

Asthma Management

Consultation on draft scope Stakeholder comments table

15/04/2015-13/05/2015

ID	Type	Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
9	SH	Airsonett UK	General	General	"If non-pharmacological management of chronic asthma is excluded from the current terms of reference, what provision is there for the inclusion of new evidence concerning such therapies in the NICE guideline review and process to develop the management of asthma pathway at a later date before publication in 2017?"	Thank you for your comment. We acknowledge that non-pharmacological management is an important part of asthma care. However we consider this topic is well covered by existing guidance and therefore not a priority area for inclusion in this guideline, and moreover, many of the interventions are unlicensed. Please note we have clarified in the scope that the aspects of non-pharmacological management that will not be covered are those outside of self-management and breathing exercises (which will be covered).
8	SH	Airsonett UK	6-7	163-109	If NICE excludes non-pharmacological management of asthma (for example TLA, Airsonett) then there is a risk that such novel non-pharmacological therapies would be excluded from the updated NICE Asthma Management Pathway thereby potentially limiting patients' access to the full range of treatment options. TLA offers a novel non-pharmacological alternative to add-on therapies such as omalizumab and bronchial thermoplasty that is currently already included in the management pathway step 3: Difficult or severe asthma. We would like to highlight the NICE advice MIB 8 on page 6, row 148/149 concluded that the estimated cost for TLA use is £5.72 per day and the estimated cost of omalizumab, is £23 per day. In addition, the 2013/14 NHS Standard Contract For Respiratory: Severe Asthma (Adult) lists "To identify and remove aeroallergen and occupational triggers" as a core objective of the severe difficult to control asthma service. We believe that TLA will become an important option helping the specialist units to fulfil this objective.	Thank you for your comment. The production of a NICE guideline on Asthma Management will not prevent patients from accessing the non-pharmacological aspects of patient care that are already a part of current clinical practice. TLA is covered by NICE MIB8.

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6	SH	Airsonett UK	3	57	<p>The draft scope currently excludes non-pharmacological management of chronic asthma. We would suggest that NICE include this as allergen exposure (if sensitized) is an independent risk factor for asthma exacerbations^{1,2} and consequently minimization of allergen exposure should be important in the management of children and adults with uncontrolled allergic asthma. Domestic animal and mite allergens are potent inducers of airway inflammation and the related asthma symptoms in people with allergic asthma. Despite this, allergen avoidance, even as a secondary prevention strategy, is not recommended in general by the BTS/SIGN guidelines, due to the complexity and lack of proven cost effective clinical benefits of traditional methods.</p> <p>We would like to draw the committee's attention towards a novel methodology, using a filtered Temperature controlled Laminar Airflow (TLA, Airsonett) to remove allergens and other airborne particles from the patients' breathing zone (nose and mouth) during sleep. This convenient, non-invasive, non-pharmacological method is focussed on eliminating allergens from a more confined area, and thus much more targeted compared with traditional methods focussing on removing allergen from a relatively large environment (ie whole room, whole house). TLA has been shown to reduce the exposure to allergens in the breathing zone by 99% and to maintain this low exposure level for 8 hrs (one night's sleep)³. TLA is intended to be used as an add-on therapy for children and adults with severe persistent allergic asthma whose disease, despite high-intensity pharmacotherapy, remains poorly controlled. This includes patients who</p>	Thank you for your comment. As above.

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					<p>have reached BTS/SIGN Step 4 or above who would be considered for long-term oral steroids, omalizumab or bronchial thermoplasty. TLA has, in randomized controlled clinical trials, been shown to reduce inflammation and provide clinically relevant improvements in the main outcomes listed in section 1.6. In the intended patient population, the addition of TLA has been shown to provide statistical and clinically significant improvements in health-related quality of life and asthma control without any treatment related adverse events.^{5,6,7} In addition, there are emerging evidence supporting the effect also on reducing exacerbations and related healthcare utilisation from studies both in a real-life setting as well as on-going controlled trials.^{7,8,9}</p> <p>Regarding cost, NICE recently concluded in their advice MIB8, referred to on page 6 line 148/149 of the briefing document, that the estimated cost for TLA use is £5.72 per day.⁷ The estimated cost of an add-on therapy currently used in NHS practice, omalizumab, is £23 per day.⁷ Results from other analyses suggest that TLA is a cost-effective add-on therapy and if used as a replacement of the current treatment standard (omalizumab) in patients with poorly controlled severe allergic asthma TLA it may be budget beneficial.¹⁰</p> <p>In summary, the addition of TLA offers a novel approach in patients with poorly controlled allergic asthma despite BTS/SIGN Step 4 therapy. We would suggest that NICE include the evaluation of this new intervention in the scope, as it has been calculated that 50% of the asthma expenditure is</p>	

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					<p>spent on the 5% of patients with the most severe asthma.¹¹</p> <p><u>References (incl links):</u></p> <ol style="list-style-type: none"> 1. Global Strategy for Asthma Management and Prevention, Global Initiative for Asthma (GINA) 2015. http://www.ginasthma.org 2. Murray CS, et al. Thorax. 2006;61(5):376-382. 3. Gore RB, et al. Indoor Air 2015;25:3644 4. Sigsgaard, T et al. Allergy 2010;65 (Suppl. 92):735 5. Pedroletti C, et al. Respir Med 2009;103:1313-9 6. Boyle RJ, et al. Thorax 2012;67:215-221 7. NICE Medtech Innovation Briefing 8. Available at http://www.nice.org.uk/advice/mib8 8. Schauer U and Hamelmann E. Clinical and Translational Allergy 2015;5(Suppl 2):O5 9. The LASER Trial. Availble at http://lasertrial.co.uk/ 10. Persson U and Hofmarcher T. Health Economic Analysis of Airsonett in the Swedish health care system. Summary of IHE's consulting report 2013. 11. Serra-Battles J, et al. Eur Respir J 1998; 12:1322-6. 	
121	SH	Asthma UK	General	General	<p>We welcome NICE's continued work to improve the quality of asthma care through clinical guidelines and standards, and welcome the opportunity this guideline will present to improve the lives of people with asthma.</p> <p>When developing an asthma management guideline, it is important to produce recommendations that ensure people with asthma receive the knowledge, skills and support they need to manage their condition outside</p>	<p>Thank you for your comment.</p> <p>Patient information and support will be covered by the guideline.</p>

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					<p>of the clinical environment in their day to day lives, to prevent potentially life-threatening asthma attacks.</p> <p>It must also be practical, implementable and easy to use for health care professionals: it should be developed in a way which considers how it will best complement existing guidelines (which include other NICE guidelines and non-NICE guidelines) and limit any potential confusion for healthcare professionals.</p> <p>Some clinicians have raised their concerns with us that the existence of the BTS/SIGN guidelines on asthma (2014) may not be taken into account during the development of this guideline and that failing to do so, in line with the agreed concordat (2013), could impact negatively on care (for example, if there are discrepancies between the two it could mean that people with asthma may receive inconsistent care). It would therefore be helpful for the scope to articulate the rationale for developing this guideline and to describe how it aims to improve care within the context of other existing guidelines including the NICE Diagnosis and Monitoring Guideline and the BTS/SIGN guideline (2014). For example, the new NICE guideline on Monitoring will include key aspects of management (inhaler technique, control assessment etc), and needs to be considered in conjunction with management.</p>	<p>The rationale for any NICE recommendation will be clearly explained in the 'linking evidence to recommendations' section (LETR).</p> <p>These points will be captured in the introduction to the full guideline and NICE version.</p>
122	SH	Asthma UK	General	General	While we welcome the focus on effectiveness of pharmacological treatment as something which we know is very important to people with asthma, both pharmacological and self-management aspects of care must not be treated	Thank you for your comment. This will be captured in the guideline recommendations.

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					<p>as mutually exclusive aspects of care, despite their need for separate questions. People with asthma can only take their medicines effectively if they have the knowledge, skills and tools to understand how to self-manage their asthma, and the importance of this should not be overlooked by covering the two aspects in separate sections. The evidence on self-management in asthma is extensive and it has been suggested that the strongest evidence of self-management reducing healthcare utilisation can be found in respiratory disorders (Panagioti M, et al, 2014).</p> <p>How this is delivered together (through dynamic and innovative deliver of an asthma review) should be covered within the scope, in addition to how it relates to adherence (especially around oral steroids).</p>	
123	SH	Asthma UK	General	General	Greater emphasis should be placed on the significance of the findings of National Review of Asthma Deaths (RCP, 2014). Where it is referenced in the 'Current Practice' section, more than just the pharmacological findings should be referenced as there were many other recommendations which focused on patient perceptions and risk, in addition to self-management and the organisation of care.	Thank you for your comment. Thank you we have made this change.
124	SH	Asthma UK	General	General	The evidence is strong on 'written' asthma action plans in comparison to verbal (Pinnock, H. et al, 2014) and, as such, all reference to asthma action plans should include the word 'written'. It is important that healthcare professionals understand the difference between a written and verbal asthma action plan.	Thank you for your comment. We have not made this change as action plans with a pictorial component may also be effective and before doing a formal review of the evidence we are unable to confine the scope to 'written' action plans.
125	SH	Asthma	Gen	General	We think it is important that the guidelines are meaningful for people with	Thank you for your comment. We have

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		UK	eral		asthma and would urge the term 'exacerbation' to be replaced with 'attack'. This is consistent with existing clinical guidelines, patient information and common language.	made this change.
152	SH	Asthma UK	Equality Impact Assessment	General	In the equality impact assessment, consideration should be made with regards to written asthma action plans and patient information for those people who have sight, reading or language barriers.	Thank you for your comment. We have made this change. Please see above regarding 'written' action plans.
129	SH	Asthma UK	2-3	47-55	While we were pleased to note that smoking has been removed from the exclusions, there is still no mention of this within the document itself. We know the huge impact that smoking has on the management of asthma both in terms of the literature (Polosa & Thomson, 2012) and the National Review of Asthma Deaths (RCP, 2014). Either specific questions should be created on this or (if to be considered in light of each question anyway) it should be noted in the 'Areas that will be covered' section more broadly.	Thank you for your comment. We entirely agree that smoking prevention is of critical importance. However, we would suggest that undertaking an evidence review, which is an intrinsic part of NICE methodology, is unnecessary in this instance, since the evidence for adverse effects of smoking is overwhelming and widely known. The recommendations will take into account differences in the management of people with asthma who smoke where evidence on this exists.
131	SH	Asthma	2/3	54-55	We welcome the focus on stratification of care according to risk of attack	Thank you for your comment.

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		UK			and self-management.	
135	SH	Asthma UK	3/4	73-105	<p>Because the scope suggests that people with more difficult and severe forms of asthma are included, it is important that the questions in this section reflect the different needs of this population group in terms of escalation of treatment and adherence challenges.</p> <p>Also, the scope should be clearer in how the committee will form pharmacological recommendations (will it consider medication types, brands, or general approach for all severity levels?), and how it will be updated to remain accurate. With evolving treatments on the market it is important that people with asthma are not prevented from accessing certain treatments simply because they are not referenced in the guideline.</p>	<p>Thank you for your comment. Guidance on the management of people with severe, difficult to control asthma will be given if pertinent evidence is found for this population.</p> <p>The pharmacological agents covered will be decided by the GDG during development.</p>
126	SH	Asthma UK	1	10	It would be helpful if it was specified when the NICE quality standard for asthma will be updated using this guideline and how that will work in practice. Will the sections not covered by NICE be based on BTS/SIGN guidelines (2014), as is currently the case?	<p>Thank you for your comment. The specific date that the NICE quality standard on asthma will be updated using this new clinical guideline is not yet known, hence the quality standard on asthma is not listed under the subheading 'NICE guidance in development that is closely related to this guideline' but rather 'NICE guidance that will be updated by this guideline'.</p> <p>Regarding the second point, yes that is correct.</p>
127	SH	Asthma	2	34-41	We welcome the groups that will be covered, although it may be helpful to	Thank you for your comment. These

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		UK			also cover 'those in transition': essentially young people who may be treated in paediatric and / or adult services. This is especially important if the subgroups are divided at age 16. Adjusted age divisions are welcome as we know that different age groups may require different pharmacological and non-pharmacological approaches. There should also be flexibility in applying these based on the individual: for example, some children may prefer a more adult written asthma action plan while others may prefer a less mature version.	considerations (transitioning from paediatric to adult services) will be captured in the guideline recommendations if evidence specific to asthma is found. Please also see forthcoming general NICE guideline on transitioning to adult care.
128	SH	Asthma UK	2	43-45	It is positive to see the range of settings covered: it is important to consider the guideline in light of the whole patient journey from the perspective of someone with asthma, rather than from the perspective of services. The asthma review which is already incentivised by the Quality Outcomes Framework scheme has the potential to be the cornerstone of good asthma care if provided effectively and dynamically. As such it should have a role within this guideline. A definition of 'chronic' should also be provided – does this refer to chronic as opposed to acute, or a clinical diagnosis of 'chronic asthma'?	Thank you for your comment. All NICE clinical guidelines are patient-centred; however, the final recommendations cannot cover the whole patient care pathway in a single guideline as there is a need to prioritise areas for inclusion. The population will be defined by the GDG.
130	SH	Asthma UK	2	48 & General	It should also consider the benefits associated with achieving optimal control on the lowest therapy dose: this is important in terms of side effects and the development of co-morbidities in addition to potential adherence challenges, and this should also be considered in the cost analysis.	Thank you for your comment. The guideline considers both clinical and cost-effectiveness. The committee will define outcomes related to the side effects of interventions. Step down of treatment will be covered by

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						the question on page 4, line 90 of the consultation version of the scope.
132	SH	Asthma UK	3	58	While Omalizumab is noted as excluded, it should be referenced within the guideline itself (for example, being signposted to the other relevant guideline where it does feature) to ensure completeness.	Thank you for your comment. The recommendations will make references to related NICE guidance as appropriate, and the NICE pathway for asthma will include treatments such as Omalizumab which are covered by NICE Technology Appraisals.
133	SH	Asthma UK	3	68	Please elaborate what PSS means.	Thank you for your comment. 'Personal social services' has been added to the scope for clarification.
134	SH	Asthma UK	3	69	How exactly will the committee ensure they balance the economic, clinical and patient perspectives appropriately when making their recommendations? What process will be used? It would be helpful to compare the cost effectiveness for different interventions, for different patients, and at different points in the patient pathway. These costs should take into consideration the implementation to ensure that this is not a barrier to the guidelines being implemented and people with asthma gaining access. Also, analysis should be stratified according to severity as people with severe asthma will have much different economic impact than those with mild.	Thank you for your comment. Development of all clinical guidelines follow standard NICE methodology where a guideline committee made up of multidisciplinary healthcare professionals and patient members consider the clinical and cost-effectiveness evidence to inform decision-making on recommendations. NICE clinical guidelines recommend the most clinically and cost effective strategies based on the best available evidence; addressing implementation challenges is not part of the committee's remit and are tackled by other mechanisms.

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						As above, the management of severe, difficult to treat asthma is not an area of priority for inclusion.
136	SH	Asthma UK	3	74-77	<p>We welcome the focus on people on 'step 1' treatment as the National Review of Asthma Deaths (2014) showed that 58% of those who died had mild or moderate asthma.</p> <p>However, the definition of 'treatment-naïve' should be further clarified. Should these questions include references to short acting reliever inhalers? This question should also clarify whether it is referring to those who are 'not currently taking regular preventative treatment' because they are non-adherent or because it has not been prescribed.</p> <p>This question must also take into consideration the impact on all health outcomes, not just asthma outcomes – for example, it may be more clinically and cost effective to put patients on a high dose of oral steroids to improve their asthma control, but the potential for side effects to cause development of co-morbidities and the impact on the social and mental health of the patient must also be considered.</p>	<p>Thank you for your comment.</p> <p>We have clarified in the scope that the population in the review question on treatment-naïve is 'people with asthma who are not taking treatment for asthma'.</p> <p>The pharmacological agents under consideration will be decided by the committee during development.</p> <p>Regarding the last point, quality of life is one of the main outcome measures. The committee will define outcomes related to the side effects of interventions.</p>
137	SH	Asthma UK	3	74-83	<p>This section should also include reference to symptom severity and/or extent of poor control with regards to the sequence (for example, as recommending what works, it should also cover patients who do not respond well at each stage of treatment).</p>	<p>Thank you for your comment. This will be captured in the recommendations.</p>

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					<p>These questions should also reflect the suggestion made in the box above.</p> <p>It would also be helpful to refer to the best methods of control in this section (outlined in existing guidelines if not directly addressed here).</p>	
138	SH	Asthma UK	4	85-86	<p>It may be helpful to separate this question into two reflecting a) intentional non-adherence and b) unintentional non-adherence as the interventions required to address these two types of poor adherence could be quite different (Horne, R, 2006).</p> <p>Some potential interventions include: behaviour change programs, training for healthcare professionals and people with asthma, patient information, inhaler technique training and medicines reviews with the GP, nurse, or community pharmacist (for example, MURs).</p> <p>An additional question should also be asked: 'What are the clinical features (symptoms and/or objective measurements) which indicate that adherence is poor?'</p>	<p>Thank you for your comment. We agree that strategies to address non-adherence will be different if the non-adherence is unintentional, and if possible we will reflect this in recommendations. However, in terms of the search question, there is no value in separating the two.</p> <p>Thank you for these suggestions which will be considered by the committee when devising the review protocol for this question.</p> <p>Regarding your last point, this is covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring.</p>
139	SH	Asthma UK	4	89-92	<p>This question should be amended (or supplemented with another question) to reflect the non-clinical features which indicate that an adjustment in treatment is appropriate. For example, when a patient does not want to adhere to their medicine because of the impact that side effects are having on their quality of life or because the treatment regime does not</p>	<p>Thank you for your comment. We are confused as to the 'non-clinical features' you are suggesting. The example you give (about the impact of side effects) is a clinical feature. Please note that the guideline will</p>

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					<p>complement the individual's lifestyle making adherence challenging. However, adherence should always be confirmed before treatment is adjusted.</p> <p>The question could read: 'After adherence has been confirmed, what are the clinical features (symptoms and/or objective measurements) and non-clinical features (patient request) which indicate that an adjustment in treatment is appropriate?'</p>	<p>make reference to the NICE guidance on medicines adherence and medicines optimisation.</p>
140	SH	Asthma UK	4	92-94	<p>This question is welcomed as it will help to inform the specialised commissioning service specification for severe difficult to control asthma in England, and aid other parts of the UK in establishing or confirming criteria for referral to similar services.</p> <p>However, the question seems to miss a portion of the patient pathway by neglecting to mention referral to secondary care. At present the question assumes that the services delivered in tertiary care are correct, uniform, and unavailable in primary or secondary care. The question should rather be based on when a patient should be referred for different levels of support when appropriate, and this would often include secondary care. What defines 'secondary' and 'tertiary' care should also be addressed as we know that there is currently variation across the UK with regards to which services are delivered where.</p> <p>For example, the question could be expanded to read: 'What are the indications for referral to secondary care (which should provide x, y, z</p>	<p>Thank you for your comment. After some debate we have removed the question on referral criteria to tertiary care for severe, difficult to treat asthma. There is no evidence base that we are aware of to inform recommendations, and priority has therefore been given to other questions.</p>

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					<p>services) for difficult to treat asthma?' and 'What are the indications for referral to tertiary care (including x, y, z services) for severe, treatment resistant asthma?'</p> <p>These questions could form an algorithm of who to refer where, when, to treat patients as close to home as often as possible (in line with NHS England's Five Year Forward View (NHSE, 2014) vision), but to ensure speedy referral to specialist centres when appropriate (as noted in the National Review of Asthma Deaths (RCP, 2014)). It may be that some patients should be referred directly to a tertiary centre from primary care and others can be treated closer to home.</p>	
141	SH	Asthma UK	4	95-98	<p>We very much welcome the consideration of risk stratification in the scope of this guideline. However, it is necessary to add another question on the best strategies for stratifying based on risk of attack, as it is difficult to review or recommend such an approach without understanding the effectiveness of different interventions and recommending which should be used (for example, a recent risk tool which has been developed based on the evidence (Blakey, 2011, 2012, Walker, 2014)). Another question would also be helpful to look at whether different care should be provided to different risk levels.</p> <p>The criticality of data systems linking to show hospitalisations will need to be considered within this section.</p>	Thank you for your comment. This is already covered by the review question ('exacerbation' has now been changed to 'attack').
142	SH	Asthma UK	4	99-103	<p>We very much welcome the focus on self-management and action plans as the evidence suggests that people who have a written asthma action plan</p>	Thank you for your comment.

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					<p>are four times less likely to be admitted to hospital for their asthma (Adams, et al., 2000).</p> <p>However, the overall title of this section should simply be entitled 'supported self-management' to cover the broader aspects of self-management that are vital to help people with asthma manage their symptoms (Taylor et al., 2014). A question should also be added: 'What are the most clinical and cost effective self-management strategies for people with asthma?'</p> <p>Reference should be made within the scope about the fact that self-management should underpin asthma management, and that effective pharmacological management can only occur when people with asthma are given the tools and skills they need to manage their asthma effectively when they are not in a clinical environment.</p> <p>Will management of occupational asthma also be covered here?</p>	<p>The title of this section has been changed to 'supported self-management'.</p> <p>This will be covered in the guideline itself, not in the scope.</p> <p>Occupational asthma is covered by virtue that asthma by any aetiology is covered.</p>
143	SH	Asthma UK	4	109	We were disappointed to see societal impact removed from the original proposed scope and think that this should be reinstated. Economic implications (in terms of impact of days lost from school, work, and disability payments etc) should also be considered.	Thank you for your comment. NICE clinical guidelines cost effectiveness analysis does not normally consider societal economic impact. This appeared in the workshop version of the scope in error.
144	SH	Asthma UK	4	112	We are very pleased to see attacks included as an outcome measure.	Thank you for your comment.
145	SH	Asthma UK	5	121	The Asthma Diagnosis and Monitoring Guideline should be included within this section. It is paramount that the two NICE guidelines work in	Thank you for your comment. Please see page 6 line 160 of the consultation version of

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					conjunction together (or that a separate implementation document could be created) to enable healthcare professionals to refer to a single guideline within, say, an asthma review, rather than referring to one on monitoring and one on management. The NICE COPD Quick Reference Guide is a good example of how this could be achieved.	the scope.
146	SH	Asthma UK	7	190	The Asthma Overview diagram is not very clear. It should show the management box and the diagnosis and monitoring box side by side rather than underneath, as the monitoring should inform the management which should occur when being reviewed.	Thank you for your comment. We will refer this issue to the NICE Pathways team.
147	SH	Asthma UK	8	208	Should read 'and minimise future risk'.	Thank you for your comment. We have made this change.
148	SH	Asthma UK	8	212-215	This sentence should include reference to self-management and written asthma action plans, and that medicines should be 'tailored to the person's severity of illness and individual needs'.	Thank you for your comment. We have made this change. Please see above regarding 'written' action plans.
149	SH	Asthma UK	8	205-206	The word 'some' should be changed to 'significant' regarding evidence on ethnicity affecting asthma control.	Thank you for your comment. Without doing a formal systematic review of this evidence we cannot give any indication as to its significance.
150	SH	Asthma UK	8	223-224	This sentence should be reviewed: while the NRAD findings did imply a failure to step up as appropriate, they also indicated a failure to address adherence, and to review patients as necessary. It should read something like: 'implying a failure to address poor adherence and control'.	Thank you for your comment. We have made this change.
151	SH	Asthma UK	8	229-232	This sentence should be reviewed as patients with poor control should not be referred to specialist care; rather, patients who have poor control despite	Thank you for your comment. We have made this change.

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					being on optimum therapy should be referred to specialist care.	
153	SH	AstroZeneca	General	General	AstraZeneca would like to thank NICE for the opportunity to submit comments regarding the Asthma Management clinical guideline draft scope.	Thank you for your comment.
154	SH	AstroZeneca	General	General	The clinical guideline needs to specifically define the following terminology since they are open to interpretation in this therapy area: <ul style="list-style-type: none"> - Adequate control - Loss of control - Exacerbation 	Thank you for your comment. This will be captured in the full guideline, and not in the scope.
155	SH	AstroZeneca	2	34	In order to reflect the typical age-groups recognised by regulatory bodies and therefore the licences of respiratory medicines, we would suggest the guidelines reflect this; this will ensure maximum alignment of guidelines with licences <ul style="list-style-type: none"> o 5 years and under o 6 to 11 years o 12 to 17 years o Adults (18 years and above) 	Thank you for your comment. Please see lines 38-41 of page 2 of the consultation version of the scope. The over-riding principle is that the recommendations will be driven by the available evidence, which may or may not align with licences.
156	SH	AstroZeneca	3	59	AstraZeneca does not believe that "Comparison of drug-delivery devices (inhalers)" should be an "Area that will not be covered" in this clinical guideline. The clinical data used to assess the clinical effectiveness of pharmacological treatments cannot be reviewed in isolation of the mode of	Thank you for your comment. The guideline will review the clinical and cost-effectiveness evidence for different drug classes, but a comparison of the many different modes of drug-delivery is not a priority area for inclusion in this guideline. Comparison of

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					<p>delivery to the lungs (ie device) for it is a critical component in successful asthma treatment.</p> <p>Guidelines for management of both asthma and COPD where inhaled therapies are usually first line treatment place a strong emphasis on the patient's ability to use the chosen device further demonstrating the importance of device as an integral part of the decision making process for the selection of any inhaled therapy.</p>	<p>devices is confounded by differences in the contained agent and its dose and whatever such a comparison shows the emphasis will always be, as you point out, on ensuring that the individual patient is able to use the chosen device. We therefore do not think that a detailed comparison of the numerous available devices is an appropriate use of the resources available for this guideline. Please also note that as part of the review question on inhaler technique in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring, a literature search was undertaken for RCT evidence comparing the outcomes of checking inhaler technique vs. not checking and no relevant RCT evidence was found.</p>
157	SH	Astrozene ca	3	61	<p>AstraZeneca recommends that the "Management of acute asthma in primary care" should be included in this clinical guideline for it is a critical component of the asthma management and is usually part of personal asthma action plans.</p>	<p>Thank you for your comment. We acknowledge that the management of acute asthma is an important issue, however we feel this topic is covered well by existing guidance and therefore not a priority area for inclusion in this guideline. Regarding your point about acute asthma being part of personal asthma action plans, we have</p>

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						clarified in the scope that the guideline will not cover management of acute asthma by 'a healthcare professional' and therefore does not preclude self-management of acute asthma.
158	SH	Astrozene ca	3	73	<p>The publication of the National Review of Asthma Deaths in May 2014 highlighted the apparent over reliance of patients on their short acting bronchodilator and the under usage of their maintenance therapy.</p> <p>This raises important questions regarding how SABAs are positioned in asthma management guidelines and how patients perceive SABAs should be used.</p> <p>Any new asthma management guidelines should address this issue and ensure that SABAs are not positioned with patients as the "go to" solution for symptom relief when the goal is to control the underlying inflammation for which an ICS is required.</p>	Thank you for your comment. This will be addressed in the draft review questions on page 3 lines 75-83 of the consultation version of the scope.
159	SH	Astrozene ca	3	74	<p>AstraZeneca recommend that the first key issue should be split according to the following to ensure all patients are clearly covered in this clinical guideline</p> <ul style="list-style-type: none"> - newly diagnosed asthmatics on no pharmacological therapy - preventative treatment naive asthmatics (or asthma patients treated only with a short acting beta agonist) 	Thank you for your comment. We have clarified in the scope that the population in the review question on treatment-naïve is 'people with asthma who are not taking treatment for asthma'.

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160	SH	Astrozene ca	3	75	Replace "drug" with "drug class" to ensure the appropriate treatment comparisons are conducted.	Thank you for your comment. We have made this change.
161	SH	Astrozene ca	3	80	"Treatment regimens" should be factored into the assessment of clinically and cost effective treatment options for this patient group, not just the addition of new medicines. For example as per the BTS/SIGN guidelines <ul style="list-style-type: none"> - Symbicort Single Maintenance and Reliever Therapy (SMART) treatment regimen - The stepping up and down of maintenance therapy 	Thank you for your comment. SMART and MART will be covered.
162	SH	Astrozene ca	4	87	Patient choice of inhaler device and familiarity of technique is a critical component of adherence to therapy. Branded prescribing for dry powder inhalers in this therapy area helps ensure device continuity and helps negate potential adherence issues and patient confusion.	Thank you for your suggestions which will be considered by the committee when devising review protocols.
163	SH	Astrozene ca	4	87	The Symbicort SMART treatment regimen is an appropriate regimen to consider as it provides both maintenance and relief of symptoms in a single inhaler.	Thank you for your suggestions which will be considered by the committee when devising review protocols.
164	SH	Astrozene ca	4	102	This key issue does not provide the clarity required, and there needs to be acknowledgment of seeking medical attention when control is "lost" Therefore in addition to the point made in n comment #1 regarding definition of loss of control, AstraZeneca would also like the following to be addressed: What degree of pharmacological treatment should patients self manage before seeking medical attention.	Thank you for your comment. This will be captured by the recommendations.
237	SH	Barts Health	3	59	Comment on importance of correct device delivery system; mandatory consultation by pharmacist or prescriber when newly initiated.	Thank you for your comment. We do not propose to include a comparison of drug-

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		NHS Trust				delivery devices as an area for prioritisation.
238	SH	Barts Health NHS Trust	3	55	A locally agreed self-management plan, consistent across primary and secondary care interface	Thank you for your comment.
239	SH	Barts Health NHS Trust	3	75	Review the guidance of a short acting beta agonist alone at STEP 1. Preventer therapy (minimal BDP) should be added at this step as we would not be treating the cause of the asthma, only providing symptomatic relief; poor prognosis.	Thank you for your comment. The question on which therapy to start in treatment-naïve people will include the option of using beta-agonist only, and compare this to use of preventers.
244	SH	Barts Health NHS Trust	3	59	A statement to include the use of a spacer/aerochamber device with MDIs is recommended, as we know these are the most poorly designed and patient's find most difficult to use. This will improve drug delivery, the impact here will be larger in comparison to use of DPIs.	Thank you for your comment. Comparison of delivery devices has not been prioritised as a primary question for the guideline, but if we find good evidence of differences related to use of spacers whilst reviewing the evidence around the pharmacological questions in the scope, we will consider making an appropriate recommendation.
245	SH	Barts Health NHS Trust	3	78	Guidance on how to step patient's corticosteroid doses down if well controlled, this will give clinicians some guidance on this well documented high dose of corticosteroid prescribing in patients, leading to increased unwanted effects in relation to additive benefit of therapy.	Thank you for your comment. This will be covered in the draft review question on page 4 line 90 of the consultation version of the scope.
243	SH	Barts	4	106	The use of reliever therapy over a defined period i.e. a certain amount of	Thank you for your comment. This will be

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		Health NHS Trust			times per day or week.	covered in the draft review questions on page 3 lines 75-83 of the consultation version of the scope.
246	SH	Barts Health NHS Trust	7	192	Good information to highlight impact of care, relating to NRAD report reinforces importance of appropriate management.	Thank you for your comment. NRAD has been referenced in the scope.
240	SH	Barts Health NHS Trust	8	212	Pharmacists involvement in primary care is not addressed, envisage this will increase by 2017 - publication date. Currently pharmacist are running clinics in GP clinics etc.	Thank you for your comment. We have made this change.
241	SH	Barts Health NHS Trust	8	222	NICE should provide guidance to qualify what is excessive prescribing (i.e. no more than 3 reliever inhalers/year)	Thank you for your comment. This will be captured in the full guideline.
242	SH	Barts Health NHS Trust	8	229	A figure to demonstrate a referral pathway, indicating features of clinical history, objective and subjective measures, such as ACQ, spirometry, use of reliever etc. to guide patient pathway.	Thank you for your comment. This will be captured in the full guideline.
81	SH	Boston Scientific	General	General	We feel that the exclusion of management for severe asthma within the scope of the "Asthma: The management of asthma" guidelines is inappropriate for guidelines that are aimed at "providing guidance on cost-effective management of asthma in children and adults to improve control of asthma and minimising future risk of exacerbations". Exclusion of this	Thank you for your comment. Guidance on the management of people with severe, difficult to control asthma will be given if pertinent evidence is found for this population.

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					<p>patient group would render the guidelines incomplete and insufficient to address management of the entire patient population. In addition, as outlined by the All Party Parliamentary Group on Respiratory Health's June 2014 "Report on inquiry into Respiratory Deaths", "severe asthma puts someone at a higher risk of having a fatal asthma attack" – making it all the more important to ensure that appropriate guidelines are in place to manage their care to a high level.</p> <p>We would also like to note that the draft scope appears inconsistent in its decision to exclude management of severe asthma in these guidelines. We are unclear why "indications for referral to tertiary care for severe, difficult to treat asthma" (page 4, line 92) and "stratification of asthma care according to exacerbation risk" (page 4, line 95) are in scope yet the treatments that may be provided to these patients in a tertiary hospital setting are not. If the treatment of these patients is not covered under this guidance, we would like to know if there is a sufficient plan in place to develop such clinical guidelines for the treatment pathway of severe asthma in the near future.</p> <p>Furthermore, we understand that during the scoping workshop on 25 March 2015 the justification given for the exclusion of this patient group was the risk of potentially lengthening the review process beyond the June 2017 publication date in order to incorporate these patients. We do not feel that this is an appropriate rationale for excluding this patient population.</p>	
82	SH	Boston Scientific	3	60	As per the NICE IPG (IPG419), the device therapy for severe, difficult to treat asthma is called "Bronchial Thermoplasty", not Thermoplasty	Thank you for your comment. We have made this change.

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83	SH	Boston Scientific	4	92	We assume that the indications for referral to tertiary care for severe, difficult to treat asthma will be in line with current BTS/SIGN and/or GINA guidelines	Thank you for your comment. This question has been removed from the scope.
84	SH	Boston Scientific	8	197-199	We also believe that asthma management should aim to ensure access to appropriate levels of treatment depending on the severity of the patient's disease and would encourage the inclusion of such an aim in the scoping document.	Thank you for your comment. This will be covered in the draft review questions on page 3 lines 75-83 of the consultation version of the scope.
10	SH	British Thoracic Society	General	General	<p>The British Thoracic Society welcomes the interest in asthma from NICE in supporting the ongoing management of asthmatic patients. There are a number of guidelines for asthma including the BTS/SIGN British Guideline on the Management of Asthma - a "living guideline" (that is consistently in the top 5 downloaded guidelines produced by SIGN). This is potentially confusing for those referring to guidelines and we would strongly advise close cooperation between SIGN and NICE to develop a consistent message across the healthcare economy.</p> <p>The NRAD report suggested complacency and a potential lack of knowledge of guideline management as significant factors in some asthma deaths. A complex set of conflicting guidelines will not improve things but consistency has a greater chance of preventing further asthma deaths. Therefore, there is a great opportunity to improve care by working together.</p> <p>The BTS / SIGN guideline section on pharmacological management is currently being updated and we would recommend early communication if possible.</p>	Thank you for your comment. We share your desire to avoid confusion between guidelines. Any inconsistency which emerges will be carefully considered, but it is hard to be more specific until the evidence has been reviewed.

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12	SH	British Thoracic Society	2	33	There should be attention paid to the diagnosis of asthma and its definition. We are moving towards a patient centred approach to asthma care and this should be considered when discussing this section with some attention to phenotypes that may guide treatment pathways.	Thank you for your comment. This guideline covers everyone with asthma. If evidence is found which suggests that specific sub-groups require different treatment, the recommendations will encompass this.
13	SH	British Thoracic Society	3	59	It may not be practical to exclude delivery devices from the scope of this guideline due to manufacturer's products and availability and this should be reviewed.	Thank you for your comment. The guideline will review the clinical and cost-effectiveness evidence for different drug classes, but a comparison of the many different modes of drug-delivery is not a priority area for inclusion in this guideline. Comparison of devices is confounded by differences in the contained agent and its dose and whatever such a comparison shows the emphasis will always be on ensuring that the individual patient is able to use the chosen device, We therefore do not think that a detailed comparison of the numerous available devices is an appropriate use of the resources available for this guideline. Please also note that as part of the review question on inhaler technique in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring, a literature search was undertaken for RCT evidence comparing the

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						outcomes of checking inhaler technique vs. not checking and no relevant RCT evidence was found.
14	SH	British Thoracic Society	3	73	One of the key charts in the current BTS / SIGN guidelines is the stepwise approach. This is fundamental to quick reference guides and any recommendation from NICE should be in line with SIGN.	Thank you for your comment. We will consider how best to present the recommendations on increasing/decreasing therapy. We agree that users have found the BTS/SIGN steps extremely useful.
11	SH	British Thoracic Society	4	84 & 99	We welcome the assessment of self-management and adherence which are important considerations in reviewing medication need.	Thank you for your comment.
15	SH	British Thoracic Society	4	89	It is not made explicit although mention is made of adjustment in treatment features. Guidance on stepping down therapy when appropriate should be included.	Thank you for your comment. This review question will cover stepping down. We have amended the scope to confine this question to stepping down.
225	SH	Chiesi	2	34 to 41	Licensing of products is generally from 12 years and 18 years which does not align with the age 5, 5-16 and 16+. Recommendation for pharmacological interventions should align with the commonly licensed ages of the assessed pharmacological interventions. We would suggest three age groups the first being 5 to 12 years to reflect the children grouping, although depending on the intervention, the upper limit could be adjusted upwards. The second category for adolescents would be 13 to 17 years again, the range being subject to adjustments depending on the intervention, finally the third category being adults aged 18 years and	Thank you for your comment. We state how we plan to stratify by age on page 2 lines 38-41 of the consultation version of the scope.

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					above.	
226	SH	Chiesi	2	47 to 53	We would like to see that recommendations on assessment, review, monitoring and compliance\concordance be included in the section regarding the pharmacological management of chronic asthma.	Thank you for your comment. These areas are outside scope. Recommendations on diagnosis and monitoring are covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring.
227	SH	Chiesi	2	49 to 51	Exceptionally, and only if clearly supported by evidence and no alternative licence therapy is available , use outside a licensed indication may be recommended.	Thank you for your comment. This is stated in the scope.
228	SH	Chiesi	3	59	Whilst comparison of drug delivery devices is not in scope it would still be important to include the necessary step of appropriate device selection for patients and their ability to use the device prescribed together with support in terms of training/counselling?	Thank you for your comment. What you describe is a process of ensuring that an individual patient is given an appropriate device, and we will refer to this in the narrative of the guideline.
229	SH	Chiesi	3	63 to 69	Recommend that where economic evaluation is carried out on pharmacological interventions intra- as well as interclass recommendations may be beneficial. The NICE multiple technology appraisals for pharmacological interventions date back to 2007/8 therefore more recently produced ESMNs may well help fill the voids of HTAs that do not include recently introduced pharmacological interventions.	Thank you for your comment. The pharmacological agents to review will be decided by the committee.
230	SH	Chiesi	4	87 to 88	Suggestions of interventions to improve adherence- a. Patient/prescriber/parent/school education on asthma, control, triggers through HCPs/pharmacy b. Regular review	Thank you for your suggestions which will be considered by the committee when devising review protocols.

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					<ul style="list-style-type: none"> c. Device training and availability of training devices d. Apps/telemonitoring e. Device choice, affecting both intentional and non-intentional non-adherence (critical errors) f. PAAPs and self-management g. Patient audit (e.g. SABA RxS) 	
231	SH	Chiesi	4	89 to 91	<ul style="list-style-type: none"> a. Review of unnecessary prescribing (e.g. high dose ICS) b. The risk of losing asthma control from changing the pharmacological intervention of controlled asthmatic patients is documented in literature (1,2, 3). An evidence-based decision regarding specific pharmacotherapy change is therefore warranted. Therefore, when reviewing/stepdown/up/across is there any evidence of safely switching between devices/drugs/etc. Ref 1 : Thomas M et al. BMC Pulm Med 2009;9:1 Ref 2: Doyle S et al. Prim Care Respir J 2010;19(2):131-9 Ref 3: Barnes N et al. Pulm Pharm & Therapeutics 2013; 26: 555 -561 c. Adherence and inhaler technique should always be a part of a review of pharmacological therapy 	Thank you for your comment. Points a and b are covered by these review questions. Point c is covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring.
232	SH	Chiesi	4	92 to 94	A distinction between severe and difficult to treat asthma may have to be made.	Thank you for your comment. This question has been removed from the scope.
233	SH	Chiesi	4	95 to 98	There are many variables to asthma and so stratifying treatment according to exacerbation risk may not be simple for such a heterogeneous disease.	Thank you for your comment. We agree this is a complex issue; however, we feel this is an area of asthma care that a NICE guideline could usefully address and

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						therefore we will undertake this review question.
235	SH	Chiesi	4	110 to 111	Would like to ensure that both the ACT and RCP questionnaires are also included.	Thank you for your comment. This will be decided by the committee when agreeing the protocol for this review question.
234	SH	Chiesi	4 to 5	106 to 116	Although not a patient reported outcome, will effect on lung function not be considered for the outcomes as is often the primary endpoint for asthma RCTs.	Thank you for your comment. The outcomes listed in the scope are those critical for decision making. Other additional outcomes will be decided by the committee during protocol development.
40	SH	Cochrane Airways Group	2	37	Asthma is very hard to diagnose in children under the age of 2 years, so you may wish to restrict the youngest age group to exclude children under 2. Would 5-12 work better than 5-16 as an age group?	Thank you for your comment. We acknowledge that diagnosing asthma in very young children is difficult; however, we do not propose to exclude children under 2 years because if they have been prescribed asthma treatment then their management should be in accordance with this forthcoming guideline. Regarding your second point, please see page 2 lines 38-41 of the consultation version of the scope for how we plan to stratify by age.
41	SH	Cochrane	2	54	We do not understand what is meant by "Stratification of asthma care	Thank you for your comment. We do not

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		Airways Group			according to exacerbation risk." What sort of asthma care do you mean?	wish to restrict any possible recommendations at the scoping stage, but the aspects of care we have in mind are exemplified in the ARRISA trial.
42	SH	Cochrane Airways Group	3	55	How will you look at personal asthma plans without including acute asthma (where they are used)?	Thank you for your comment. We have clarified in the scope that the guideline will not cover management of acute asthma by 'a healthcare professional' and therefore does not preclude self-management of acute asthma.
43	SH	Cochrane Airways Group	3	77	Please specify whether you mean people with asthma who have never been prescribed regular preventative treatment, or who have been prescribed it but not taken it, or who have just decided to stop taking it!	Thank you for your comment. We have clarified in the scope that the population in the review question on treatment-naïve is 'people with asthma who are not taking treatment for asthma'.
44	SH	Cochrane Airways Group	4	87	Combination inhalers (inhaled steroids and long-acting beta-agonist in the same inhaler) avoid the danger of patients stopping the inhaled steroid. Also some combination inhalers can be used for maintenance and relief of symptoms, which might affect adherence and increase the dose of inhaled steroids when the asthma symptoms worsen. It is not clear whether once-daily preventer inhalers improve adherence in real life. Starting new asthma patients with reliever inhalers alone may worsen adherence with inhaled steroids later on (as we are sending the message that the reliever is what will make the asthma symptoms better)!!!	Thank you for these suggestions. The committee will consider them when debating the evidence.

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45	SH	Cochrane Airways Group	4	91	Please include stepping down in the adjustment in treatment question.	Thank you for your comment. This is covered; please refer to page 4 line 91 of the consultation version of the scope.
46	SH	Cochrane Airways Group	4	112	There is currently overlap between exacerbations (undefined) and other outcomes (admissions, unscheduled attendance). Defining exacerbations by use of increased reliever treatment or % fall in lung function may bias the results in favour of bronchodilators. One common exacerbation type to be reported in trials is the need for a course of oral corticosteroids; perhaps this would work best.	Thank you for your comment. We agree that there is some overlap between the critical outcomes but they are not identical, and each is important in its own right.
114	SH	Glaxo Smith Kline	General		In terms of the process outlined on the NICE website under guideline milestones, GSK does not believe that it was given the opportunity to attend the stakeholder workshop held on the 25 th March 2015. Could NICE confirm that this meeting went ahead and if so why GSK were not included.	Thank you for your comment. This meeting took place on 25 March 2015. All registered stakeholders for this guideline were emailed at the provided email address all the notifications pertaining to this guideline development including the invitation to attend the stakeholder workshop. We believe that GSK was included in the workshop invitation; if you would like to discuss the details of this further please contact us.
116	SH	Glaxo Smith Kline	3	58	We note biologics have been excluded in the scope. We assume this is because they are covered in the STA process and in order to be comprehensive we would expect these to be referred to in the final guideline.	Thank you for your comment. Yes that is correct.
117	SH	Glaxo	3	59	It is accepted that devices play a key role in the effective management of	Thank you for your comment. Comparison of

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		Smith Kline			asthma regardless of age. In a large observational study, inhaler mishandling is associated with increased risk of hospitalisations, emergency room visits, courses of oral steroids and courses of antimicrobials. ¹ In addition the last review of inhaler devices referred to in the scope was carried out in 2000. GSK therefore considers that devices should be reconsidered to be integral to the scope. Ref 1. Melani et al. Resp Med 2011;105: 930–8	devices is confounded by differences in the contained agent and its dose and whatever such a comparison shows the emphasis will always be on ensuring that the individual patient is able to use the chosen device, We therefore do not think that a detailed comparison of the numerous available devices is an appropriate use of the resources available for this guideline. Please also note that as part of the review question on inhaler technique in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring, a literature search was undertaken for RCT evidence comparing the outcomes of checking inhaler technique vs. not checking and no relevant RCT evidence was found.
118	SH	Glaxo Smith Kline	4	84	It is important that there is alignment here with the NICE Medicines Optimisation Clinical Guideline (NICE Guideline 5) where there is a clear need to reduce the suboptimal use of medicines. The role of structured medication review was also highlighted and its potential to reduce suboptimal use of medicines and medicines-related safety incidents is covered in this document.	Thank you for your comment.
119	SH	Glaxo Smith	4	87, 88	Simpler dosing regimens, device design and patient preference to impact adherence. This emphasises the need to consider devices as relevant and	Thank you for your suggestions which will be considered by the committee when devising

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		Kline			within the scope of this guideline.	review protocols.
120	SH	Glaxo Smith Kline	4	90	Patient reported outcome measures (PROMS) such as the Asthma Control Test (ACT) is a valid and reliable test to assess the control of asthma ² to indicate that an adjustment in treatment is appropriate. Ref 2. http://www.thoracic.org/members/assemblies/assemblies/srn/questionnaires/act.php	Thank you for your comment.
115	SH	Glaxo Smith Kline	7	general	Subsequent to the guideline how will the related NICE advice be amended?	Thank you for your comment. This guideline will not update or incorporate any existing NICE guidance.
57	SH	Medicines and Prescribing Centre	1	4	If the scope excludes the management of acute asthma does the title need to be narrowed to reflect this? Should it be management of chronic asthma? Or do the key areas of stratification of risk and self-management cover acute asthma?	Thank you for your comment. NICE will consider amending the guideline title to reflect the final contents of the scope if the current title is no longer fit for purpose.
58	SH	Medicines and Prescribing Centre	2	34	We note this says different age divisions may be used as appropriate. Might this include the management of children under the age of 2 where management might be different? Although this may be more relevant to diagnosis and the management of acute asthma.	Thank you for your comment. The committee will consider your suggestion when agreeing the review protocols for each review question.
59	SH	Medicines and Prescribing	2	49	The wording of this may have unintended consequences where recommendations are driven by what the marketing authorisation (product licence) says rather than what the evidence says. For example, many drugs	Thank you for your comment. This is standard text. NICE recommendations that are off-label will be clearly indicated by a

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		g Centre			have good quality evidence to support an indication but if a manufacturer doesn't seek a licence for that, then the SPC will not reflect the evidence-base. We would suggest that we should state that the content of guidelines and recommendations should primarily be driven by the evidence, while taking into account the content of relevant SPCs. It is difficult to make a blanket statement about this as each SPC issue will need to be looked at individually. There may be issues relating to licensed indications or safety issues that will need to be looked at on a case by case basis. Each recommendation will need to make sense from a clinical perspective in terms of the evidence and SPC content. We would be happy to work with the guideline team to produce a wording to reflect this.	footnote.
60	SH	Medicines and Prescribing Centre	3	58	Rather than excluding all 'biologics', we would suggest making reference to the TAG for omalizumab. People will then be aware that 'biologics' would be part of the treatment pathway if certain criteria are met.	Thank you for your comment. The scope sets out the areas in which an evidence review will be performed, and since omalizumab is the subject of an existing NICE Technology Appraisal it is correctly excluded in the scope. The NICE pathway will include Technology Appraisals and therefore make the position of omlizumab clear.
61	SH	Medicines and Prescribing Centre	3	59	We understand that the evidence for drug-delivery devices (inhalers) <i>per se</i> will not be included, but the device used can have a large impact on the dose delivered to the patient. This will inevitably need to be addressed as many new products also have new inhaler devices and separating drug	Thank you for your comment. We agree with the points you make, and indeed these help explain why a comparison of devices will not be carried out. Comparison of devices is

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					effects from inhaler effects can be difficult. Care is also needed around the equivalence of different ICS from different devices. Different inhaler devices may also be relevant to the question around adherence and to 'patient factors' which should be part of any decision making process around appropriate treatment.	confounded by differences in the contained agent and its dose and whatever such a comparison shows the emphasis will always be on ensuring that the individual patient is able to use the chosen device, We therefore do not think that a detailed comparison of the numerous available devices is an appropriate use of the resources available for this guideline. Please also note that as part of the review question on inhaler technique in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring, a literature search was undertaken for RCT evidence comparing the outcomes of checking inhaler technique vs. not checking and no relevant RCT evidence was found.
62	SH	Medicines and Prescribing Centre	3	60	As a 'non-pharmacological management' option, thermoplasty is excluded from the scope under this criterion. Was thermoplasty specifically named as it will be covered by making reference to IPG419?	Thank you for your comment. Yes that is correct.
63	SH	Medicines and Prescribing Centre	3	61	Management of acute asthma attacks is given as an exclusion but this term may be confusing. Asthma can be a variable and fluctuating condition so any deterioration of asthma such as increased coughing at night may be considered 'an acute attack' We wonder if the term emergency treatment of acute/severe asthma in emergency care settings better conveys what is	Thank you for your comment. We have not made this change because it is not only 'emergency treatment of acute asthma attacks in emergency settings' that will not be covered; we have clarified in the scope

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					<p>being excluded from the scope.</p> <p>Also self-management plans should include details of what to do if asthma deteriorates or there is an acute attack, and these are included, hence the potential for confusion and scope creep.</p>	<p>that we do not propose to cover the 'management of acute asthma attacks by a healthcare professional'.</p>
64	SH	Medicines and Prescribing Centre	3	74	<p>Is there a discrepancy between the heading 'people with asthma who are treatment naïve' and the content which says 'not currently taking regular preventative treatment for asthma'. Presumably people could be at step 1 taking a SABA so in this case won't be treatment naïve but ICS naïve.</p>	<p>Thank you for your comment. We have clarified in the scope that the population in this review question is 'people with asthma who are not taking treatment for asthma'.</p>
65	SH	Medicines and Prescribing Centre	3	78	<p>This says 'people with asthma on ICS only' but could people also be on a SABA?</p> <p>When the pharmacological management of chronic asthma is set out will there be a treatment pathway/stepped approach outlined? At the moment the way the questions are phrased may inadvertently miss steps out. The new type 2 diabetes guideline has adopted an approach of initial drug treatment, first intensification of drug treatment and second intensification of drug treatment etc. It would be helpful for consistency between guidelines to use consistent terminology so we would suggest the asthma treatment guidance adopts a similar approach (initial treatment, first intensification, second intensification etc etc) to allow analysis of the evidence at each point and construction of the recommendations along those lines.</p>	<p>Thank you for your comment. We agree and have clarified in the scope that the population in this review question is 'people with asthma currently on an optimal single preventer (BTS/SIGN step 2)'.</p> <p>This will be informed by the evidence reviews; we cannot pre-empt the conclusions regarding the clinical and cost effectiveness of the BTS/SIGN stepwise approach.</p>

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					As a general point it is also important to acknowledge that treatment needs to be individualised as appropriate at the various steps.	
66	SH	Medicines and Prescribing Centre	3	73	When drug treatment is being reviewed will the equivalence of different ICS formulations be considered? Will the BTS/SIGN equivalence table be used or will something new be created for this guideline? There are several new ICS formulations with different potencies etc. How will different ICS formulations be grouped in terms of reviewing the evidence for efficacy and safety? And how will the fact that different inhaler devices are used be handled?	Thank you for your suggestions which will be considered by the committee when devising review protocols and reviewing the evidence.
67	SH	Medicines and Prescribing Centre	4	84	Can the section on adherence to pharmacological therapy link to the NICE guideline on medicines optimisation (NG5)?	Thank you for your comment. Yes.
68	SH	Medicines and Prescribing Centre	4	90	We wanted to double check that this covers both step up and step down.	Thank you for your comment. This question has been confined to stepping down. Stepping up will be covered in the reviews on pharmacological therapy by way of a subgroup analysis if evidence exists to provide this guidance.
69	SH	Medicines and Prescribing	4	93	Is referral always to tertiary care for severe, difficult to treat asthma – could it be to an appropriately configured secondary care setting in some cases?	Thank you for your comment. We have removed the question on referral criteria to tertiary care for severe, difficult to treat

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		g Centre				asthma.
70	SH	Medicines and Prescribing Centre	4	102	This states 'what is the optimal increase in preventer therapy when control is lost' in relation to self-management. Is this also covered in the general section on pharmacological therapy? Presumably this doesn't just relate to self-management but is related to drug treatment intensification as a whole. Also could 'control is lost' mean an acute attack? See previous comments about the exclusion of acute asthma.	Thank you for your comment. This question relates specifically to short term dose adjustment within a self-management plan, and the scope has been changed to clarify this.
71	SH	Medicines and Prescribing Centre	5	121	How will the publication of this guideline affect TA138 and TA131 on ICS? Will these TAs be incorporated or will the guideline supersede these? These TAs talk about using ICS as in BTS steps. Will this still be applicable if the new NICE guideline has a different stepped care treatment pathway?	Thank you for your comment. This guideline will not update or incorporate any existing NICE guidance, with the exception of the NICE quality standard on asthma.
72	SH	Medicines and Prescribing Centre	6	138	Also Asthma: tiotropium (Spiriva Respimat) (ESNM55).	Thank you for your comment. This recently-published NICE guidance has now been added.
73	SH	Medicines and Prescribing Centre	7	150	Also NG5: Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes.	Thank you for your comment. This recently-published NICE guidance has now been added.
21	SH	Napp	2 - 3	46-55	We would suggest that NICE covers education and training for HCP's in section 1.3 to include the development of a core competency framework for teaching and monitoring inhaler technique, outlining the correct steps	Thank you for your comment. Training and competence setting for healthcare professionals are beyond NICE's remit.

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					and inspiratory flow for each inhaler type; dry powder inhaler (dpi), metered dose inhaler (mdi) with and without spacers. This will help to identify poor inhaler technique, adherence issues and allow HCPs to offer the most appropriate inhaler to patients to improve outcomes and reduce over prescribing of rescue medication. This will also encourage a consistency of communication around inhaler technique through an inter-disciplinary approach, e.g. The Isle of Wight Respiratory Inhaler Project is documented on the NICE shared learning database. A focus on improving inhaler technique across the Isle of Wight resulted in a 50% reduction in asthma-related hospital admissions, and a 75% reduction in deaths. https://www.nice.org.uk/savingsandproductivityandlocalpracticeresource?ci=http%3A%2F%2Fsearch.nice.org.uk%2Fsl_461	
28	SH	Napp	1.6	106	We would like to see consideration given to the use of data outside of RCTs and suggest that NICE should add Real World Data to the list of outcomes.	Thank you for your comment. The key outcomes are not only for randomised controlled trials (RCT). The committee will decide what type of evidence will be appropriate to consider for each review question in the event of no RCT data.
16	SH	Napp	2	36	We agree with the proposal to consider sub-groups based on age however it should be noted that existing guidance is for those under 5, 5 to 12 and 12+ including adults. This is also in line with approved product licences for commonly used asthma medicines.	Thank you for your comment. Please see page 2 lines 38-41 of the consultation version of the scope for how we plan to stratify by age.

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17	SH	Napp	2	44	<p>We are unsure that the term “community care settings” is explicit enough and would therefore recommend that the GDG and Collaborating Centre ensure that community pharmacies are considered as part of the primary care setting. This is especially pertinent for targeted medicines use reviews (tMURs) and with the increasing numbers of new non-medical prescribers (including pharmacists) this would also benefit asthma patients.</p> <p>A good example of GP practices and pharmacists working together is the “Walk in my shoes” project in Lewisham.</p> <p>http://psnc.org.uk/our-news/walk-in-my-shoes-project-for-gp-staff-and-pharmacy-teams/</p>	Thank you for your comment. We have made this change.
18	SH	Napp	2	48	<p>How will NICE / GDG take into account any changes to product licences that may possibly occur during the development of the guideline? (E.g. an extension to a wider age group).</p>	Thank you for your comment. This issue is not unique to this guideline and the committee will use intelligence on imminent changes to product licences during guideline development when formulating recommendations. In the example given, any off-label recommendations will be indicated with a footnote, but if the licence changes during guideline development such that the population group becomes covered by the licence, the footnote will be removed/amended as appropriate.

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19	SH	Napp	2	54	<p>We welcome the fact that NICE would like to include the stratification of asthma care according to exacerbation risk, however we would recommend that the GDG considers the capabilities and limitations of the current / future IT systems within the NHS to enable effective stratification of these patients. The communication between primary care and secondary care could be improved to encourage a more integrated service with the patient at the centre. The role of community pharmacy in highlighting patients at risk should be considered and how to provide support and management for these patients, e.g. those with poor adherence, over use of rescue inhalers and patients not attending annual review. The SIMPLE project in Leicester is one example where good intervention by HCPs has led to reductions in unscheduled visits to GP practices.</p> <p>http://improvementsystem.nhsiq.nhs.uk/ImprovementSystem/login.aspx</p> <p>http://www.pharmaceutical-journal.com/news-and-analysis/news/simple-project-which-revolutionised-patients-asthma-control-scoops-award/11103761.article</p> <p>http://www.leicestershospitals.nhs.uk/aboutus/our-news/press-release-centre/?entryid8=13521</p> <p>Risk stratification can be managed by using systems such as Eclipse pioneered in Norfolk. Eclipse Solutions is leading the way in providing revolutionary IT solutions for the NHS, specialising in Cost-Effectiveness, Risk Stratification Tools, Integrated Care Systems and Patient Self-</p>	<p>Thank you for your comment. A review of the IT systems within the NHS is outside the remit of this guideline. Please note that service delivery guidance on acute medical emergencies will be provided in the forthcoming NICE guideline on Acute Medical Emergencies.</p>

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					Management Plans. These interfaces save the NHS money whilst improving patient outcomes and reducing emergency admissions, by utilising the most advanced Risk Stratification Software available, radically improving integrated care and allowing the generation of automated Self-Management Plans across a range of Long Term Conditions. The risk stratification system 'Eclipse Live' was a finalist in four national Patient Safety Awards in 2012 and is being formally appraised for its ability to prevent emergency admissions from medicine related events (RADAR). http://www.prescribingservices.co.uk/businesscases.html	
20	SH	Napp	3	55	Although NICE have highlighted self-management plans as a key area to be covered, we believe that this should include a strong emphasis on the importance of ensuring engagement with the patient and also with self-management plans in clear and simple language to encourage effective use. As part of the implementation plan could NICE consider developing a template that would allow HCPs to agree with the patient efficiently and effectively a self-management plan. This could also feed into any Quality Standards and QOF targets.	Thank you for your comment. This will be covered in the guideline narrative. Implementation plans will be formulated at the end of guideline development.
22	SH	Napp	3	55	We suggest that NICE may wish to consider a new bullet point 4 which supports improving patient education including use of inhalers and how to recognise the need for more or less treatment. This then links to 1.3, 3 the use of self-management plans.	Thank you for your comment. This is covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring.
23	SH	Napp	3	78	Patients are very rarely prescribed an inhaled corticosteroid only. Most	Thank you for your comment. We have

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					patients in Step 2 would / should be prescribed a rescue reliever inhaler.	removed the word 'only' for clarification.
24	SH	Napp	4	84	<p>Napp recommends that a “back to basics” approach to the monitoring of patients, in particular those at high risk, could be implemented cheaply and successfully.</p> <p>This would involve identifying those asthma patients (including high risk patients) who have:</p> <ul style="list-style-type: none"> • Increasing use, or those using excessive regular amounts, of rescue inhalers • Sub-optimal use of combination inhalers (could also have a financial impact compared to prescribing single agent inhalers) • Poor adherence (lower than expected number of prescriptions collected or fulfilled by pharmacy for preventer medication, use of LABA without preventer inhaled corticosteroids) • Experienced 2 or more severe exacerbations in 12 months: Severe exacerbation defined as asthma-related inpatient or emergency room attendance, or acute courses of oral corticosteroids. <p>This could offer the opportunity for some partnership working between GP practices and community pharmacists to conduct reviews e.g. MUR and NMS. A good case study for this type of collaborative working is the award winning “SIMPLE approach to asthma management” by Anna Murphy in Leicestershire which resulted in improved outcomes for patients with</p>	Thank you for your comment. Monitoring is covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring.

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					<p>asthma. This was a joint project between Leicester City PCT and University Hospitals Leicester NHS Trust.</p> <p>http://improvementsystem.nhs.uk/ImprovementSystem/login.aspx</p> <p>http://www.pharmaceutical-journal.com/news-and-analysis/news/simple-project-which-revolutionised-patients-asthma-control-scoops-award/11103761.article</p> <p>http://www.leicestershospitals.nhs.uk/aboutus/our-news/press-release-centre/?entryid8=13521</p>	
25	SH	Napp	4	84 (continued)	<p>Napp suggests that to aid adherence it may be possible to simplify patient treatment regimens by using the same inhaler type for rescue and prevention, and when stepping up and down through treatment doses to gain better control. The challenges with inhaler technique education would therefore be minimised by introducing only 1 technique to a patient rather than 2 different techniques for 2 different inhaler types.</p> <p>When stepping up and down a therapy we recommend that patients remain on the same steroid and the same type of device until asthma control is stabilised. If changing more than one treatment parameter (e.g. dose, steroid, inhaler type) when stepping up or down and a lack of control occurs, the true reason for this may be masked.</p> <p>Asthma patients experience periods of adequate control and exacerbations.</p>	<p>Thank you for your suggestions which will be considered by the committee when devising review protocols.</p> <p>These issues will be addressed in the evidence reviews.</p>

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					We recommend due to this changeable nature of asthma, the choice of treatment should take in to consideration the availability of a flexible range of dosing. Therefore, this will allow step up and step down with the same inhaler type and / or the same combination where appropriate.	
26	SH	Napp	4	89	<p>We would like to suggest that NICE considers the following when deciding which symptoms or objective measurements to indicate when a change in treatment is appropriate:</p> <p>These should include information from simple metrics collected from GP practices, community pharmacies and patients.</p> <ul style="list-style-type: none"> • number of reliever inhalers used per month, • prescriptions not fulfilled that lead to exacerbations • number of exacerbations • peak flows, • spirometry, • does the patient have a self-management plan, • whether the patient is using an app or not to support the self-management plan, • number of disturbed nights sleep, • lost days at work or school. <p>We would encourage the GDG to support the provision of guidance to the patient on how to optimise the use of their existing therapy before a HCP has to consider making a change. Where a change of therapy is appropriate, we recommend that patients should be provided with clear and</p>	Thank you for your comment.

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					<p>simple information relating to the rationale for changes to their treatment regimen, e.g. step up, step down, change from individual component inhalers to combination inhalers.</p> <p>When prescribing more than one inhaler, HCPs should be encouraged to consider the most cost-effective asthma treatment combination in line with NICE guidance TA138.</p>	
27	SH	Napp	4	102	<p>Within the self- management plan the agreed steps need to clearly state how to achieve the optimal dose or combination of doses to control the person's asthma.</p> <p>With the encouragement of patient self-management through personal asthma action plans, we believe that patients should have access to inhalers with easy to understand dose counters to enable them to monitor use and order a repeat prescription when necessary. Without a dose counter, and with the introduction of flexible dosing product licenses, patients may be using an empty inhaler without realising.</p>	<p>Thank you for your comment. This issue is covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring.</p> <p>A comparison of drug delivery devices (including inhalers with dose counters) has not been prioritised for inclusion as the comparison is confounded by differences in the contained agent and its dose and whatever such a comparison shows the emphasis will always be on ensuring that the individual patient is able to use the chosen device. We therefore do not think that a detailed comparison of the numerous available devices is an appropriate use of the resources available for this guideline.</p>

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29	SH	Napp	8	222	<p>The scope refers to the RCP NRAD report and excessive prescribing of reliever treatment and underprescribing of preventer treatment. We would suggest that this is addressed specifically through the guideline and refer you to our previous comment (2 above reference to line 44) which relates to the involvement of the community pharmacist. Monitoring the frequency of reliever inhaler prescriptions can be carried out at both practice and pharmacy level, checks can be carried out on adherence to preventer or lack of collection of prescription of preventer, correct inhaler use, simplification of treatment regimen, e.g. using a combination inhaler instead of two separate inhalers.</p> <p>This may not just simply imply a failure to step-up treatment but possibly a failure to adhere to a complicated regimen.</p> <p>In recent years there has been a rapid development of health apps and the use of digital technology to support healthcare. How can NICE “future proof” the guideline to ensure that asthma patients benefit from the technology advances that are, and will become, available? The use of technology to collect patient data, feed into electronic data records and alert patients to changes in health or to prompt better adherence is already available. This links to adherence and the appropriate use of medicines.</p>	<p>Thank you for your comment. These issues are covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring.</p> <p>In terms of future proofing, all NICE guidelines undergo a review for update process every 2-3 years (which includes consultation with stakeholders on the need to update) and if there is sufficient new evidence to warrant an update of the guideline a partial or full update of the guideline will be commissioned.</p>
92	SH	National Inhaler Group	General		<p>We welcome any efforts to ensure that asthma patients, carers and parents receive good advice about how to get the best benefit from their inhalers. This is also beneficial to the NHS, since it ensures that their considerable</p>	<p>Thank you for your comment. We agree on the importance of correct use of inhalers. However, formal comparison of devices is</p>

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					<p>expenditure on inhalers is used to maximum effect to control asthma. Our comments below are focused only on points relating to inhaler usage, as this is the remit of our group. Inappropriate selection of inhaler for an individual patient, and poor or inaccurate instructions on how to use inhalers can contribute to loss of control which can result in exacerbations and hospitalisations, which are costly to the NHS and distressing for the patient.</p> <p>At present it is not explicit whether a focus on pharmacological management will encompass guidance on deriving best value from inhalers per se – both from a prescriber's and a patient's perspective. We strongly recommend that issues relating to inhaler devices are included in any guidance on use of medicines for asthma.</p>	<p>confounded by differences in the contained agent and its dose, and whatever such a comparison shows the emphasis will always be on ensuring that the individual patient is able to use the chosen device, We therefore do not think that a detailed comparison of the numerous available devices is an appropriate use of the resources available for this guideline. We will refer to the importance of correct inhaler usage in the guideline narrative. Please also note that as part of the review question on inhaler technique in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring, a literature search was undertaken for RCT evidence comparing the outcomes of checking inhaler technique vs. not checking and no relevant RCT evidence was found.</p>
93	SH	National Inhaler Group	General		As there is already an asthma guideline from BTS/SIGN, it is important that a second guideline does not cause confusion for busy healthcare professionals.	Thank you for your comment.
99	SH	National Inhaler Group		64	<p><u>Cost effectiveness</u> should take into account: (i) cost of drug; (ii) cost of device; (iii) percentage of patients likely to be able to use the device effectively (iv) Adherence feedback measures. Prescribing an inhaler device that is difficult to use is</p>	Thank you for your comment.

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					not cost effective.	
103	SH	National Inhaler Group		87	<u>Adherence</u> - suggestions: Education Packages, Email, text alerts, Dose counters, development of electronic counters with alarms, Simplifying treatment at every opportunity	Thank you for your suggestions which will be considered by the committee when devising review protocols.
94	SH	National Inhaler Group	2	36	<u>Age bands of children/young people.</u> Dexterity and ability to coordinate breathing with activating an inhaler are important factors in selecting age-appropriate inhalers for children to use. An analysis of the main inhalers and their suitability for age bands of children would be extremely useful, and must include spacer devices and face masks. It is also important that the spacer devices and masks used have been designed, tested and confirmed to be effective with specific inhalers. This may also be important for older patients too. You indicate that a comparison of drug delivery devices is not in the remit of this guideline. However, the ability of patients to benefit from their medicines is dependent on the choice of an appropriate inhaler device, and their ability to use it properly. It is important for the age bands to align with BTS/SIGN which is 5-12, not 5-16	Thank you for your comment. Please see page 2 lines 38-41 of the consultation version of the scope for how we plan to stratify by age. The age banding in recommendations will be informed by the evidence; we cannot pre-empt the conclusions regarding the clinical and cost effectiveness of the age banding used in the BTS/SIGN guideline.
95	SH	National Inhaler Group	2	48	<u>Pharmacological management of chronic asthma</u> Since most medicines for asthma are delivered by inhalers, it is critical that the issues relating to inhaler use are examined in this NICE guideline. A patient may be on appropriate medication for their type of asthma, yet may not be well controlled because of an inappropriate inhaler device, or incorrect use of an appropriate device. The correct use of an appropriate	Thank you for your comment. As above (response to comment 92). Please note that checking inhaler technique is covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring. Also service delivery guidance is outside the remit of this

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					<p>inhaler is therefore an intrinsic aspect of any examination of pharmacological management of asthma. Key questions for NICE to consider include:</p> <ul style="list-style-type: none"> • What factors should clinicians take into account when selecting an appropriate device for a patient? • What is the frequency with which clinicians should check inhaler technique? • How best to teach and support a patient with more than one inhaler type when a different technique is required? • How best to teach and review how a parent can help a child to use their inhaler correctly? • How is inhaler technique best checked – by prescribing clinician? by pharmacist at point of dispensing? • What is the cost to the NHS of inappropriate choice of inhaler, or incorrect use of an inhaler? • What training do clinical staff need in order to teach a patient to use an inhaler properly? • What techniques are most effective in teaching a patient to use their inhaler? • Would the availability of standardised videos on each inhaler improve the teaching and learning of inhaler technique? Would MHRA making a video a standard part of a licence application alongside the patient information leaflet be a valuable addition? • Are certain inhalers more effective than others at delivering the drug to 	<p>guideline.</p>

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					the lungs as opposed to being deposited in the mouth or throat?	
97	SH	National Inhaler Group	2	47	<u>Regular review</u> It seems to be a significant omission that regular review does not feature as a key component of asthma management. While there is good evidence for individual pharmacological compounds, the evidence behind approaches to asthma management and components of regular review is more sparse. Checking inhaler technique is a key component of regular review as recognised in the QOF indicator on regular review in asthma and in the quality standard statement.	Thank you for your comment. This is covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring.
96	SH	National Inhaler Group	3	55	<u>Self management</u> It is encouraging that self management will be looked at in this guideline. Knowing how to use an inhaler is obviously a key aspect of self management for an asthma patient. Self management needs to be considered in the broadest context, and is certainly about more than a self management plan. It could include guiding patients to clean their spacers and inhalers for example.	Thank you for your comment. The wording of this section is deliberate to focus these review questions on personal action plans, and not more broadly on any self-management strategy.
98	SH	National Inhaler Group	3	59	<u>Comparison of drug-delivery devices (inhalers)</u> We note that there is no plan to compare drug-delivery devices (inhalers). This is a significant omission, as a large number of licensed asthma treatments are inhaled therapies. There should be some consideration of inhaler devices, as different inhaler devices are useful for different patients.	Thank you for your comment. We agree on the importance of correct use of inhalers. However, formal comparison of devices is confounded by differences in the contained agent and its dose, and whatever such a

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					<p>Indeed many would suggest that inhaler technique and a patient's ability to master this is as important as choice of drug.</p> <p>Additionally, there should be some clear evidence statements on the importance of ensuring consistent prescribing of inhaler devices through brand name prescribing. At present, it is possible for a patient to be dispensed an inhaler they have never used before if a product is prescribed by its generic name.</p> <p>We note that on lines 122 and 129, technology appraisal guidance on the use of inhaler devices in children under 5 years and 5-16 is mentioned (TA10 and TA 38). These are now very out of date as there are many new inhaler devices available.</p> <p>There should be consideration of:</p> <ol style="list-style-type: none"> 1. Ease of use of different inhaler devices by age group. 2. Impact of poor inhaler technique on asthma control. 3. The unacceptably low proportion of patients and healthcare professionals that can use a variety of existing inhaler devices 4. How inhaler technique should be taught and by whom. 5. The need for competency assessment (and reassessment) of the HCPs teaching inhaler technique 6. Frequency that inhaler technique should be assessed and reinforced. <p>We have suggested that a table of appropriate devices by age is an output of this guideline.</p>	<p>comparison shows the emphasis will always be on ensuring that the individual patient is able to use the chosen device, We therefore do not think that a detailed comparison of the numerous available devices is an appropriate use of the resources available for this guideline, We will refer to the importance of correct inhaler usage in the guideline narrative. Please also note that as part of the review question on inhaler technique in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring, a literature search was undertaken for RCT evidence comparing the outcomes of checking inhaler technique vs. not checking and no relevant RCT evidence was found.</p>

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100	SH	National Inhaler Group	3	70	<p><u>Key issues and questions</u></p> <p>There are important questions to be asked about inhaler devices in the context of your focus on pharmacological management of asthma.</p> <ul style="list-style-type: none"> • What factors should clinicians take into account when selecting an appropriate device for a patient? • What is the frequency with which clinicians should check inhaler technique? • How best to teach and support a patient with more than one inhaler type when a different technique is required? • How best to teach and review how a parent can help a child to use their inhaler correctly? • How is inhaler technique best checked – by prescribing clinician? by pharmacist at point of dispensing? • What is the cost to the NHS of inappropriate choice of inhaler, or incorrect use of an inhaler? • What training do clinical staff need in order to teach a patient to use an inhaler properly? • What techniques are most effective in teaching a patient to use their inhaler? • Would the availability of standardised videos on each inhaler improve the teaching and learning of inhaler technique? Would MHRA making a video a standard part of a licence application alongside the patient information leaflet be a valuable addition? 	Thank you for your comment. As above.

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					<ul style="list-style-type: none"> Are certain inhalers more effective than others at delivering the drug to the lungs as opposed to being deposited in the mouth or throat? 	
101	SH	National Inhaler Group	4	85	<p><u>Adherence to pharmacological therapy</u> Any section on adherence, should not only concentrate on intentional nonadherence (i.e. failing to take medication as prescribed), but also unintentional nonadherence which can occur through poor inhaler technique, which is known to adversely affect asthma control. Patients who do not use their inhalers correctly and persist with symptoms often feel it is the inhaler medication that is not working rather than their faulty technique.</p>	Thank you for your comment. Strategies to address non-adherence may be different if the non-adherence is unintentional, and if appropriate we will reflect this in recommendations. However, in terms of the search question, there is no value in separating the two.
102	SH	National Inhaler Group	4	85	<p>Inappropriate choice of inhaler may be a factor in adherence with treatment – and ease of use for a patient may impact persistence to continue using it, so should be considered in this context. This section should not only consider how to improve adherence across the whole system, but also how to identify patients who are not using their medications as prescribed, in particularly the accuracy of different measurement tools (e.g. prescribing data, pharmacy dispensing records, questionnaires etc.)</p>	Thank you for your comment. This was reviewed in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring.
104	SH	National Inhaler Group	4	90	<p><u>Review of pharmacological therapy</u> It is important that clinicians always consider poor inhaler technique as a cause of poor control before switching from one class of medication to another, or increasing the dose of the existing treatment. Checking inhaler</p>	Thank you for your comment. This is covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring, but we will mention it again when discussing

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					technique is therefore a key step in any routine review, but particularly where there appears to be inadequate control.	treatment adjustment in this management guideline.
105	SH	National Inhaler Group	4	106	An important outcome measure should be a measure of improvement in inhaler technique.	Thank you for your comment. We do not feel this is a critical outcome for all review questions.
205	SH	National Paediatric Respiratory and Allergy Nurses Group (NPRANG)		75	Will NICE be recommending specific drugs – as many local formulary's dictates which drugs we use.	Thank you for your comment. The answer to this will be informed by the clinical and cost effectiveness evidence review; we cannot pre-empt the conclusions.
206	SH	National Paediatric Respiratory and Allergy Nurses Group (NPRANG)		85	Suggestions of other nonpharmacological interventions to improve adherence should be mentioned i.e. education packages etc	Thank you for your suggestions which will be considered by the committee when devising review protocols.
207	SH	National Paediatric		89 - 91	NPRANG would reinforce that any professional performing objective measurements – should have the training and understanding to make a	Thank you for your comment. We agree.

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		Respiratory and Allergy Nurses Group (NPRANG)			competent judgement.	
208	SH	National Paediatric Respiratory and Allergy Nurses Group (NPRANG)		206	A reference is need to back the staement made regarding adherence in ethnic groups	Thank you for your comment. We agree but citations are not normally included in the NICE scope. Such evidence will be properly cited in the full guideline.
209	SH	National Paediatric Respiratory and Allergy Nurses Group (NPRANG)		211-212	Asthma reveiws should be carried out by specifically trained professionals. They should have an asthma qualification, which should be regularly updated, revalidated and peer reveiwed. If the professional is dealing with the paediatric patient – they should have the competence and confidence to do so.	Thank you for your comment. We agree.
210	SH	National Paediatric Respirator		233	NPRANG agrees whole heartedly that adherence to treatment shoule be monitored. However as NRAD also alerts us to – the need for attendance at regular follow up should also be monitored.	Thank you for your comment. We agree but these issues are covered in the forthcoming NICE guideline on Asthma Diagnosis and

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		y and Allergy Nurses Group (NPRANG)				Monitoring.
203	SH	National Paediatric Respiratory and Allergy Nurses Group (NPRANG)	2	37	NPRANG still feels strongly that to avoid confusion by the users of the proposed guideline – NICE should follow the ages set out by BTS/SIGN guidelines.	Thank you for your comment. Please see page 2 lines 38-41 of the consultation version of the scope for how we plan to stratify by age. The age banding in recommendations will be informed by the evidence; we cannot pre-empt the conclusions regarding the clinical and cost effectiveness of the age banding used in the BTS/SIGN guideline.
204	SH	National Paediatric Respiratory and Allergy Nurses Group (NPRANG)	2	57 - 60	NPRANG appreciates that some pharmacological/non pharmacological management is not being included in this guidance – because NICE already had guidance on these (i.e. Omalizumab) but this needs to be made clearer to the reader.	Thank you for your comment. Please see page 3 line 58 of the consultation version of the scope.
86	SH	Neonatal and Paediatric	general	general	We agree with the proposed guideline scope	Thank you for your comment.

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		Pharmacists Group				
85	SH	Neonatal and Paediatric Pharmacists Group	1	4	As the guideline will cover the management of chronic asthma (p2, line 48) and not acute asthma attacks (p3, line 61), should the guideline title be amended to 'Asthma: The management of chronic asthma'.	Thank you for your comment. NICE will consider amending the guideline title to reflect the final contents of the scope if the current title is no longer fit for purpose.
1	SH	NHS England	General	General	The scope of the proposed guideline is narrow compared to the current BTS/SIGN guideline and other recent publications (e.g. Australian Asthma handbook). In particular it excludes acute management, non-pharmacologic management and more modern approaches for severe asthma (biologics etc.) How will it link to these other more comprehensive guidelines?	Thank you for your comment. We acknowledge that important aspects of asthma care such as non-pharmacological management and acute asthma are proposed to be excluded which would leave gaps in the overall care pathway for asthma management; however there is a need to prioritise areas for inclusion in this guideline if it is to be published in a standard 3-year timeframe.
2	SH	NHS England	General	General	The guideline is set to update the Quality Standard but can only partially influence the QS for items 3,4,5,6,7,11. Other QS will not be addressed in the guideline	Thank you for your comment. Yes this is correct but the aspects of the NICE quality standard on asthma which are not covered in this guideline will be informed by other guidelines like the BTS/SIGN guideline as happens currently.
3	SH	NHS	Gen	General	It is good to see that there will be a focus on exacerbation risk and personal	Thank you for your comment.

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		England	eral		asthma plans	
4	SH	NHS England	General	General	The key issues are all reasonable ones to address and the outcome selection is correct.	Thank you for your comment.
211	SH	Novartis Pharmaceuticals	General	General	It is unclear how the NICE Asthma Management Guideline will align with the BTS/SIGN Asthma Guidelines. We feel that this should be clearly explained. We believe within the NICE Guidelines, where recommendations differ to the BTS/SIGN Guidelines these should be clearly noted and the rationale for the differing recommendation provided for clarity for users and to avoid management disparities.	Thank you for your comment. The rationale for any NICE recommendation will be clearly explained in the 'linking evidence to recommendations' section (LETR).
212	SH	Novartis Pharmaceuticals	General	General	We believe that the Guidelines should include a section on the training requirements for Healthcare Professionals involved in the management of asthma. We believe that all Healthcare Professionals involved in the management of asthma should have on-going specialist asthma training to ensure the appropriate management of patients.	Thank you for your comment. Training issues for healthcare professionals is not part of NICE's remit.
213	SH	Novartis Pharmaceuticals	2	36-41	The specific age subgroups proposed to be covered in the draft scope are 'children under 5 years; children aged 5-16; and adults and young people over 16 years of age. However, the age division may be adjusted for specific reviews according to the most appropriate age groupings to make different recommendations for the intervention in question'. We note that this has been amended since the draft version of the scope (circulated in advance of the stakeholder workshop held on 25 th March 2015). These proposed age subgroups differ to those in the BTS/SIGN Asthma Management Guidelines. Additionally, clinical trials assessing the efficacy	Thank you for your comment. The age banding in recommendations will be informed by the evidence; we cannot pre-empt the conclusions regarding the clinical and cost effectiveness of the age banding used in the BTS/SIGN guideline.

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					and safety of medicines have generally been conducted in following age subgroups: patients aged >18 years, patients 12-18 years, patients 12 years and below. We are concerned that this difference may cause confusion and be difficult to implement.	
214	SH	Novartis Pharmaceuticals	2	47	The 'key areas that will be covered' section does not include 'Severe, difficult to control asthma'. We note that this has been removed from the 'Areas that will not be covered' since the draft version of the scope (circulated in advance of the stakeholders workshop held on 25 th March 2015). We would like clarity on whether 'Severe, difficult to control asthma' is included in this scope. We believe that this should be included in the guidelines as a key area to be covered. As this guideline is intended for Healthcare Professionals in the secondary/tertiary setting we believe this patient group should be included, especially as they present a significant cost to the NHS. These patients are at significant risk of exacerbations and should be appropriately managed. The National Review of Asthma Deaths (NRAD) report highlighted that there are a significant proportion of undiagnosed and under treated uncontrolled severe asthma patients who have not been referred for specialist assessment. We believe that clear criteria for identification and referral in primary care and management of these patients in secondary and tertiary care should be provided in the guidelines.	Thank you for your comment. Guidance on the management of people with severe, difficult to control asthma will be given if pertinent evidence is found for this population.
216	SH	Novartis Pharmaceuticals	2	47	A key area to include is 'management of co-morbidities' e.g. rhinitis, GORD, vocal cord dysfunction and COPD. We believe that this should be included in the scope as improving the management of these conditions may improve the asthma symptoms in patients and their overall condition.	Thank you for your comment. Management of these co-morbidities will not be included. We agree that they can co-exist with asthma, but it is not feasible to cover their

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215	SH	Novartis Pharmaceuticals	3	57	Areas that will not be covered include 'Non-pharmacological management of chronic asthma'. We note that this has been changed since the draft version of the scope (circulated in advance of the stakeholders workshop held on 25 th March 2015). We believe that there are non-pharmacological management options e.g. allergy avoidance, smoking cessation that are helpful in the management of patients and should be included.	management within the available timescale. Thank you for your comment. We acknowledge that non-pharmacological management is an important part of asthma care; however we consider this topic is well covered by existing guidance and therefore not a priority area for inclusion in this guideline as a formal review of the evidence is unlikely to suggest that anything different from current advice should be recommended, for example, allergen avoidance and cessation/avoidance of smoking. Please note we have clarified in the scope that the aspects of non-pharmacological management that will not be covered are those outside of self-management and breathing exercises (which will be covered).
217	SH	Novartis Pharmaceuticals	3	58	We note that the areas that will not be covered include 'Biologics (for example Omalizumab)'. We believe that as the guideline is intended for Healthcare Professionals in the secondary/tertiary setting, biologics should be included. As already outlined in the scope the clinical guidelines should cross reference to existing NICE technology appraisal guidance for biologics e.g. TA278 for omalizumab. Additionally, for primary care Healthcare Professionals, we believe that there should be clear reference	Thank you for your comment. The guideline will make reference to the NICE technology appraisal guidance TA278, as opposed to re-reviewing the evidence for omalizumab.

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					to the availability of further treatment options, including biologics, so that severe/difficult asthma patients, at significant risk of exacerbations, can be identified and referred. There is limited knowledge of specialist treatments in primary care and this reduces referral of appropriate severe asthma patients. We therefore recommend that these management options are clearly highlighted within a prominent position in the guidelines and summary documents with clear criteria for referral.	
218	SH	Novartis Pharmaceuticals	3	78	We note that patients at BTS/STEP 2 treatment would not be on inhaled corticosteroids only. Patients will also be receiving inhaled short-acting β_2 agonist as required.	Thank you for your comment. We have removed the word 'only' for clarification.
219	SH	Novartis Pharmaceuticals	4	84	Strategies that could improve medicine adherence include monitoring of inhaler technique, cortisol levels and prescription usage and increased education for patients. The guideline should provide clear criteria and timelines for assessing adherence alongside training on how to conduct adherence assessments for Healthcare Professionals.	Thank you for your suggestions which will be considered by the committee when devising review protocols. Please note that implementation timelines and service delivery guidance are outside the scope of this guideline.
220	SH	Novartis Pharmaceuticals	4	90	Clinical features that indicate adjustment in treatment may be needed include: <ul style="list-style-type: none"> • Exacerbations • Use of healthcare resources (out of hours visits, GP visits, AE visits, hospitalisations, bed days) • Rescue medication usage (OCS course and SABA usage) 	Thank you for your comment.

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					<ul style="list-style-type: none"> • Daytime asthma symptoms • Night-time awakening due to asthma • Limitations on daily activity including exercise and days of works/education • Reduced lung function • Side effects from medication <p>The guidelines should also clearly highlight when asthma patients should be referred to secondary/tertiary care based on worsening clinical features.</p>	
221	SH	Novartis Pharmaceuticals	4	92	<p>The NRAD Report provided the following recommendations regarding referral of difficult asthma patients:</p> <ul style="list-style-type: none"> • If patients have required more than two courses of systemic corticosteroids, oral or injected, in the previous 12 months • If patients require management using British Thoracic Society (BTS) stepwise treatment 4 or 5 to achieve control • After every hospital admission for asthma • Patients who have attended the emergency department two or more times with an asthma attack in the previous 12 months <p>Referral of severe difficult asthma patients should be considered in the following situations:</p> <ul style="list-style-type: none"> • Patients who fail to improve despite good inhaler technique, good compliance and optimised therapy • Patients using reliever inhalers excessively (>12 in previous 12 	<p>Thank you for your comment. We are aware of the NRAD findings which are important; however these data were retrospective in a small population of people who died from asthma and not necessarily representative of all people with asthma. We plan to cover a systematic review of the clinical and cost effectiveness evidence base to formulate recommendations on the referral criteria for people with suspected severe, difficult to treat asthma.</p>

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					<p>months)</p> <ul style="list-style-type: none"> • An event of acute severe asthma which is life threatening, requiring invasive ventilation within the last 10 years • Fixed airflow obstruction, with a post bronchodilator forced expiratory volume in 1 second (FEV1) less than 70% of predicted normal. <p>We recommend that a clear definition of difficult, severe asthma is provided in the guidelines to help primary care Healthcare Professionals identify and refer these patients.</p>	
222	SH	Novartis Pharmaceuticals	4	100	We believe that self-management plans improve outcomes for patients with asthma. The NRAD reported that a significant proportion of asthma patients do not have asthma management plans. There should be clear recommendations that all patients should have an asthma management plan that is regularly reviewed especially when there are changes in patients' condition.	Thank you for your comment. This issue will be covered, please see page 4 lines 100-103 of the consultation version of the scope. The scope cannot state what will be recommended.
223	SH	Novartis Pharmaceuticals	4	106	We believe that an additional outcome that should be considered when assessing evidence is lung function as this has been a primary endpoint in a number of trials assessing the efficacy and safety of asthma treatments. Other outcomes for consideration are reduction in rescue medication usage and returning to work/education.	Thank you for your comment. The outcomes listed in the scope are those critical for decision making. Other additional outcomes will be decided by the committee during protocol development.
224	SH	Novartis Pharmaceuticals	4	112	If comparing treatment options we note that different definitions for exacerbation and other outcomes may have been used in clinical trials therefore the comparison on the clinical and cost effectiveness of	Thank you for your comment. Outcome definitions will be defined by the committee during protocol development. The protocol

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					treatments could be challenging.	will also set out the review strategy to deal with differing definitions of the outcome reported by the individual studies.
87	SH	Portsmouth Hospitals NHS Trust	3	57	<p>The draft scope currently excludes non-pharmacological management of severe allergic asthma.</p> <p>Reduction of allergen exposure is important in the management of adults with uncontrolled allergic asthma. Many patients and HCPs value non-pharmacological approaches such as allergen reduction. We are currently testing a technology that has already proven to be of value in allergic asthma, and we are assessing it in a pragmatic trial for efficacy and cost-effectiveness in severe asthma. www.lasertrial.co.uk</p> <p>We recommend that NICE include this in the guideline scope.</p>	Thank you for your comment. We acknowledge that non-pharmacological management is an important part of asthma care; however we consider this topic is well covered by existing guidance and therefore not a priority area for inclusion in this guideline as a formal review of the evidence is unlikely to suggest that anything different from current advice should be recommended, for example, allergen avoidance. Please note we have clarified in the scope that the aspects of non-pharmacological management that will not be covered are those outside of self-management and breathing exercises (which will be covered).
88	SH	Portsmouth Hospitals NHS Trust	7	175-189	Ditto	Thank you for your comment. The guideline will make reference to the NICE technology appraisal guidance TA278.
166	SH	Primary	Gen		<u>Duplication or discrepancy?</u>	Thank you for your comment. The

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		Care Respiratory Society UK	General		<p>We are unclear what the rationale is for developing a guideline on asthma management when there is already a comprehensive guideline in existence. We fear that this may lead to confusion for both clinicians and patients. We would like to see NICE collaborate with SIGN in line with the concordat between them, which sets out to avoid duplication or discrepancies in advice given.</p> <p>We have already made comments to this effect in the response we have already submitted (jointly with RCGP) on the draft guideline on asthma diagnosis and monitoring. We continue to have serious reservations about that draft guideline, and these reservations strengthen our concerns over duplication or discrepancies in this guideline.</p>	<p>Department of Health has referred this topic to NICE to develop a clinical guideline on the management of asthma. We have prioritised areas for inclusion in a new guideline that could add value to existing guidance. Furthermore, an assessment of cost effectiveness will be undertaken in the NICE guideline which is not a feature of the BTS/SIGN guideline.</p> <p>The rationale for any NICE recommendation will be clearly explained in the 'linking evidence to recommendations' section (LETR).</p> <p>Comments regarding the forthcoming NICE guideline on Asthma Diagnosis and Monitoring have been addressed in the stakeholder response table for that guideline.</p>
167	SH	Primary Care Respiratory Society UK	General		<p><u>Fragmentation</u></p> <p>We are very concerned that a generalist in primary care – which is where most management of asthma takes place – will now not only have guidelines from 2 sources, but will have 2 guidelines from NICE on asthma, which are cherry-picking parts of care to address rather than focusing on a</p>	<p>Thank you for your comment. The separation of aspects of asthma care between two NICE guidelines was made on a pragmatic basis and the developers will ensure that both NICE guidelines on asthma do not</p>

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					<p>comprehensive approach to asthma management. Monitoring asthma control is an important component of asthma management, yet is covered with diagnosis instead of management. For the busy generalist, it is unhelpful to have relevant guidance in two different places. Will there be another NICE guideline on acute management of asthma, and another on the role of the biologics?</p> <p>NICE is clearly not trying to replace SIGN/BTS since is it only developing partial guidelines, so we remain unclear as to the rationale for spending public money duplicating parts of guidelines.</p> <p>We strongly recommend that if the scope is to be limited to medicines usage primarily, then the guideline title is adjusted to reflect that this is very much a partial guideline e.g. Asthma management – pharmacology, risk management and self management guidance</p>	<p>conflict or overlap and will make reference to each other where necessary. The topics covered by these two guidelines are not 'cherry picking' but prioritising the areas where evidence-based national guidance is urgently needed.</p> <p>Regarding the last point, NICE will consider amending the guideline title to reflect the final contents of the scope if the current title is no longer fit for purpose.</p>
168	SH	Primary Care Respiratory Society UK	General		<p><u>Focus on pharmacological management of chronic asthma</u></p> <p>There is an intrinsic flaw in producing a review of management that focuses largely on pharmacotherapy, since it will reinforce the tendency of health professionals to concentrate on this and neglect other important aspects of management. This gives out the message that aspects of care such as supporting patients to stop smoking, giving flu vaccinations, teaching inhaler technique, advising on avoiding or reducing the impact of known triggers are not a fundamental part of holistic asthma management. What we need is something that reinforces these non-pharmacological aspects of care, since they may enable the use of medicines to be minimised.</p> <p>There is already a wealth of evidence on medicines in contrast to other</p>	<p>Thank you for your comment. These areas are not proposed to be included as the current guidance is unequivocal and as you state not good use of public spending to address by a formal systematic review. The guideline will make reference to smoking cessation NICE guidelines.</p> <p>Regarding the last point, NICE will consider amending the guideline title to reflect the</p>

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					<p>aspects of asthma management. The specific questions to be addressed on medicines are not spelt out, but we feel it is key to address issues to do with selection of device, checking and teaching device technique, and adherence issues within the context of medicines usage.</p> <p>NICE would be contributing significantly to the lives of asthma patients by looking into other aspects of asthma care, and focusing on those which are implemented inconsistently currently.</p> <ul style="list-style-type: none"> • Is there a group of patients who should be seen more regularly than once a year? • What can clinicians do to avoid the spike of admissions for children with asthma in September? • How long should an appointment be to review a patient comprehensively? • What are the most effective and cost effective elements of a regular review? • What systems across primary and secondary care work best in order that patients are reviewed rapidly after receiving care in a hospital? • What can be done to influence the uptake of guidance so that patients receive guidelines based care systematically? <p>We strongly recommend that if the scope is to be limited to medicines usage primarily, then the guideline title is adjusted to reflect that this is very much a partial guideline e.g. Asthma management – pharmacology, risk management and self management guidance</p>	<p>final contents of the scope if the current title is no longer fit for purpose.</p>

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169	SH	Primary Care Respiratory Society UK	General		<p><u>National Review of Asthma Deaths (NRAD)</u> This was a major piece of work with important insights for future asthma management. We are surprised and disappointed that NICE did not take the learning and recommendations from this piece of work as its starting point, if it is going to select aspects of asthma care to focus on in this guideline. NRAD highlights important areas where the quality of care, particularly across different NHS sectors, is inadequate, and it is systems and processes across geographies as well as within individual healthcare settings that need addressing. The logical next step is for NICE to look at solutions to the issues raised, examine the evidence behind them, and propose approaches to care that will improve these aspects of care. E.g. systems to follow up patients after acute events, system to monitor overuse of short acting B2 agonists in practices</p>	<p>Thank you for your comment. NRAD exposed deficiencies in the implementation of existing guideline recommendations (including the two examples you give) and addressing these deficiencies is a matter for local healthcare providers rather than NICE. We have prioritised areas for inclusion in a new guideline that could add value to existing guidance.</p>
170	SH	Primary Care Respiratory Society UK	General		<p><u>Smoking cessation.</u> We are pleased to see that smoking cessation is no longer in the 'exempt' list as it was at the stakeholders' workshop. However, there is still no mention of how it is to be included and what the key questions are to evaluate its importance as a 'treatment' for smoking cessation, which is probably more cost effective than many medicines. A paper released online in the last 2 weeks shows that people with asthma who smoke have all-cause worse prognosis than never-smokers with asthma. This adds to the evidence already available that asthma and smoking results in worse outcomes and the conclusion would be that treating tobacco addiction must be a part of asthma management. http://www.atsjournals.org/doi/abs/10.1164/rccm.201502-</p>	<p>Thank you for your comment. The evidence in favour of smoking avoidance is unequivocal and widely known. There is little value in NICE performing a further evidence search. The recommendations will refer to existing NICE guidance on smoking cessation.</p>

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					0302OC#.VUY4QCKZBUR	
171	SH	Primary Care Respiratory Society UK	General		<p><u>Comprehensive regular review</u> The quality of regular review is a key component in asthma management. NICE has already reviewed the evidence for this for QOF and the QS, yet it seems to be overlooked here. Many patients are still not getting a comprehensive regular review in line with QOF and QS, because the detail is buried in the notes that accompany them. Prominent guidance on commissioning as well as delivering a regular review would be invaluable.</p>	Thank you for your comment. We agree but guidance on commissioning asthma reviews is outside the remit of this guideline.
172	SH	Primary Care Respiratory Society UK	General		<p><u>Updating Quality Standard (QS)</u> We note that the QS is to be updated on the basis of this guideline. Since the asthma management guideline will not be comprehensive, can NICE confirm that the whole QS will be reviewed in light of all updated asthma guidelines including BTS/SIGN?</p>	Thank you for your comment. Yes that is correct.
173	SH	Primary Care Respiratory Society UK	General		<p><u>Cost effectiveness</u> In COPD, work has been done to create a value pyramid so that clinicians and commissioners know what the relative value of interventions is, and can put in place those which are highest value before those of lower value. This work has not yet been done for asthma, and NICE would make a significant contribution to asthma care if it were to do this work. If NICE only looks at the cost effectiveness of individual medicines or classes of medication, it will not allow clinicians and commissioners to consider relative value, and will not encourage the adoption of some potentially higher value interventions. http://www.lambethccg.nhs.uk/Practice-Portal/make-a-referral/GP%20referral%20forms%20and%20checklists/COPD%20Value%</p>	Thank you for your comment. We will refer your suggestion to the NICE Implementation team for consideration towards the end of guideline development.

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					20Pyramid.pdf	
174	SH	Primary Care Respiratory Society UK	General		NICE should be aware that some high profile individuals within the asthma-interested primary care community have opted not to apply to the NICE guideline group on the basis that they do not believe the guideline is focusing on the most important areas, and do not believe that it will improve the quality of asthma care significantly.	Thank you for your comment.
176	SH	Primary Care Respiratory Society UK		21	Private providers are as important as NHS providers if that is the organisation contracted to provide care for patients. In the interests of equity, <u>all</u> providers of asthma care should be included under 11	Thank you for your comment. Please refer to page 1 lines 20-22 of the consultation version of the scope where this is included.
183	SH	Primary Care Respiratory Society UK			Smoking cessation is mentioned neither as included or excluded. Since it is important for ANY patient with a lung disease not to smoke, and since it specifically reduces the efficacy of ICS, it is important that smoking cessation is recognised and covered in this guideline as a key intervention in asthma management.	Thank you for your comment. The recommendations will take into account differences in the management of people with asthma who smoke where evidence on this exists. The recommendations will make reference to smoking cessation guidance as this guidance is unequivocal.
175	SH	Primary Care Respiratory Society UK	1	11	Who it is for? – it looks like 'everyone'. Who is excluded?	Thank you for your comment. That is correct. The guideline is for everyone with asthma.
177	SH	Primary	2	44	Shouldn't this be ALL settings where asthma care is provided, to ensure	Thank you for your comment. We have

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		Care Respiratory Society UK			consistency for patients, regardless of the provider organisation?	made this change.
178	SH	Primary Care Respiratory Society UK	2	48	We have already said that we think the scope of this guideline is too narrow and by focusing on pharmacological management, will miss other important aspects of asthma management. By definition, there is a wealth of evidence on individual medicines from the licensing process. Will NICE be focusing on the role of classes of medication rather than on individual medicines? Can NICE be more specific about the aspects of pharmacological treatment that will be covered? What about adherence with treatment? Will NICE look into the role of teaching and checking inhaler technique as a tool to ensure the prescribing of medicines is cost-effective? Will NICE look at the types of system that will enable overuse of B2 agonists to be spotted and prevented? Will NICE look at how prescribing of LABAs (Long acting bronchodilators) without ICS (inhaled corticosteroids) can be assisted by GP prescribing systems?	Thank you for your comment. The guideline will review the clinical and cost-effectiveness evidence for different drug classes, and we have clarified this in the scope. The detail of the pharmacological reviews will be agreed by the committee during guideline development. Checking inhaler technique is covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring.
179	SH	Primary Care Respiratory Society UK	2	54	We are delighted to see that <u>stratification of asthma patients</u> is included here. Two issues have held this back to date – the evidence base for the factors that indicate risk of exacerbation, and once patients have been stratified, what this means for differential management. Asthma UK has done a significant amount of work on the former with their Triple A test for patients, and this needs turning into a list of factors for use with asthma registers. Health Intelligence has developed a tool to run on practice	Thank you for your comment.

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					computers that will identify the most high-risk patients. It is essential that any list of risk factors can be turned into an automated programme to identify the risk status of patients on GP registers, to be useful to primary care.	
180	SH	Primary Care Respiratory Society UK	3	55	<p><u>Self management.</u> It is good that at least one non-pharmacological tool for managing asthma has been included here. There is Grade A evidence for self management which has been the subject of several Cochrane reviews and this has been reviewed comprehensively by the SIGN/BTS asthma guideline in the recent update, which resulted in an expanded chapter, that importantly, was moved to the front of the guideline to emphasise its pre-eminent place in asthma management. It is questionable whether there is value to patients or clinicians in NICE doing this work all over again. No-one doubts the importance of this. It is important that it is not only the issuing of a self-management plan that is addressed, but also the wider context of supporting patients in understanding and managing their own condition. Patients with long term conditions, such as asthma, spend on average 8756 hours a year managing their own condition and only between 1 and 4 hours in the presence of healthcare professionals. What is more of an issue than the evidence base, is what can be done to make self management support central to all contacts with patients. Many patients don't have self management plans in spite of the strength of evidence. So real value could derive from NICE looking at measures to embed self management support as the bedrock of asthma care. BTS/SIGN have explicitly addressed implementation and provide clear recommendations with implications for organisations, professionals and patients. The conclusions were similar to</p>	Thank you for your comment. We agree but the feedback we received from stakeholders at the workshop indicated that it would be a serious omission to not cover a review question on self-management plans and without undertaking this review we cannot make recommendations on them in this guideline hence their inclusion, although we agree that current guidance is unequivocal.

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					the NIHR funded overview of self-management http://www.nets.nihr.ac.uk/projects/hsdr/11101404	
181	SH	Primary Care Respiratory Society UK	3	58	It is not clear what the rationale is for omitting biologics, since tertiary care is included in pg1 line 15 as an audience for this guideline. And there is a question at (p4, 93) for indications for referral to tertiary care. This is even more relevant with the current work addressing the different phenotypes and biomarkers to enhance control in difficult to treat asthma.	Thank you for your comment. The guideline will make reference to the NICE technology appraisal guidance TA278 as opposed to re-reviewing the evidence for omalizumab.
182	SH	Primary Care Respiratory Society UK	3	59	Presumably the important role of teaching inhaler technique - and its role in making the use of an inhaler cost effective - will be covered here.	Thank you for your comment. We do not propose to perform a literature review on the role of teaching inhaler technique but will refer to this in the narrative of the guideline.
184	SH	Primary Care Respiratory Society UK	4	87	Material on adherence - Refill prescriptions (Gamble and Heaney); Digital interventions, Shared decision making, Electronic monitoring (Chipped inhalers), Simplified regimes Asthma UK has a wealth of material on adherence - existing literature and other resources, the excellent online videos on inhaler technique, various Apps, and teaching resources for schools such as the one developed by Respiratory Education UK.	Thank you for your suggestions which will be considered by the committee when devising review protocols.
185	SH	Primary Care Respiratory Society UK	4	96	As above - Two issues have held this back to date – the evidence base for the factors that indicate risk of exacerbation, and once patients have been stratified, what this means for differential management. Asthma UK has done a significant amount of work on the former with their Triple A test for patients, and this needs turning into a list of factors for use with asthma	Thank you for your comment.

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					registers. Health Intelligence has developed a tool to run on practice computers that will identify the most high-risk patients. It is essential that any list of risk factors can be turned into an automated programme to identify the risk status of patients on GP registers, to be useful to primary care.	
186	SH	Primary Care Respiratory Society UK	4	100-102	As above - What is more of an issue than the evidence base, is what can be done to make self management support central to all contacts with patients. Many patients don't have self management plans in spite of the strength of evidence. So real value could derive from NICE looking at measures to embed self management support as the bedrock of asthma care. There is Grade A evidence for self management and this has been reviewed comprehensively by the SIGN/BTS asthma guideline in the recent update, which resulted in an expanded chapter, that importantly, was moved to the front of the guideline to emphasise its pre-eminent place in asthma management. It is questionable whether there is value to patients or clinicians in NICE doing this work all over again. No-one doubts the importance of this. Patients with long term conditions, such as asthma, spend on average 8756 hours a year managing their own condition and only between 1 and 4 hours in the presence of healthcare professionals.	Thank you for your comment. As above.
187	SH	Primary Care Respiratory Society UK	4	84	Should adherence not be mentioned specifically as a topic for investigation under Key areas that will be covered at 1.3?	Thank you for your comment. This change has been made.
188	SH	Primary	4	90	Should criteria for adjusting medication not be mentioned specifically as a	Thank you for your comment. This change

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		Care Respiratory Society UK			topic for investigation under Key areas that will be covered at 1.3?	has been made.
189	SH	Primary Care Respiratory Society UK	4	71/72	Other questions not included in the current scope include: <ul style="list-style-type: none"> - What is the cost of misuse of inhalers from patients not being taught to use them properly? - What is the most cost effective approach to a regular review? And what can NICE to do embed this in routine practice? - 	Thank you for your comment. These issues are outside the scope of this guideline.
190	SH	Primary Care Respiratory Society UK	4	100	As stated earlier – the time and resources it will take to review the large body of Grade A evidence on self management may be better spent on other aspects of self management support- such as how to embed it in routine practice.	Thank you for your comment. We agree – please see above.
191	SH	Primary Care Respiratory Society UK	4	110	Will NICE look into the evidence for the best tool for evaluating control? QOF currently mentions RCP 3 questions but as mentioned here, there are other options, and the Asthma Control test is used very widely.	Thank you for your comment. This is covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring.
5	SH	Roche	2	54	To ensure consistency with the NICE guideline on diagnosis and monitoring, we suggest that the scope is widened to include the stratification of patients based on 'airway inflammation measures'.	Thank you for your comment. We will consider stratification according to exacerbation risk. The committee will consider what predictors of exacerbation risk

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						to include when devising the protocol for this particular question.
236	SH	Royal College of Emergency Medicine	General	General	The Royal College of Emergency Medicine note that the scope does not include acute asthma. In the absence of acute asthma, where we feel our speciality has more involvement, we do not have any specific comments to add	Thank you for your comment.
58	SH	Royal College of General Practitioners	General	General	Further to (1) should there be a general look at where combination inhalers fit into the routine management as well as the place of changing dose to gain/regain control of symptoms. An explicit look at the role of "Maintenance and Reliever Therapies" with single inhaler?	Thank you for your comment. MART and SMART will be covered.
47	SH	Royal College of General Practitioners	2	48	.A different approach is needed in contrast to the therapy escalator which exists seeing many patients over treated but poorly controlled. Thus the component parts of a structured review need to be elaborated and deployed prior to treatment escalation e.g. <u>Prim Care Respir J</u> . 2013 Sep;22(3):365-73. doi: 10.4104/pcrj.2013.00075.'SIMPLES': a structured primary care approach to adults with difficult asthma. <u>Ryan D¹, Murphy A, Ställberg B, Baxter N, Heaney LG.</u> Note this approach would permit achievement of stratification of asthma by severity and identify those who needed specialist referral. It also subsumes the issuance of an SMP. Thus the approach should be an integrated structured review	Thank you for your comment. This is covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring (please see recommendation 1,3,7).

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					divided into it's constituent parts.	
48	SH	Royal College of General Practitioners	3	57	This is an error. The major area for improvement which presents itself is an improvement in care delivery with specific reference to patient education, inhaler technique and self management plans (SMP) SMP are covered in this scoping document but cannot be achieved with addressing the former two items and addressing the current knowledge and skills deficit which exists in both primary and secondary care	Thank you for your comment. Self-management plans will be assessed in the context of patient education (most studies include an element of education). Please note we have clarified in the scope that the aspects of non-pharmacological management that will not be covered are those outside of self-management and breathing exercises (which will be covered). Please also note that patient education will be covered in the review question on adherence.
49	SH	Royal College of General Practitioners	3	64	Adopting the approach suggested above may help achieve the financial gains made in Filand in their 10 year asthma programme which reduced costs while reducing morbidity. Failure to adopt a novel approach will produce the dismal results the urrent approach has achieved	Thank you for your comment.
50	SH	Royal College of General Practitioners	3	70	One of the failures of the current approach has been it's wholesale adoption by the health service which has eliminated clinical reasoning and the concept of Evidence based medicine, as espoused by Sackett, which suggests guideline informed , patient centred decisions rather than the guideline directed approaches which have been universally adopted	Thank you for your comment.
57	SH	Royal	3	75	I wonder whether there needs to be explicit reference made to the use or	Thank you for your comment. The drug

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		College of General Practitioners			not of combination LABA/ICS inhalers, with regard to both compliance, and also cost effective management.	comparisons will be decided by the committee.
51	SH	Royal College of General Practitioners	4	84	Subsumed and integral to the first comment made above	Thank you for your comment.
52	SH	Royal College of General Practitioners	4	92	As above	Thank you for your comment. As above.
53	SH	Royal College of General Practitioners	4	95	As above	Thank you for your comment. As above.
54	SH	Royal College of General Practitioners	4	99	As above	Thank you for your comment. As above.

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55	SH	Royal College of General Practitioners	4	106	Essential reading: A 10 year asthma programme in Finland: major change for the better. Haahtela T, Tuomisto LE, Pietinalho A, Klaukka T, Erhola M, Kaila M, Nieminen MM, Kontula E, Laitinen LA. Thorax. 2006 Aug;61(8):663-70.	Thank you for your comment.
56	SH	Royal College of General Practitioners	9	237	The views of the many stakeholders given at the scoping meeting was that they wished to have care delivery addressed. It is quite probable that the NICE methodology needs to be revised in order to make it fit for purpose. The current emphasis on taking evidence only from RCT's and elevating meta analysis to it's current lofty status, is flawed and has little relevance to day to day practice. Pragmatic trials and observational data have an important role to play: I would suggest that the team read and digest: The arch conference declaration. Helping to further the science of pragmatic research. Martin RJ, Chisholm AM, Price D. Ann Am Thorac Soc. 2014 Feb;11 Suppl 2:S83-4. doi: 10.1513/AnnalsATS.201308-256RM.	Thank you for your comment. The committee will decide what level of evidence will be appropriate to consider for each review question in the event of no RCT data. Recommendations are informed by the best available clinical evidence as well as the committee's expert clinical judgement of the evidence.
91		Royal College of Nursing			This is to inform you that the Royal College of Nursing have no comments to submit to inform on the above draft scope consultation.	Thank you for your comment.
192	SH	Royal College of Paediatric Health		1.1	There is a need to specify a lower age limit, rather than lumping all under 5s together, as the aetiology, assessment and response to therapeutic interventions vary (<2 and 2-5)	Thank you for your comment. Please see page 2 lines 38-41 of the consultation version of the scope for how we plan to stratify by age. The committee will consider your suggestion when agreeing the review protocols for each review question.

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193	SH	Royal College of Paediatric Health		1.3	A discussion on Biologics and BioSimilar is very relevant in a newly produced guideline today. Even though limited by cost, some details should be included. There will be an overlap with the 2013 guidance, but this guideline is due to start from 2017.	Thank you for your comment. The guideline will make reference to the NICE technology appraisal guidance TA278 as opposed to re-reviewing the evidence for omalizumab.
194	SH	Royal College of Paediatric Health		1.4	Vital to look at the economic aspects of the use of Omalizumab in tertiary care	Thank you for your comment. The guideline will make reference to the NICE technology appraisal guidance TA278 as opposed to re-reviewing the evidence for omalizumab.
195	SH	Royal College of Paediatric Health		1.5 line 75	Include, "with best safety profile"	Thank you for your comment. Drug safety will be considered - adverse events is listed as a critical outcome.
196	SH	Royal College of Paediatric Health		1.5 line 85	Include "nurse-led consultations", "school-based asthma education and training": for both children and teachers, "asthma camps for teenagers",	Thank you for your suggestions which will be considered by the committee when devising review protocols.
197	SH	Royal College of Paediatric Health		1.5 line 102	A short-term (up to 2 weeks) doubling of ICS for temporary worsening of symptoms, with either a return to previous dose thereafter, or a review (phone/clinic)	Thank you for your comment. The answer to this will be informed by the clinical and cost effectiveness evidence review; we cannot pre-empt the conclusions.
198	SH	Royal College of Paediatric Health		1.6	To include: school absences per term; risk-taking behaviour, including smoking and drugs	Thank you for your comment. The outcomes listed in the scope are those critical for decision making. Other additional outcomes will be decided by the committee during

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						protocol development.
199	SH	Royal College of Paediatric Health		1.3, line 50	The guideline will, other than exceptionally, stick with licensed indications (and I presume doses). This can be unnecessarily restrictive, particularly with Salbutamol where licensed dose is 2 puffs four times a day. The BNF(C) has good advice on appropriate doses and this should be made clear in guidance. In particular, if the same guidance is intended for parents/patients as well as professionals, the licensed doses might cause users (parents/patients) to worry about or modify their treatment inappropriately. This may also lead to unnecessarily high rate of request for referral to tertiary centre for confirmation that appropriate for dose to be different to that in license,	Thank you for your comment. This is standard text. NICE recommendations that are off-label will be clearly indicated by a footnote.
200	SH	Royal College of Paediatric Health		1.3 line 56	List of areas not covered by guideline includes non-pharmacological management of asthma. If this includes issues such as environmental clearance, pets, foods, allergies, etc then this is a lost opportunity to educate parents/patients/professionals on value of such interventions and links. I think this should be included, as they are commonly asked questions by affected families.	Thank you for your comment. We acknowledge that non-pharmacological management is an important part of asthma care; however we consider this topic is well covered by existing guidance and therefore not a priority area for inclusion in this guideline as a formal review of the evidence is unlikely to suggest that anything different from current advice should be recommended, for example, allergen avoidance. Please note we have clarified in

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						the scope that the aspects of non-pharmacological management that will not be covered are those outside of self-management and breathing exercises (which will be covered).
201	SH	Royal College of Paediatric Health		1.5 line 92	The guideline will include advice on when to refer to tertiary care; there is no mention of 'when to refer to secondary care'; this should be included for primary care practitioners.	Thank you for your comment. We have removed the question on referral criteria to tertiary care for severe, difficult to treat asthma.
202	SH	Royal College of Paediatric Health		General	This guideline apparently won't cover the diagnosis of asthma. This is an important area, particularly in small children where it's now wrongly diagnosed as being present more often than being missed as a diagnosis. There should be reference in this guideline to any such separate guideline (on diagnosis of asthma at all ages) or this guideline should include it. Otherwise someone who hasn't got asthma and been diagnosed with it risks having their treatment escalated rather than reconsider diagnosis.	Thank you for your comment. Diagnosis of asthma is covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring; please see page 6 line 160 of the consultation version of the scope where this guideline is listed.
106	SH	Royal College of Physicians	2	36	Age range (<5, 5-12, 12-16, 16+) as few clinical trials tend to use age 12 as cut off point	Thank you for your comment. Please see page 2 lines 38-41 of the consultation version of the scope for how we plan to stratify by age.
107	SH	Royal College of Physicians	3	83	Mild intermittent asthma (LAMA is not for this level of asthma)	Thank you for your comment. We are not clear what this comment relates to.

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		s				
108	SH	Royal College of Physicians	4	101	SMART or MART therapy styles need to be considered	Thank you for your comment. These will be considered.
110	SH	Royal College of Physicians	4	107	Adherence (to focus on how to diagnose and manage it)	Thank you for your comment. This is covered in a review question and is not a critical outcome.
109	SH	Royal College of Physicians	5	120	Assessing risk of exacerbation (important area to cover)	Thank you for your comment. This will be covered.
247	SH	Royal Pharmaceutical Society	General	General	The Royal Pharmaceutical Society is happy to endorse the UKCPA Respiratory Group response to the NICE consultation on the asthma management guidance scope as attached.	Thank you for your comment.
30	SH	Sanofi	3	58	Please can you provide clarification/reconsider as to why biologic medicines will not be covered in these guidelines given that other pharmacological management options are to be included?	Thank you for your comment. The guideline will make reference to the NICE technology appraisal guidance TA278 as opposed to re-reviewing the evidence for omalizumab.
111	SH	St Johns Ambulance	2	44	The settings still do not specifically include NHS commissioned care given provided by independent ambulance services.	Thank you for your comment. We propose to exclude acute asthma and therefore ambulance services is not specifically listed.

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112	SH	St Johns Ambulance	3	55	<p>SJA Chief Medical Officer Louis Lillywhite commented that <i>'whilst it covers self-management, it does not cover the management of acute asthma attacks.'</i> This does not appear to be as inclusive as it should be as self-management must surely include what to do in an acute attack.</p> <p>Another of our senior medical colleagues added that <i>'The exclusion of 'management of acute attacks' and 'service delivery for acute attacks' significantly limits the aspects that will be relevant to SJA. We might be able to give support to people for their 'Self- management (personal asthma action plan) but I think that would be about it.'</i></p> <p>At the stakeholder workshop, it was mentioned that acute asthma attacks might be covered in another NICE guideline or standard and that if it were not then consideration would be given to its inclusion here; the NICE acute medical emergencies guideline, (publication expected in November 2016) in particular was discussed. It would be important to provide assurance that management of acute asthma attacks is being included in this guideline to stakeholders so that they may communicate this to others in their organisations.</p>	<p>Thank you for your comment. We acknowledge that the management of acute asthma is an important issue, however we feel this topic is covered well by existing guidance and therefore not a priority area for inclusion in this guideline. Regarding your point about acute asthma being part of personal asthma action plans, we have clarified in the scope that the guideline will not cover management of acute asthma by 'a healthcare professional' and therefore does not preclude self-management of acute asthma.</p> <p>Regarding your last point about the forthcoming Acute Medical Emergencies guideline, we can confirm that service delivery guidance relating to acute medical emergencies including asthma attacks will be covered in this guideline. Development of this guideline can be followed on the NICE website at this link: http://www.nice.org.uk/guidance/indevelopment/gid-cgwave0734/documents</p>

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113	SH	St Johns Ambulance	4	92	One of our senior medical colleagues stated that ‘The section on 'Indications for referral to tertiary care' refers to a more chronic clinical situation than we are likely to come across in SJA although I suppose we might be able to advise patients about talking to their GP for a further review.’ Again this will not support or guide our personnel providing commissioned services to the NHS to take appropriate actions in referring patients they care for with asthma.	Thank you for your comment.
34	SH	Teva UK		general	Real world evidence should be considered rather than just studies (RCT's) used proving efficacy and used in licensing of medicines	Thank you for your comment. The committee will decide what type of evidence will be appropriate to consider for each review question in the event of no RCT data. Recommendations are informed by the best available clinical evidence as well as the committee's expert clinical judgement of the evidence.
35	SH	Teva UK		general	There should be a focus on adherence / compliance with treatment regimens	Thank you for your comment. Please see page 4 lines 85-86 of the consultation version of the scope.
36	SH	Teva UK		general	Comparison of inhaler devices should not be excluded	Thank you for your comment. Comparison of devices is confounded by differences in the contained agent and its dose and whatever such a comparison shows the emphasis will always be on ensuring that the individual

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						patient is able to use the chosen device, We therefore do not think that a detailed comparison of the numerous available devices is an appropriate use of the resources available for this guideline. Please also note that as part of the review question on inhaler technique in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring, a literature search was undertaken for RCT evidence comparing the outcomes of checking inhaler technique vs. not checking and no relevant RCT evidence was found.
37	SH	Teva UK		general	Severe, difficult to control asthma should be included	Thank you for your comment. Guidance on the management of people with severe, difficult to control asthma will be given if pertinent evidence is found for this population.
38	SH	Teva UK		general	Severe, IGE, eosinophilic asthma definitions should be included	Thank you for your comment. These will be defined in the full guideline, not in the scope.
39	SH	Teva UK		general	ACOS – Asthma COPD overlap syndrome should be included	Thank you for your comment. This is outside the remit of this guideline.
31	SH	Teva UK	2	34	Groups should reflect licenses for medicines, so <5, 5-12, 12 – 18, 18 and above	Thank you for your comment. Please see page 2 lines 38-41 of the consultation

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						version of the scope for how we plan to stratify by age.
32	SH	Teva UK	3	56	Inclusion of specifics on devices is key as this is an extremely important component in the management of asthma. Nice guidance in this area is only for below 15 years and also is 13 years or more old and there have been many devices launched since then – with many studies highlighting the importance of errors and correct technique with regard to the devices used. There has been no guidance for over 15 years old and adults	Thank you for your comment. See answer to your point above (no. 36)
33	SH	Teva UK	3	56	Severe asthma should be included and other biologicals are likely to be licensed in the time frame of the development of this guidance	<p>Thank you for your comment. Guidance on the management of people with severe, difficult to control asthma will be given if pertinent evidence is found for this population.</p> <p>Regarding your point about new biologics becoming licensed in this guideline's development timeframe, should this be the case then NICE's likely contribution would be to review the evidence via the Technology Appraisal process in the first instance.</p>
74	SH	United Kingdom Clinical Pharmacy Association	3	58	We would question why biologics such as omalizumab will not be considered within the scope of this guideline. Although NICE TA 278 covers omalizumab, there should be some consideration within the context an asthma management guideline.	Thank you for your comment. The guideline will make reference to the NICE technology appraisal guidance TA278 as opposed to re-reviewing the evidence for omalizumab and it will be included in the NICE Pathway.

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		n Respiratory Group				
75	SH	United Kingdom Clinical Pharmacy Association Respiratory Group	3	59	<p>It is surprising that there is planned to be no comparison of drug-delivery devices (inhalers). This is a significant omission, as a large number of licensed asthma treatments are inhaled therapies. There should be some consideration of inhaler devices, as different inhaler devices are useful for different patients.</p> <p>Additionally, there should be some clear evidence statements on the importance of ensuring consistent prescribing of inhaler devices through brand name prescribing.</p> <p>We note that on line 122, that NICE technology appraisal guidance TA10 considered the use of inhaler devices in children under 5 years. This is now out of date as there are many new inhaler devices available. Furthermore, there are no guidance or technology appraisal available in other age groups.</p> <p>There should be consideration of:</p> <ol style="list-style-type: none"> 7. Ease of use of different inhaler devices by age group. 8. Impact of inhaler technique on asthma control. 	<p>Thank you for your comment. Comparison of devices is confounded by differences in the contained agent and its dose and whatever such a comparison shows the emphasis will always be on ensuring that the individual patient is able to use the chosen device, We therefore do not think that a detailed comparison of the numerous available devices is an appropriate use of the resources available for this guideline. Please also note that as part of the review question on inhaler technique in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring, a literature search was undertaken for RCT evidence comparing the outcomes of checking inhaler technique vs. not checking and no relevant RCT evidence was found.</p>

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Asthma Management

Consultation on draft scope Stakeholder comments table

15/04/2015-13/05/2015

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

ID	Type	Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					9. Proportion of patients and healthcare professionals that can use different inhaler devices. 10. How inhaler technique should be taught. 11. Frequency that inhaler technique should be assessed and reinforced.	
76	SH	United Kingdom Clinical Pharmacy Association Respiratory Group	3	74	The pharmacological management of chronic asthma contains significant omissions surrounding choice of inhaler device. The management of asthma is not only influenced by drug choice, but also by the inhaler device. Cost effectiveness should take into account: (i) cost of drug; (ii) cost of device; (iii) percentage of patients likely to be able to use the device effectively. This is a major omission, as prescribing an inhaler device that is difficult to use is not cost effective.	Thank you for your comment. As above.
77	SH	United Kingdom Clinical Pharmacy Association Respiratory Group	4	84	Adherence to Pharmacotherapy, should not only consider how to improve adherence, but also how to identify non-adherent patients, in particularly the accuracy of different measurement tools (e.g. prescribing data, pharmacy dispensing records, questionnaires etc)	Thank you for your comment. This is covered in the forthcoming NICE guideline on Asthma Diagnosis and Monitoring.
78	SH	United	4	84	Any section on adherence, should not only concentrate on intentional	Thank you for your comment. As above -

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		Kingdom Clinical Pharmacy Association Respiratory Group			nonadherence (i.e. failing to take medication), but also unintentional nonadherence through poor inhaler technique, which is known to adversely affect asthma control.	strategies to improve adherence are all-encompassing and this review question will cover both intentional and non-intentional poor adherence.
79	SH	United Kingdom Clinical Pharmacy Association Respiratory Group	4	95	Stratification of asthma care should be made according to validated measure of asthma controls, in addition to any measures of exacerbation risk.	Thank you for your comment. The committee will consider this on the best available evidence.
80	SH	United Kingdom Clinical Pharmacy Association	4	106	An important outcome measure should be a measure of improvement in inhaler technique.	Thank you for your comment. We do not feel this is a critical outcome for all review questions.

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		Respiratory Group				

Registered stakeholders who did not respond were:

Aintree University Hospital NHS Foundation Trust
Alder Hey Children's NHS Foundation Trust
Allocate Software PLC
Association of Ambulance Chief Executives
Association of Anaesthetists of Great Britain and Ireland
Association of Chartered Physiotherapists in Respiratory Care
Association of Respiratory Nurse Specialists
Bedfont Scientific Ltd
Belfast Health and Social Care Trust
BOC Healthcare

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**Boehringer Ingelheim
British Association for Community Child Health
British Medical Association
British Medical Journal
British Nuclear Cardiology Society
British Paediatric Respiratory Society
British Psychological Society
British Red Cross
British Society for Allergy & Clinical Immunology
Caplond Services
Care Quality Commission
Chartered Society of Physiotherapy
CLEAR Cannabis Law Reform
Clementine Churchill Hospital
Department of Health
Department of Health, Social Services and Public Safety - Northern Ireland
Dr Pathak & Partners
East Riding of Yorkshire Council
Education for Health
Gloucestershire Hospitals NHS Foundation Trust
Greater Manchester, Lancashire and South Cumbria Strategic Clinical Network
Guy's and St Thomas's NHS Trust
Halton Fibromyalgia Support Group
Health and Care Professions Council
Health and Social Care Information Centre
Healthcare Improvement Scotland
Healthcare Quality Improvement Partnership
HQT Diagnostics**

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**Humber NHS Foundation Trust
Intermedical
Lancashire Care NHS Foundation Trust
Liverpool University
Meda Pharmaceuticals Limited
Medicines and Healthcare Products Regulatory Agency
Ministry of Defence
Muslim Doctors and Dentists Association
National Clinical Guideline Centre
National Collaborating Centre for Cancer
National Collaborating Centre for Mental Health
National Collaborating Centre for Women's and Children's Health
National Deaf Children's Society
National Institute for Health Research
NHS Bedfordshire CCG
NHS Chorley and South Ribble CCG
NHS Eastbourne, Hailsham and Seaford CC
NHS Havering CCG
NHS Health at Work
NHS North East Lincolnshire CCG
NHS Sheffield CCG**

**NIHR CCRN ENT Specialty Group
North West Severe Asthma Network
Northern Health and Social Care Trust
Nottinghamshire Healthcare NHS Trust
Nursing and Midwifery Council**

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**Public Health England
Public Health Wales NHS Trust
Royal College of Anaesthetists
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Pathologists
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Speech and Language Therapists
Royal College of Surgeons of England
Royal Cornwall Hospitals NHS Trust
Royal Wolverhampton Hospitals NHS Trust
Sandoz Ltd
Scottish Intercollegiate Guidelines Network
Sheffield Children's NHS Trust
Sheffield Teaching Hospitals NHS Foundation Trust
Social Care Institute for Excellence
Society for Acute Medicine
South Eastern Health and Social Care Trust
South Western Ambulance Service NHS Foundation Trust
Southern Health & Social Care Trust
Staffordshire and Stoke on Trent Partnership NHS Trust
Surrey Downs CCG
The Firs
The Practice Lincoln Green Medical Centre
University Hospital Birmingham NHS Foundation Trust
University Hospital Of South Manchester NHS Foundation Trust**

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**Wandsworth Borough Council
Welsh Government
Welsh Scientific Advisory Committee
Western Health and Social Care Trust
Yorkshire and Humber Strategic Clinical Network**

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