providers and commissioners</u> Service providers should develop protocols for the provision of a package of advice and support for people with asthma and their carers from diagnosis through to self-management to exacerbation.</p>

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			<p>This should include providing good quality annual asthma reviews, provision of written asthma action plans and checking inhaler technique.</p> <p>There should be effective provision or signposting to educational and supportive materials/services for patients so that they may be better equipped to self-manage their condition. Local policies/care bundles should be considered at diagnosis and after an asthma attack that include items such as provision of written asthma action plans.</p> <p>A good example of an evidence based care bundle is the BTS Asthma Care Bundle. Training should be offered to help clinicians work with their patients to create effective care plans.</p> <p>Commissioners should see asthma action plans as part of a wider package of advice and support which may involve signposting to organisations such as Asthma UK that provide detailed and evidence-based health advice and information. The use of digital written plans and digital advice and support should also be considered to fit with changing lifestyles and preferences.</p>
49	British Thoracic Society	Statement 2	PAAP - some advice on standardisation would be good. Target is fair and should be achievable.
50	Circassia Plc	Statement 2	<p>Circassia welcome this statement to provide a written asthma treatment action plan for patients aged 5 and over.</p> <p>Given that the primary outcome for this measure (as stated on p10) is a) Rate of hospital attendance or admission for an asthma attack, we propose that the statement details routine FeNO testing to mitigate risk of asthma exacerbations in high risk patients. Therefore routine FeNO monitoring should be described as an integral and routine addition within the patient record.</p> <p>The evidence to support the improvement in exacerbation rate with FeNO testing routinely incorporated into an asthma monitoring protocol is as follows: Elevated FeNO (> 50ppb) has been shown to be a significant independent risk factor for uncontrolled asthma (Malinovich 2016). Furthermore, in a 3 year longitudinal study examining loss of lung function, a persistently high FeNO level of >40 ppb was independently associated with an accelerated decline in FEV1 (Matsunaga 2016).</p> <p>The most compelling evidence to support the use of monitoring FeNO in asthma management has been summarized in two recent Cochrane meta-analyses that concluded exacerbations were reduced 40-50%. The 2016 Cochrane Systematic Review on “Exhaled Nitric Oxide Levels to Guide Treatment for Adults with Asthma” included 7 randomized controlled trials and 1,700 adult participants. (Petsky 2016) By monitoring FeNO, the number of exacerbations were reduced by 40% and the exacerbation rates by at least 41%. The number of people having one or more asthma exacerbations was significantly lower in the FeNO group compared to the control group (odds ratio (OR) 0.60, 95% confidence interval (CI) 0.43- 0.84). Those in the FeNO group were also significantly more likely to have a lower exacerbation rate than the controls (rate ratio 0.59, 95% CI 0.45 – 0.77). The quality of the evidence to support the effect on FeNO on reducing asthma exacerbations was determined to be moderate even though exacerbations were not defined the same across all of the studies included in the</p>

ID	Stakeholder	Statement number	Comments ¹
			analysis. In a second 2016 Cochrane Systematic Review focusing on pediatrics, Petsky and colleagues evaluated the efficacy of tailoring asthma interventions based on monitoring FeNO, in comparison to management based on clinical symptoms (with or without spirometry/peak flow) or asthma guidelines (or both), for asthma-related outcomes. This meta-analysis included 9 randomized controlled trials and 1,426 children. Using traditional monitoring, 40 out of 100 children experienced at least one exacerbation over 48.5 weeks, compared to 28 out of 100 children where treatment was guided by FeNO (OR 0.58, 95% CI 0.45 to 0.75; 1279 participants; 8 studies; $p < 0.0002$) (Petsky 2016).
51	National Paediatric Respiratory and Allergy Nurse Group (NPRANG)	Statement 2	<p>Management / action plans are readily available for HCP's to give to patients and families therefore costs should be low. HCP's reviewing patients with asthma should ensure that they are appropriately trained and should remain up to date with their asthma education and inhaler technique advice.</p> <p>PAPs should include the individual's demonstrated understanding of their own treatment, devices, triggers, ideal 'normal' expectations and symptom recognition with actions to take when control not 'normal'. Training needs to be given to staff who should accept responsibility for provision of PAPs with patients and sufficient time must be allowed for consultations so that the finer points of PAP can be discussed. PAPS should be easy to access for patients. They do not necessarily have to be printed –use mobile phone device if this is what patient prefers.</p> <p>Consideration should be given to viral wheezy children under five years old who may be developing asthma. They should have PAP for wheezy episodes and ongoing monitoring.</p> <p>Validated asthma action plans should be utilised eg Asthma UK. These are available to download and cost will be minimal. The HCP's involved in asthma education need to ensure they have received training to provide up to date evidence based advice. Different levels of training have different pricing structures.</p> <p>Asthma Action Plans are readily available and can be downloaded from reliable sources if not available through individual health boards and therefore this standard should be easily achievable.</p>
52	NHS England	Statement 2	This statement may be difficult to measure for patients who may not have access to latest information technology or difficulties in reading information in English. It could also be improved by adding that written care plans should meet the NHS standards for written information.
53	NHS England Specialised Commissioning	Statement 2	QS2: NHS England would recommend that it states have an <i>up to date</i> written personalised action plan. The PAAP should include the following key components: maintenance treatment, and an escalation plan. Asthma UK have recently updated their plan and should form the basis of all PAAPs (which can then be adapted to include specific local information).

ID	Stakeholder	Statement number	Comments ¹
			<p>It is illogical not to include children under 5 years with established asthma. NICE guideline did not recommend this but was also a flaw.</p> <p>Qu 4: This could include what preventers to use, and when to take relievers as well as when to seek medical advice is most important.</p> <p>This will be hard to monitor. Most plans are filled out by hand in clinic (using local or Asthma UK template) and given to parent, so unless recorded in clinic letter there will be no electronic record of which patients have one.</p> <p>Needs to be available in multiple languages (equality considerations).</p> <p>Action plans are fundamental to improving outcomes for people with asthma. As we mentioned in our stakeholder engagement response, the quality measure should emphasise the education and involvement of the patient in creating a personalised action plan that falls in line with the NICE Guidelines recommendation 1.10.</p> <p>Asthma is a variable and often unpredictable condition. A great deal of responsibility falls upon the patient and their carers to keep doing the basics of self-care. They must also respond to a changing environment, symptoms and tailor their behaviours and treatment accordingly. A written asthma action plan helps support people with asthma to stay well and so that they know what to do when symptoms change.</p> <p>A written asthma action plan would support the NHS Outcomes Framework indicators “Ensuring people feel supported to manage their condition” and “Reducing time spent in hospital with LTCs”. Having a written asthma action plan reduces risk of hospitalisation due to asthma by 4 times. It is not sufficient to give a patient a written asthma action plan, they should be completed with the patient.</p> <p>A digitised action plan may be more likely to be carried by the patient (on a mobile device), be more readily shared with other people responsible for care (other health providers, care agencies, schools) and could be shared in the patient record and patient-held record when the data-sharing technology becomes available.</p> <p>The international clinical and research consensus is that the Asthma UK written asthma action plan is the benchmark by which all action plans are tested. The Asthma UK plans are developed based on evidence about what comprises an effective action plan. They have recently been updated in line with NICE Asthma diagnosis and monitoring guidelines.</p> <p>Quality measures</p>

ID	Stakeholder	Statement number	Comments ¹
			<ul style="list-style-type: none"> - The quality measure “Proportion of people aged 5 and over with asthma who have a written personalised action plan” should be amended to read “Proportion of people aged 5 and over with asthma who have a written personalised action plan documented within their records, not just a Read Code)”. <ul style="list-style-type: none"> - Regarding measured outcomes, the amount of prednisolone prescribing in asthma and/or use of SABA inhalers should be measured in addition to the rate of hospital attendance or admission for an asthma attack. Prescribing data can be used as a data source for the rate of prednisolone and/or SABA use. <p>Recommendations for service providers and commissioners</p> <ul style="list-style-type: none"> - Service providers should develop protocols for the provision of a package of advice and support for people with asthma and their carers from diagnosis through to self-management to exacerbation. - This should include providing good quality annual asthma reviews, provision of written asthma action plans and checking inhaler technique. - There should be effective provision or signposting to educational and supportive materials/services for patients so that they may be better equipped to self-manage their condition. Local policies/care bundles should be considered at diagnosis and after an asthma attack that include items such as provision of written asthma action plans. - A good example of an evidence based care bundle is the BTS Asthma Care Bundle. Training should be offered to help clinicians work with their patients to create effective care plans. - Commissioners should see asthma action plans as part of a wider package of advice and support which may involve signposting to organisations such as Asthma UK that provide detailed and evidence-based health advice and information. The use of digital written plans and digital advice and support should also be considered to fit with changing lifestyles and preferences
54	Primary Care Respiratory Society UK	Statement 2	<p>Statement 2 People aged 5 and over with asthma have a written personalised action plan. [2013]</p> <p>There is solid evidence for written action plans being a high value intervention, and there is clear evidence that patients with them have better control and fewer exacerbations. We are pleased to see that written personalised action plans have been retained in this updated QS.</p> <p>It should be noted that to be effective, they need to be co-created with the patient, personalised and to create an opportunity for the patient to understand their asthma better, ie. educational, not just printed templates.</p>
55	Royal College of Physicians	Statement 2	<p>Comment 1: Solid evidence for usefulness of written action plans and evidence that patients with them have better control and fewer exacerbations. This would be a better metric if it was patient reported. This tests the system that people with asthma come into contact with that goes beyond GP ie pharmacist, school, ED, OPD.</p> <p>Comment 2: Quality needs to be specified eg which includes..... also all these QS require a local audit to be carried out is that going to happen if it is worth asking NICE how because that could be the basis for a England primary care audit</p>

ID	Stakeholder	Statement number	Comments ¹
56	Royal Pharmaceutical Society	Statement 2	<p>What the quality statement means for different audiences</p> <p>Checking that the person with asthma has a personalised action plan could be brought up by the pharmacist during a Medicines Use Review (MURs). Community pharmacists currently carry out targeted MURs for people with respiratory disease, and as such are ideally placed to check that the person understands what their medicines are for, inhaler technique and adherence, inhaler suitability, potential side effects of medicines (both prescribed and purchased), checking that there is a personalised action plan in place and that the person knows how and when to step up and step down their medicines as appropriate, as well as giving lifestyle advice which may benefit the person, for example smoking cessation, weight loss.</p>
57	Sanofi	Statement 2	<p>Sanofi fully supports Statement 2 – <i>People aged 5 and over with asthma have a written personalised action plan</i> – as a key pillar in effective asthma management and patient empowerment. A patient’s action plan must be reviewed following any asthma attack or exacerbation, with a specific focus on assessing whether their current treatment is being optimised.</p> <p>Although having a written personalised action plan is an accepted form of clinical practice, from the most annual Asthma UK survey (2017) we know that only 43.9 percent of patients have an action plan in place. More needs to be done to ensure this statement is better implemented in clinical practice.</p>
58	National Paediatric Respiratory and Allergy Nurse Group (NPRANG)	Statement 2 - Question 4	<p>The action plan needs to be clear and concise making it easy to follow by any age group.</p> <p>Needs distinction between ongoing preventative treatment</p> <p>The plan should include how to manage an increase in symptoms due to exposure to a trigger factor eg viral infection and how to recognise and manage an attack and when to call for help.</p> <p>It should also advise on weaning SABA’s as the exacerbation resolves.</p> <p>Along with recognising and managing worsening of symptoms it is helpful if triggers are identified and avoidance strategies included on the plan.</p> <p>The written action plans however needs to be supported with time and resources from a HCP to provide education verbally and demonstration on using inhaler devices correctly. Opportunity to clarify any queries is needed otherwise it will not be utilised by the person with asthma.</p> <p>The HCP needs to have adequate knowledge and skills to support the written explanation.</p> <p>Patients should be encouraged to take photos of these on their phones so they have a copy with them at all times</p>
59	Primary Care Respiratory Society UK	Statement 2 - Question 4	<p>- Which specific components of the written personalised action plan are most important?</p> <p>Asthma action plans should be delivered in the context of supported self-management and should summarise the ‘what to do if....’ questions:</p>

ID	Stakeholder	Statement number	Comments ¹
			<ul style="list-style-type: none"> • Maintenance management (triggers and avoidance if possible; regular medication; allergic rhinitis if appropriate) • Recognising deterioration (based on symptoms, peak flow, or both) • Actions to take (increasing inhaled steroids, commencing orals steroids, seeking emergency medical care) • Returning to maintenance medication after an attack <p>- Would it be helpful to focus on ensuring specific components are included in the written personalised action plan?</p> <p>We don't think it helps to prioritise specific components over others. This is a package which in itself is one component of supported self-management (see Pearce G, Parke H, Pinnock H, Epiphaniou E, Bourne CLA, Sheikh A, Taylor SJC. The PRISMS Taxonomy of Self-Management Support: Derivation of a Novel Taxonomy and Initial Testing of Utility. J Health Serv Res Policy 2016 21: 73-82 for a picklist of self-management support for LTCs</p>
60	Association of Respiratory Nurse Specialists (ARNS)	Statement 2 – Question 4	Previous research tells us that a PAAP needs 3-4 points at the most. To be covered must be what the patient normally takes, what to do in deteriorating asthma, who to contact and how, review dates.
61	Asthma UK	Statement 2 – Question 4	The Asthma UK written asthma action plan is evidence based and designed based on research into the effective components of a written asthma action plan. Both BTS and NICE guidelines reference the Asthma UK written action plan. A recent update has been developed to bring it into line with both NICE and BTS guidelines.
62	Association of Respiratory Nurse Specialists (ARNS)	Statement 3	The wording should not just say monitored but assessed as well using a validated tool such as the ACT or ACQ
63	Association of Respiratory Nurse Specialists (ARNS)	Statement 3	As well as checking inhaler technique and adherence, new triggers should also be assessed before adjusting treatment.
64	Asthma UK	Statement 3	<p>The rationale statement should be changed from “Monitoring asthma control at every review will enable the identification of any difficulties with adherence, medication use or inhaler technique” to “Monitoring asthma control at every review is essential. Evidence of poorly controlled asthma should lead to an assessment of possible reasons including medication adherence, inhaler technique, triggers and co-morbidities”.</p> <p>Asthma control may be normal when assessing at a single point and may not alert the clinician to poor asthma control between reviews. Other signs of poor asthma control include changes to peak flow, extra use of reliever medication and asthma exacerbations. Patients and clinicians should be encouraged to identify these features and address them. Clinicians should consider additional asthma reviews/assessment of control at other times (exacerbation, prescribing of reliever medications).</p>
65	Asthma UK	Statement 3	<p><u>Comments on the quality measures</u></p> <p>We welcome checking the number of reliever inhalers prescribed using electronic prescribing data.</p>

ID	Stakeholder	Statement number	Comments ¹
			<p>Objective testing</p> <ul style="list-style-type: none"> In addition to using evidence that spirometry or peak flow variability testing is available locally, we need to verify the ability of clinicians in each setting to perform and interpret these tests appropriately. <p>Asthma reviews to monitor asthma control</p> <ul style="list-style-type: none"> The measure that indicates the proportion of asthma reviews that include monitoring of asthma control should specify that the monitoring should be through symptom questionnaires and objectives measures. <p>Short-acting beta agonist reliever inhaler use to identify at-risk patients</p> <ul style="list-style-type: none"> Most of the respiratory community recommend that we should monitor people more carefully who have been prescribed 6 short-acting beta agonist (SABA) reliever inhalers within the past 12 months. The Department of Health policy paper "Community Pharmacy in 2016/17 and Beyond" contains a measure that "asthma patients dispensed more than 6 short-acting bronchodilator inhalers without any corticosteroid inhaler with a 6-month period are referred to an appropriate healthcare professional for an asthma review". A NICE evidence review suggests that prescribing of 12 SABA reliever inhalers (as the quality standard does) is a clear marker of risk for death. The respiratory and prescribing communities suggest 6 SABA inhalers is a threshold for action.
66	AstraZeneca UK	Statement 3	<p>(outcome)</p> <p>Suggested change: proportion of people with asthma using SABA 3 times or more per week and/or >2 SABA inhalers within the last 12 months and/or proportion of people with asthma that are not collecting the expected number of inhaled corticosteroids (ICS) for their dose within the past 12 months – considering that the number of inhalers varies by dose.</p> <p>Rationale: In asthma, adherence with inhaled controller medications, particularly inhaled corticosteroids (ICS), is important to achieve good asthma control. However, poor adherence to maintenance pharmacotherapy is a reality in asthma. Adherence to ICS has been demonstrated to be only 46%. Poor adherence contributes to mortality and morbidity, including uncontrolled symptoms, impaired quality of life, exacerbations and urgent healthcare utilisation. Studies confirm that when symptoms worsen, the majority of patients increase short-acting β2-agonist (SABA) use, instead of using controller medication. This is also evident from the continued high ratio of reliever: preventer medication prescriptions in many countries, often well above a ratio of 2:1. As this ratio decreases, asthma morbidity declines, thereby reducing the utilisation of emergency services, hospitalisations and deaths. In the light of the above, it is clear that well-controlled asthma is associated with little or no need for short-acting bronchodilator (SABA or reliever) inhalers, so the need for excess SABA inhalers is a signal that asthma is poorly controlled.</p>

ID	Stakeholder	Statement number	Comments ¹
			<p>This is confirmed also by BTS/SIGN 2016, which suggests that those patients with symptoms or that use SABA 3 times or more per week are uncontrolled and should be considered for increased preventative therapy.</p> <p>Monitoring of ICS prescribing is important as well. In fact, under prescribing/underutilisation of ICS can lead to a poor asthma control. It has been demonstrated that a sub-optimal use of inhaler corticosteroids is linked to a reduced asthma control and increased risk of exacerbations. To comply with recommendations, most people would usually need at least 12 preventer prescriptions per year (we acknowledge this is dose dependent). From 168 people on preventer inhalers at the time of death, either as stand-alone or in combination, the number of prescriptions was known for 128, and 49 of these (38%) were known to have been issued with fewer than 4 and 103 (80%) issued with fewer than 12 preventer inhalers in the previous year.</p>
67	AstraZeneca UK	Statement 3	<p>(outcome)</p> <p>Suggested change: define a clear change in therapy or behaviour to be followed when a patient with asthma is identified at risk (high SABA prescribing, low ICS prescribing), such as, immediate follow-up, medication review, review of inhaler technique, referral to a specialist, training of the patient.</p>
68	AstraZeneca UK	Statement 3	<p>(Data source: Local data collection, section b)</p> <p>Suggested change: define clearly what the actions to undertake are when a lack of adherence or poor technique have been assessed (e.g., patients not well monitored should be referred to a specialist asthma team; specific training, and consideration of electronic monitoring of the adherence).</p> <p>Rationale: BTS/SIGN guidelines estimated that between a third and a half of all medicines prescribed for long term conditions are not taken as recommended, and evidence in asthma confirms widespread non-adherence to regular preventer medication, that increases over time.</p> <p>Additionally, asthma sufferers who are unable to use their inhaler correctly are at increased risk of poor asthma control, potentially resulting in an attack.</p>
69	AstraZeneca UK	Statement 3	<p>Quality measures, Data source, section C)</p> <p>Suggested change: define time to review. In the QS a specific time should be identified (for instance, no longer than every 6 months for uncontrolled patients and 12 months for stable controlled patients).</p>
70	British Thoracic Society	Statement 3	<p>Statement 3 is less clear. What does this mean? How do ACT, PEF, Spiro and FeNO fit.</p>
71	Circassia Plc	Statement 3	<p>Since the listed outcomes of this statement are: a) Proportion of people with asthma prescribed more than 12 short-acting beta agonist (SABA) reliever inhalers within the past 12 months. b) Rate of hospital attendance or admission for asthma attack, we propose that routine FeNO testing is detailed in the statement in order to monitor these outcomes.</p> <p>P 24, paragraph 1.14.5 of NG80 states: Consider FeNO measurement as an option to support asthma management in</p>

ID	Stakeholder	Statement number	Comments ¹
			<p>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.)</p> <p>The evidence for FeNO testing in mitigating the risk of asthma exacerbations in high-risk patients has been given in the response to statement 2 above.</p> <p>Routine FeNO monitoring may also determine which patients display poor adherence to ICS therapy or those who do not administer their medication correctly.</p> <p>The BTS-SIGN 2016 guidelines state that biomarker testing with FeNO may have a role in establishing (non-) adherence (to ICS therapy) in people with severe, difficult asthma. The BTS-SIGN 2016 guidelines cite as evidence a study by McNicholl et al that clearly demonstrates the dynamic effect of ICSs on FeNO may be used as an accurate discriminator of non-adherence to inhaled corticosteroids in adults (McNicholl 2012). Patients in this study received 7 days of direct observed administration of their ICS medication (DOICS). Those patients who had a history of poor adherence as measured by ICS refills of less than 50% experienced a greater reduction in FeNO following 7 days of DOICS compared to the group of adherent patients who had > 80% history of ICS refills (47 +/- 21% versus 79 +/- 26%) of baseline measurement (P < 0.003).</p> <p>Delgado-Corcoran et al investigated the relationship of FeNO to asthma control and medication adherence in 30 pediatric and adolescent patients that were followed periodically for 2.5 yrs using NHLBI Guidelines. FeNO levels correlated to improved asthma control and were significantly reduced in subjects with good compliance to steroids compared with patients with poor and moderate compliance. FEV1 levels were not substantially different between compliance groups. (Delgado-Corcoran 2004)</p>
72	National Paediatric Respiratory and Allergy Nurse Group (NPRANG)	Statement 3	<p>Investment in the community / gp surgeries to monitor medication adherence by ICS prescription collection and SABA requests could be cost effective. Alerts could trigger patient's being called in for reviews by GP's / Practice Nurses aiding treatment adherence and reducing emergency hospital attendances / admissions.</p> <p>Should specify that children should have 6 monthly reviews. If SABA prescriptions > 12 per year should have 6 monthly reviews.</p> <p>Need to increase resources to have dedicated trained pharmacists who can assess inhaler technique when medicine is dispensed. Improved systems of patient monitoring and communication to Primary care in pharmacies to alert patients who do not collect prescriptions. Utilise and direct patients to Asthma UK and UK Inhaler Group resources.</p>

ID	Stakeholder	Statement number	Comments ¹
			<p>HCP's need formal training to monitor asthma and keep up to date with different inhaler techniques – referral to resources such as UKIG/Asthma UK resource on technique will be helpful when available.</p> <p>Monitoring asthma control through regular reviews is important in highlighting any issues and reducing the risks associated with deteriorating asthma. It is important however if treatment is adjusted that further review is offered to ensure symptoms have improved – this follow up could potentially be a telephone consultation to reduce number of face to face appointments and time missed off school/work etc.</p>
73	NHS England	Statement 3	<p>This could be improved by including a check on inhaler technique. This important area is not mentioned elsewhere.</p>
74	NHS England Specialised Commissioning	Statement 3	<p>It might be sensible to add in that people with asthma attending for an 'asthma review have'... rather than 'every review' - as many would be upset turning up for review of a fractured ankle (and have a review by an orthopaedic surgeon) or pill check (by family planning clinician or practice nurse) etc.</p> <p>Depending on how control is measured, patients with poor control on maximal therapy should also be referred for further assessment.</p> <p>The QS is too imprecise and meaningless and easy to meet. Better QS would be: "People with asthma have their asthma control monitored at least annually as part of a structured review"</p> <p>This would also be in line with the recommendation from NRAD.</p> <p>The rationale statement should be changed from "Monitoring asthma control at every review will enable the identification of any difficulties with adherence, medication use or inhaler technique" to "Monitoring asthma control at every review is essential. Evidence of poorly controlled asthma should lead to an assessment of possible reasons including medication adherence, inhaler technique, triggers and co-morbidities".</p> <p>Asthma control may be normal when assessing at a single point and may not alert the clinician to poor asthma control between reviews. Other signs of poor asthma control include changes to peak flow, extra use of reliever medication and asthma exacerbations. Patients and clinicians should be encouraged to identify these features and address them. Clinicians should consider additional asthma reviews/assessment of control at other times (exacerbation, prescribing of reliever medications).</p> <p>Quality measures - Objective testing</p>

ID	Stakeholder	Statement number	Comments ¹
			<ul style="list-style-type: none"> - In addition to using evidence that spirometry or peak flow variability testing is available locally, it needs to be possible to verify the ability of clinicians in each setting to perform and interpret these tests appropriately. - Asthma reviews to monitor asthma control - The measure that indicates the proportion of asthma reviews that include monitoring of asthma control should specify that the monitoring should be through symptom questionnaires and objectives measures. - Short-acting beta agonist reliever inhaler use to identify at-risk patients - Most of the respiratory community recommend that we should monitor people more carefully who have been prescribed 6 short-acting beta agonist (SABA) reliever inhalers within the past 12 months. - The Department of Health policy paper "Community Pharmacy in 2016/17 and Beyond" contains a measure that "asthma patients dispensed more than 6 short-acting bronchodilator inhalers without any corticosteroid inhaler with a 6-month period are referred to an appropriate healthcare professional for an asthma review". - A NICE evidence review suggests that prescribing of 12 SABA reliever inhalers (as the quality standard does) is a clear marker of risk for death. The respiratory and prescribing communities suggest 6 SABA inhalers is a threshold for action.
75	Novartis Pharmaceuticals UK Ltd	Statement 3	<p>We suggest the addition of annual review to quality statement number 3. This is in line with recommendation 2 from the 'medical and professional care' section of the National Review of Asthma Deaths (NRAD) report which recommended that 'People with asthma should have a structured review by a healthcare professional with specialist training in asthma, at least annually.'</p> <p>Suggested wording as follows: People with asthma have their asthma control monitored at every review, at least annually.</p>
76	Primary Care Respiratory Society UK	Statement 3	<p>Statement 3 People with asthma have their asthma control monitored at every review. [2013, updated 2018]</p> <p>This is an important measure to retain. We are pleased to see ACQ and ACT mentioned here, though the omission of referencing RCP 3 questions alongside this is unhelpful. RCP 3 questions should be included here. It is not clear whether NICE is working in a joined up way so that the QOF review team and QS team are coordinating their simultaneous consultations. QOF focuses on RCP 3 questions as the primary measure, so lack of reference to this in the revised QS would create a disconnect with QOF. For the time being, we suggest that all three are mentioned in both to ensure alignment and lack of confusion. It may be that the evidence base is now stronger for ACQ/ACT than RCP 3 questions, and that concerns of copyright/intellectual property have been overcome.</p>

ID	Stakeholder	Statement number	Comments ¹
			<p>We applaud the reference to checking inhaler technique and inclusion of a specific quality measure (process), and are delighted to see that the overuse of short acting beta agonists (SABAs) highlighted by the National Review of Asthma Deaths (no more than 12 SABAs/yr) now features as a specific measure of control.</p> <p>Given the points made at comment 1 above, it is heartening that the value of PEF is recognised alongside spirometry in the context of monitoring asthma control. However we would again warn against the limited value of single measurements of airway obstruction in the monitoring context, particularly since patients are already on medication.</p>
77	Royal College of Physicians	Statement 3	<p>Comment 1: Our experts agree that this comment is sensible – mentions ACQ and ACT but not RCPx3 -though this is obviously still in QOF - we should not at this stage recommend ACT or ACQ because RCP is actually used now and a change will not be helpful. Mentions inhaler technique, and even checking no more than 12 SABAs/yr which is good. Add in here that an annual objective test is far from always helpful and certainly not currently feasible in primary care but reinforce a 2 week per diary for example as this supports self care behaviour and provides evidence that is more than a single point in time</p> <p>Comment 2: Agree, again will depend on which questionnaire used and how often the review takes place</p> <p>Our experts believe that QS3 is too vague and could be interpreted in a number of ways rendering it ineffective. Suggest rewording in line with NRAD:</p> <p>‘People with asthma have their asthma control monitored at least annually as part of a structured review’</p>
78	Royal Pharmaceutical Society	Statement 3	<p>Quality measure a Pharmacists regularly conduct Medicine Use Reviews (MURs), see point 4 above.</p>
79	Royal Pharmaceutical Society	Statement 3	<p>Outcome a People with asthma may receive inhalers other than by the standard prescription route, and as such data may not be complete and may miss where people with asthma have received more than 12 SABA inhalers within the past 12 months. Inhalers obtained by the emergency supply or PGD route or via out of hours services may not be recorded on the SCR, as pharmacists do not have write access. Permitting pharmacists write access to SCRs may allow the SCR to be a more complete record of what medicines have been supplied.</p>
80	Sanofi	Statement 3	<p>Sanofi supports Statement 3 - <i>People with asthma have their asthma control monitored at every review</i> – at its basic interpretation. However, we believe management of asthma would improve if the Quality Standard:</p> <ul style="list-style-type: none"> • Considered fractional exhaled nitric oxide (FeNO) as part of routine monitoring. FeNO testing is already in use by many physicians to monitor adherence to steroids.

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			<ul style="list-style-type: none"> • Apply a holistic approach to monitoring. Consider an asthma patient’s medical history, examination, investigation which includes monitoring for number of repeated exacerbations and poor lung function. A cumulative picture will denote ‘a failure to respond’. • Monitoring should occur every six months for asthma patients in general, but for severe patients this needs to be done more frequently with many of the most severe monitored monthly. Therefore please consider offering levels of monitoring dependent on severity.
81	Association of Respiratory Nurse Specialists (ARNS)	Statement 4	Where it is written under Healthcare Professionals “ensure a notification is sent to the person’s GP practice” it should be in a timely manner to notify the surgery so that the 48hrs has not been and gone.
82	Asthma UK	Statement 4	<p>Follow-ups by GPs and reviews after A&E attendance / hospital admittance for an asthma attack are extremely important in preventing future asthma attacks. The National Review of Asthma Deaths (NRAD) found that 10% of those who died from asthma did so within 28 days of being treated in hospital for an asthma attack.</p> <p>The rationale behind the quality statement should include “This follow up is also to ensure that the exacerbation is responding to treatment and that the patient has advice and support for what to do next.”</p> <p>Regarding the requirement of evidence of local arrangements to ensure follow up happens, there is no logical reason why this should not be extended to all care providers. It could be recommended for acute care providers to arrange the follow up appointment while the patient is with them.</p> <p>Following up on patients after an asthma attack is crucial:</p> <ul style="list-style-type: none"> - However, the local systems and structures are not always in place to ensure that the patient is followed up quickly after an attack. - This also means that the data on these patients may not be collected. <p><u>Comments on the quality measures</u></p> <ul style="list-style-type: none"> - Monitoring of reliever prescribing is very important but prescription records are not always a good indicator of whether a patient is taking their medication as prescribed. This measure does not guarantee that patients with excessive reliever use will be automatically called in for review as they should be. - The number of oral steroid courses should also be monitored. We emphasised the use of prescribing alerts to trigger a specialist review in our stakeholder submission. - Audits of patient health records are reactive instead of proactive. Live alerts for at-risk patients would pre-empt A&E attendances or hospital admissions by preventing asthma attacks.
83	AstraZeneca UK	Statement 4	(quality statement)

ID	Stakeholder	Statement number	Comments ¹
			<p>Suggested change: People who receive hospital treatment and/or urgent and emergency care treatment for an asthma attack are followed up by a specialist in asthma (nurse or doctor), and their current maintenance therapy and adherence are reviewed.</p> <p>Rationale: exacerbations requiring hospital assessment should be considered severe, and prompt a review of current treatment by a specialist. Patients who receive appropriate care and follow up following an exacerbation are more likely to remain controlled– the NRAD report identified that two-thirds of people hospitalised in the month before they died did not receive the necessary follow-up care.</p>
84	British Thoracic Society	Statement 4	Statement 4 has been unachievable in some areas due to pressures on PHC. It is a very reasonable target but will require additional resource if it is to be met - perhaps again through collaborative working in specialist community hubs which can take on a concentrated workload.
85	Circassia Plc	Statement 4	As stated above in comment 2, routine FeNO testing should be specifically detailed in this statement as a key positive contributor to the measured outcome: a) Hospital readmission rate for people with an asthma attack. It is suggested that FeNO testing be incorporated into routine post-exacerbation monitoring in primary care. The evidence for a positive outcome is given in the response to statement 2 above.
86	National Paediatric Respiratory and Allergy Nurse Group (NPRANG)	Statement 4	<p>This is currently unachievable as families regularly comment they are unable to get follow up appointments with the GP practice after hospital discharge. Additional resources would be required to make this a reality.</p> <p>GP surgeries find it difficult or virtually impossible to offer appointments to patients 48hrs post discharge from hospital. Investment needed so that Practice Asthma Nurses can review these patients or possibly a telephone clinic could be held initially. Reflecting on an attack will take more than a typical appt slot in general practice.</p>
87	NHS England	Statement 4	<p>This statement may be difficult to measure as timeframes for sharing information between primary and secondary care organisations can take longer than two working days. It would be more realistic to consider one week. This would offer opportunity for the patient to complete their course of treatment and consider future management of asthma.</p> <p>The statement could be improved by suggesting that the organisation treating a patient with acute episode should provide brief review of asthma management and explore possible reasons for the asthma attack so that necessary adjustments can be made in order to minimise the risk of further acute episode.</p>
88	NHS England Specialised Commissioning	Statement 4	<p>NHS England support the sentiment of this statement however:</p> <ul style="list-style-type: none"> a. unfortunately we often don't hear about admission / A&E attendance for several days - even weeks after discharge in many areas (perhaps good as may change systems) b. many patients are not told to book - or if they are don't bother (it allows for patient choice) c. the recommendation for this is consensus based and has been in BTS / SIGN for some time but perhaps is not logical. If a patient needs seeing within 48hr (two working days) from date of discharge it might be best done by

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			<p>the specialist team who are discharging in many cases. If they need a review in a week or so it may be more appropriate for a general appointment and more feasible to get them in with a nurse with interest or GP.</p> <p>Quality statement 4: 'follow up in a GP practice within 2 working days of discharge' is difficult to deliver. The purpose of this review needs to be better defined to avoid it becoming another tick box activity for already over-stretched GP practices and there are difficulties in availability of appointments.</p> <p>It is not a new recommendation so it is important to understand whether this is happening. Presumably this is useful if someone sent home from A&E but not post admission. (IBL)</p> <p>The rationale behind the quality statement should include "This follow up is also to ensure that the exacerbation is responding to treatment and that the patient has advice and support for what to do next."</p> <p>Regarding the requirement of evidence of local arrangements to ensure follow up happens, there is no logical reason why this should not be extended to all care providers. It could be recommended for acute care providers to arrange the follow up appointment while the patient is with them.</p> <p>Following up on patients after an asthma attack is crucial:</p> <ul style="list-style-type: none"> - However, the local systems and structures are not always in place to ensure that the patient is followed up quickly after an attack. - This also means that the data on these patients may not be collected. <p>Quality measures</p> <ul style="list-style-type: none"> - Monitoring of reliever prescribing is very important but prescription records are not always a good indicator of whether a patient is taking their medication as prescribed. This measure does not guarantee that patients with excessive reliever use will be automatically called in for review as they should be. - The number of oral steroid courses should also be monitored. The use of prescribing alerts to trigger a specialist review was highlighted in the stakeholder submission. - Audits of patient health records are reactive instead of proactive. Live alerts for at-risk patients would preempt A&E attendances or hospital admissions by preventing asthma attacks.
89	Primary Care Respiratory Society UK	Statement 4	<p>Statement 4 People who receive hospital treatment for an asthma attack are followed up by their GP practice within 2 working days of discharge. [2013, updated 2018]</p> <p>We support this intention wholeheartedly but believe that this should be an aspiration for local areas to work towards. Some areas are still using paper based systems between secondary and primary care, which make</p>

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			<p>this timeframe unachievable. Achieving a 2 working days system will take considerable effort both on the part of the acute sector and primary care to be workable. Furthermore, the pressure on GP practices for short term appointments and the lack of mandate for a QS mean that it is hard to see how this will actually take effect in practice.</p> <p>It would be helpful for NICE to recommend setting up a local incentive/QI scheme to create the pathway locally and get it embedded as standard practice – even if only for a year. NICE would do well to point out the barriers to achieving this important quality statement and to suggest ways of overcoming these barriers.</p> <p>In the short term it may be more achievable to suggest that 5 working days is acceptable because achievable.</p>
90	Royal College of Physicians	Statement 4	<p>Comment 1: Details of systems that need to be in place both from the hospital side and GP side to make this happen are laudable. But we know that with paper based systems still in existence in some places, and the pressure on GP practices for short term appointments and the lack of mandate for a QS – it is hard to see how this will actually take effect in practice. A staged approach would I think come across as more pragmatic. Practice could support most being seen within a week with greater priority for certain more complex cases to 2 days. Maybe adding digital review/ telephone etc as an option too</p> <p>Comment 2: Evidence is needed to show that this is the correct time period.</p>
91	Royal Pharmaceutical Society	Statement 4	<p>What the quality standard means for different audiences</p> <p>Healthcare professionals (such as doctors and nurses) – should also include pharmacists who work in GP practices, as, for example prescribers or advisors (they can assist with ensuring that the follow-up appointments are completed).</p>
92	Sanofi	Statement 4	<p>Although Sanofi supports the intent of Statement 4 – <i>People who receive hospital treatment for an asthma attack are followed up by their GP practice within 2 working days of discharge</i> – we feel this measure is unlikely to be achieved due to the likelihood of getting a GP appointment within 2 working days is low for most patients.</p> <p>We feel the statement should be better linked to the outcome of reducing readmission with 28 days or mortality from asthma. It is also important that at the appointment the healthcare professional conducts a thorough review into reasons for the asthma attack and assesses their current treatment and their personalised action plan to ensure lessons are learned.</p>
93	UK Inhaler Group	Statement 4	<p>Quality statement 4: <i>People who receive hospital treatment for an asthma attack are followed up by their GP practice within 2 working days of discharge.</i></p> <p>The detail underpinning this appears to be more about the process of follow up, which is important, but not about the content of a review, which is equally important.</p>

ID	Stakeholder	Statement number	Comments ¹
			<p>An inhaler technique check is essential after someone with asthma has received treatment in hospital. This should be stated as an integral part of a medication review following hospital treatment – their medication should be reviewed and their ability to use their medication should also be checked.</p> <p>Indeed the COPD discharge bundle includes an inhaler technique check as part of discharge https://www.brit-thoracic.org.uk/document-library/audit-and-quality-improvement/cap-and-copd-care-bundle-docs-2016/copd-discharge-care-bundle/ as does the asthma care bundle https://www.brit-thoracic.org.uk/document-library/audit-and-quality-improvement/asthma-care-bundle/care-bundle-statement/. The quality measure (b) from Quality statement 3 could be repeated here to reinforce this.</p>
94	Asthma UK	Statement 5	<p>Severe asthma in practice is normally not diagnosed outside of specialist care as people with severe asthma need specialist assessment.</p> <p>Severe asthma should be a diagnosis made in specialist care. Clinicians in primary care do not generally have access to objective tests and/or objective measures of adherence to treatment and so can only identify people who have difficult to control asthma (suspected severe asthma)</p> <p>In practice, referrals of people with asthma are often for the purposes of confirming a suspected severe asthma diagnosis.</p> <p>We have spoken to UK severe asthma clinicians, and comorbidities that complicate asthma make diagnosis of severe asthma very difficult.</p> <p>Primary care clinicians often lack the tools, expertise and time to accurately diagnose severe asthma</p> <p>Mandating a confirmation of diagnosis before referral may have the unintended consequence of reducing appropriate referrals to specialists when primary health care professionals cannot confirm the diagnosis.</p> <p>The phrase “people with severe asthma” should be changed to “people with suspected severe asthma” to reflect the fact that severe asthma can only be diagnosed in specialist care.</p> <p>Addressing adherence and comorbidities before referral should not be mandatory. These factors should not prevent a referral if the patient requires more specialist assessment. Not all primary care clinicians have the skills, experience or tools available to further improve outcomes and exclude severe asthma as a diagnosis</p> <p>While commissioners should ensure that services have sufficient capacity to meet demand, they should also create simple pathways, proactively identify suspected severe asthma for further review in primary care by someone experienced in managing asthma, and potentially referral to a severe asthma service.</p> <p>In addition to referral to specialists, people with suspected severe asthma should also receive advice on and support for their referral and the tests/treatment they may be considered for.</p>

ID	Stakeholder	Statement number	Comments ¹
95	AstraZeneca UK	Statement 5	(Quality measures, data source section B) Suggested change: Evidence of local arrangements, including referral criteria (e.g. >3 OCS courses within the previous 12 months, number of exacerbations or hospitalisations) to ensure that people with suspected severe asthma are referred to a specialist severe asthma service for assessment.
96	AstraZeneca UK	Statement 5	(Rationale) Suggested change: People with suspected severe asthma need specialist assessment to accurately diagnose their asthma, exclude alternative causes of persistent symptoms, confirm adherence to therapy and ensure they are receiving the most appropriate treatment. Specialist care can help to improve asthma control, prevent asthma attacks, consider alternative treatment options to long-term oral corticosteroids and reduce harmful dependence on oral corticosteroids.
97	Boston Scientific	Statement 5	<p><u>Rationale</u></p> <p><i>“Specialist care can help to improve asthma control, prevent asthma attacks and reduce harmful long-term dependence on oral corticosteroids”.</i></p> <p>Since severe asthma is a life-threatening disease with significant negative impact on quality of life, we would like NICE to highlight how crucial it is for clinicians to provide more guidance on the disease treatment options. Patients should ideally be informed about and offered all therapies that have proven increasing health benefits. By therapy we mean not just pharmacological treatments but also non-pharmacological treatments (for instance therapies delivered through the use of medical devices). Healthcare professionals specializing in asthma have a fundamental role in identifying which treatment would work best at a specific point of the patient pathway, and identifying patient sub-groups proven to respond to non-pharmacological therapies, and we would ask that NICE highlight this role and the evidence available to help with this role.</p> <p>We would like NICE to consider some evidence showing the decrease in the use of corticosteroids after bronchial thermoplasty treatment and subsequently reinforcing the existence of non-pharmacological options for certain sub groups of patients:</p> <ul style="list-style-type: none"> • Chupp G, Laviolette M, Cohn L, et al. Long-term outcomes of bronchial thermoplasty in subjects with severe asthma: a comparison of 3-year follow-up results from two prospective multicentre studies. <i>Eur Respir J</i> 2017; 50: 1700017 [https://doi.org/10.1183/13993003.00017-2017]. • Langton D, Sha J, Ing A, Fielding D, Wood E. Bronchial thermoplasty in severe asthma in Australia. <i>Intern Med J.</i> 2017 May;47(5):536-541. doi: 10.1111/imj.13372. • Pretolani M, Bergqvist A, Thabut G, Dombret MC, Knapp D, Hamidi F, Alavoine L, Taillé C, Chanez P, Erjefält JS, Aubier M. Effectiveness of bronchial thermoplasty in patients with severe refractory asthma:

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			<p>Clinical and histopathologic correlations. J Allergy Clin Immunol. 2017 Apr;139(4):1176-1185. doi: 10.1016/j.jaci.2016.08.009. Epub 2016 Sep 5.</p> <ul style="list-style-type: none"> • Chakir J, Haj-Salem I, Gras D, Joubert P, Beaudoin ÈL, Biardel S, Lampron N, Martel S, Chanez P, Boulet LP, Laviolette M. Effects of Bronchial Thermoplasty on Airway Smooth Muscle and Collagen Deposition in Asthma. Ann Am Thorac Soc. 2015 Nov;12(11):1612-8. doi: 10.1513/AnnalsATS.201504-208OC. • Salem IH, Boulet LP, Biardel S, Lampron N, Martel S, Laviolette M, Chakir J. Long-Term Effects of Bronchial Thermoplasty on Airway Smooth Muscle and Reticular Basement Membrane Thickness in Severe Asthma. Ann Am Thorac Soc. 2016 Aug;13(8):1426-8. doi: 10.1513/AnnalsATS.201603-182LE. • Bicknell S, Chaudhuri R, Lee N, Shepherd M, Spears M, Pitman N, Cameron E, Cowan D, Nixon J, Thompson J, McSharry C, Thomson NC. Effectiveness of bronchial thermoplasty in severe asthma in 'real life' patients compared with those recruited to clinical trials in the same centre. Ther Adv Respir Dis. 2015 Dec;9(6):267-71. doi: 10.1177/1753465815601332. Epub 2015 Aug 24. • David Langton, Joy Sha, Alvin Ing, David Fielding, Francis Thien and Virginia Plummer. Bronchial thermoplasty: activations predict response. Respiratory Research 2017 18:134 https://doi.org/10.1186/s12931-017-0617-7 • N. Facciolo, A. Di Stefano, V. Pietrini, C. Galeone, F. Bellanova, F. Menzella, N. Scichilone, R. Piro, G. L. Bajocchi, B. Balbi, L. Agostini, P. P. Salsi, D. Formisano and M. Lusuardi. Nerve ablation after bronchial thermoplasty and sustained improvement in severe asthma. BMC Pulmonary Medicine BMC series – open, inclusive and trusted 2018 18:29 https://doi.org/10.1186/s12890-017-0554-8 <p>We would ask NICE to include non-pharmacological treatment as an alternative treatment for the management of severe asthma and difficult to control asthma.</p>
98	Boston Scientific	Statement 5	<p><i>“Definitions of terms used in the quality statement – Severe Asthma”.</i></p> <p>Alternative treatments are available today for people suffering severe asthma or difficult to control severe asthma. These treatments vary from medications, biologics, corticosteroids and to Bronchial Thermoplasty. We would ask that NICE highlight the big variation in the severity of asthma between patients, and to highlight that those on the more severe end of the spectrum can experience many limitations in their life, and require the level of treatment to be tailored and appropriate for the patient's level of asthma severity.</p>

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			<p>We would ask NICE to consider differentiating severe asthma from difficult to control severe asthma in two different quality statements. We believe this differentiation may help providing more clear guidance on the management of these group of patients who have different needs.</p> <p>In addition, we ask NICE to consider differentiating the definition of severe asthma and difficult to control severe asthma as follows (the definitions are based on the International ERS/ATS guidelines from 2014):</p> <p>Severe asthma: When a diagnosis of asthma is confirmed and comorbidities have been addressed, severe asthma is defined as asthma that needs treatment with guidelines-suggested medications for steps 4 to 5 in the Global Initiative for Asthma (GINA) guideline (a high-dose inhaled corticosteroid [ICS] with a long-acting beta 2-agonist [LABA] or leukotriene modifier or theophylline) for the previous year or systemic corticosteroids for 6 months or more of the previous year to prevent it from becoming 'uncontrolled' (Blaiss SM et al., 2017).</p> <p>Difficult to control severe asthma Controlled asthma that worsens on tapering of high doses of ICS or systemic corticosteroids (or additional biologics) or that remains 'uncontrolled' despite this therapy. In particular uncontrolled asthma is defined as at least one of the following:</p> <ul style="list-style-type: none"> • Non- respondent to current treatment (biologics, medications) • Poor symptom control: Asthma Control Questionnaire consistently more than 1.5 or Asthma Control Test less than 20 • Frequent severe exacerbations: 2 or more bursts of systemic corticosteroids (more than 3 days each) in the previous year • Serious exacerbations: at least 1 hospitalisation, ICU stay or mechanical ventilation in the previous year • Airflow limitation: after appropriate bronchodilator withhold FEV1 less than 80% predicted (in the face of reduced FEV1/FVC defined as less than the lower limit of normal) (Blaiss SM et al., 2017).
99	British Thoracic Society	Statement 5	The final statement is very clear.
100	Circassia Plc	Statement 5	<p>The outcomes of this statement are listed as: a) Rate of hospital attendance or admission for an asthma attack. b) Number of people with asthma who have 3 or more courses of high-dose oral corticosteroids per year.</p> <p>Circassia welcomes this quality statement but evidence suggests that through routine FeNO testing, both outcomes could be improved in a primary care setting. The evidence for reducing asthma attacks by incorporation FeNO testing in routine practice is given in comment 2 above.</p>

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			<p>Routine FeNO testing is also critical in optimising the dose of oral corticosteroids (objective b). Patients respond to various asthma treatments differently depending on their underlying disease characteristics. While the majority of patients with asthma demonstrate a Th2 phenotype and do respond to corticosteroid treatment, a significant portion of patients demonstrate phenotypes not characteristic of Th2 inflammation and thus will respond less. It has been observed that up to 75% of steroid-naïve patients have primarily Th2 driven asthma and respond significantly to ICSs (Bradding 2008). Current national asthma guidelines recommend periodic clinical assessment of patients and adjustment of medications by either stepping-up or -down therapy (AHRQ 2017, BTS-SIGN 2016).</p> <p>Several outcomes based studies favourably comparing FeNO to conventional therapeutic monitoring techniques have been published: Anderson (Annals Allergy Asthma Immunol 2016) Use of FeNO for dosing of ICS more accurate than FEV1 Cowan (JACI 2015) FeNO useful for ICS dosing Attanasi (Arch Med Sci 2016) Asthma control (ACT) correlates to FeNO Malinovsky (JACI 2016) Monitoring FeNO related to measures of asthma control</p> <p>A recent multi-centre study including 214 patients in UK primary care clinics showed a significant interaction between baseline FENO and treatment group for every 10 ppb increase in baseline FENO, with the change in ACQ7 greater in the inhaled corticosteroids group than in the placebo group. These results led to the conclusion that FENO measurement is an easy and non-invasive tool to use in clinical practice in patients with nonspecific respiratory symptoms to predict response to inhaled corticosteroids (Price 2017).</p>
101	National Paediatric Respiratory and Allergy Nurse Group (NPRANG)	Statement 5	Children with difficult to control asthma, severe asthma or where the diagnosis is in question should be referred to an appropriate specialist service for further management.
102	NHS England Specialised Commissioning	Statement 5	<p>From a generalist / A&E / paramedic perspective people may not be aware what severe asthma is (just one attack) and if they did many clinicians would not know where there local specialist service for severe asthma was. (This is not clear in the documentation). Does this also highlight that if seen in a secondary care environment this referral would be expected (the statement sounds good but I worry if people have the same understanding of severe asthma and act on it). (SH)</p> <p>There is currently no agreed number of steroid courses to define poor asthma control, but ERS/ATS guidance suggests 2 rather than 3 courses.</p> <p>Depending on how control is measured, patients with poor control on maximal therapy should also be referred for further assessment.</p>

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			<p>QS5: NICE have suggested using the ERS/ATS definition of severe asthma in line with NHSE specification for adult specialised respiratory services for severe asthma. Consideration should be given to children and adolescents.</p> <p>There is broad agreement with the ERS/ATS definition of severe asthma, confirming that diagnosis is often done by a severe asthma centre, who have access to a greater range of assessments and expertise however referring only those with a diagnosis of severe asthma according to ERS/ATS will exclude many who would benefit from assessment for a specialist team. This is particularly the case for children and young people where issues such as safeguarding may have a significant impact.</p> <p>Qu 5. What definition for children? Clarification is needed if GP referral to general paediatrician counts or whether this refers to referral from secondary care to tertiary respiratory specialist.</p> <p>Severe asthma in practice is normally not diagnosed outside of specialist care as people with severe asthma need specialist assessment.</p> <p>Severe asthma should be a diagnosis made in specialist care. Clinicians in primary care do not generally have access to objective tests and/or objective measures of adherence to treatment and so can only identify people who have difficult to control asthma (suspected severe asthma)</p> <ul style="list-style-type: none"> - In practice, referrals of people with asthma are often for the purposes of confirming a suspected severe asthma diagnosis. - Comorbidities that complicate asthma make diagnosis of severe asthma very difficult. - Primary care clinicians often lack the tools, expertise and time to accurately diagnose severe asthma - Mandating a confirmation of diagnosis before referral may have the unintended consequence of reducing appropriate referrals to specialists when primary health care professionals cannot confirm the diagnosis. - The phrase “people with severe asthma” should be changed to “people with suspected severe asthma” to reflect the fact that severe asthma can only be diagnosed in specialist care. - Addressing adherence and comorbidities before referral should not be mandatory. These factors should not prevent a referral if the patient requires more specialist assessment. Not all primary care clinicians have the skills, experience or tools available to further improve outcomes and exclude severe asthma as a diagnosis - While commissioners should ensure that services have sufficient capacity to meet demand, they should also create simple pathways, proactively identify suspected severe asthma for further review in primary care by someone experienced in managing asthma, and potentially referral to a severe asthma service.

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			- In addition to referral to specialists, people with suspected severe asthma should also receive advice on and support for their referral and the tests/treatment they may be considered for.
103	Primary Care Respiratory Society UK	Statement 5	<p>Statement 5 People with severe asthma are referred to a specialist severe asthma service for assessment. [2013, updated 2018]</p> <p>It is important that this QS features here as this group is under-provided for by specialised severe asthma services. So this needs attention due to inadequate capacity currently.</p>
104	Royal College of Physicians	Statement 5	<p>Comment 1: They use GINA/ERS/ATS for definition of severe asthma - NICE did not cover it. Why not BTS/SIGN. There may be capacity issues in secondary care depending on definition. Our experts question whether likely burden and ability of specialist asthma services to manage it has been modelled.</p> <p>Comment 2: Our experts question whether there is a resource to see these patients many of whom just do not take their medication, and whether there should there be a checklist first to exclude this group.</p>
105	Sanofi	Statement 5	Sanofi supports Statement 5 – <i>People with severe asthma are referred to a specialist severe asthma service for assessment</i> – but would encourage greater clarity on what is defined as severe asthma. There is currently an inconsistency in the document on numbers of courses of high-dose oral corticosteroids between the definition (2 or more) and the listed outcome (3 or more). We believe the outcome for this statement should use the definition of severe asthma that is when a patient has had 1 or more courses of high-dose oral corticosteroids per year.
106	Sanofi	Statement 5	The current goal is a reduction in steroid use, i.e. targeting GINA level 5 patients. In our experience in speaking to healthcare professionals, the ultimate goal is to get treatment options in place that remove need for oral corticosteroids (OCS) altogether. If we are able to prevent patients going on OCS, starting at GINA step 4, GINA guidelines have put biologics at step 5a, this guideline should be considered in-light of OCS sparing treatments.
107	Association of Respiratory Nurse Specialists (ARNS)	Statement 5 – Question 5	This is reasonable but will potentially need further resources to be able to identify these patients.
108	National Paediatric Respiratory and Allergy Nurse Group (NPRANG)	Statement 5 – Question 5	<p>Clarification is needed regarding difficult to treat asthma and severe asthma and whether they are perceived to be the same. Need to distinguish between ‘severe asthma’ and ‘difficult to control asthma’ and patients who do not adhere to treatment.</p> <p>Inappropriate to generalise adult criteria to the paediatric population as we know that there are differences. There should be separate specified criteria for what constitutes as a paediatric difficult asthma service including when paediatric patients with a possible “difficult to treat” or “severe asthma” are referred</p> <p>Patients could be identified by the level of treatment that they are receiving. Paediatric patients should be referred to a specialist centre if failing to respond to step 4/5 treatment.</p>

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			<p>Documentation of any objective measurements, adherence checks and inhaler technique should be done prior to referral to a specialist centre to ensure true severe asthma. Should be available via electronic documentation.</p> <p>Resources need to be available to fund the treatments and interventions needed at this level.</p>
109	Primary Care Respiratory Society UK	Statement 5 - Question 5	<p>- We have suggested using the European Respiratory Society/American Thoracic Society definition of severe asthma in line with NHS England’s specification for adult specialised respiratory services for severe asthma. Is this reasonable and will it be possible to identify this population in practice?</p> <p>Yes – it is a reasonable definition, however the limitation will be availability of services for people with severe asthma. There is still a significant issue with all patients who need severe asthma services having access to them, so there is a larger group of people with severe asthma ie. meeting the criteria you have described, than those currently accessing specialised services for severe asthma.</p> <p>It should be possible to identify the individuals who meet the criteria for severe asthma on GP computer systems as all the criteria have codes on GP computers so are all searchable with the possible exception of the final one on airflow limitation, which is frequently badly performed and coded, and such patients might even be wrongly classified as COPD.</p>

Registered stakeholders who submitted comments at consultation

- Association of Respiratory Nurse Specialists (ARNS)
- Asthma UK
- AstraZeneca UK
- Boston Scientific
- British Thoracic Society
- Circassia Plc
- Department of Health and Social Care
- National Paediatric Respiratory and Allergy Nurse Group (NPRANG)
- NHS England
- Novartis Pharmaceuticals Ltd
- Primary Care Respiratory Society UK
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Physicians
- Royal Pharmaceutical Society
- Sanofi
- UK Inhaler Group