Asthma Management
Workshop

Wednesday 25 March 2015, 1000-1300
Avonmouth House, 6 Avonmouth Street, London SE1 6NX

Group discussion notes

The workshop was held in addition to the formal consultation on the draft scope, which is taking place from 15 April to 13 May 2015. The objectives of the scoping workshop were to:

- obtain feedback from the representatives of stakeholder organisations on the specified population and key areas included in the first draft of the scope
- seek views on the proposed composition of the guideline committee (GC)
- encourage applications for GC membership.

The scoping group (NCGC technical team, NICE staff and GC Chair and early GC member) presented a summary of the guideline development process, the role and importance of patient representatives, the process for GC recruitment, the proposed constituency for the GC and the draft scope. The stakeholders were then divided into five subgroups which included a facilitator and scribes. Each subgroup had a structured discussion based around pre-defined questions on the draft scope and proposed GC composition. Comments received from each discussion subgroup are summarised below.

Scope section	Comments
Relationship to the BTS/SIGN guideline on asthma management NICE aims to produce a comprehensive algorithm for management of chronic asthma that can be used without reference to the BTS/SIGN guideline on asthma management. NICE is not aiming to replace the BTS/SIGN guideline on asthma management in its entirety.	Overall there was agreement from stakeholder representatives that this is a pragmatic way to approach development of the NICE guideline in relation to the BTS/SIGN guideline. However, some stakeholders highlighted the challenges as the BTS/SIGN guideline is fairly comprehensive in all areas and it will be difficult to have another guideline recognised as the 'gold' standard across every aspect of asthma management. A number of stakeholders advised that the differences between the two

	guidelines, and the reasons for the differences, should be highlighted to enable clinicians to make a judgement about which recommendations to follow. Some doubt was expressed about the reality of the NICE guideline being used as 'standalone' without reference to BTS/SIGN, and having two guidelines may result in clinicians 'cherry picking' aspects from both. There was some concern about the potential of having multiple conflicting guidelines which would cause confusion among untrained staff reliant on following guidelines. It was felt that NICE should work with BTS/SIGN to avoid this. One group raised a concern that the dichotomy of 'acute asthma' vs. 'chronic asthma' is incorrect. Rather, there is a spectrum between the two and people at the margins should be taken into account. Some stakeholders welcomed the prospect of a new guideline as there are still many people with asthma who are not being managed properly even with the comprehensive BTS/SIGN guideline. The stepped approach needs to be revisited; for example, it was questioned whether step 1 using SABA alone should exist, and the best treatment to add-on in step 4 is still the subject of debate. Furthermore, there was recognition from stakeholders that an important feature and added value of the NICE guideline is consideration of cost-effectiveness which would be welcome guidance.
Section 1.1 Who is the focus? **Groups that will be covered:** • Adults, children and young people with a diagnosis of asthma. • Specific consideration will be given to subgroups based on age: i. children under 12; people over 12 OR	There was a range of opinions on the best age groupings. Stakeholders agreed that it is important to separate adolescents from adults and from younger children. Also that under 5 years should be considered separately.

ii. children under 5 years; children 5-16; adults and young people aged 16 and older OR iii. children under 5 years; children 5-12; adults and young people aged 12 and older.	There was acknowledgement that it was once the norm to stratify by under 12s and over 18s; but things have changed and new trials are putting adolescents and children into different categories, such as under 5 years, and over 18 years, but without stratifying by age 12 etc. Consideration of product licensing for ages will be important as drug companies will only get a licence for age groups they have proven studies on. One group suggested that different age thresholds for different questions should be adopted according to the evidence and clinical practice.
Section 1.2 Settings that will be covered: All primary, secondary, tertiary and community care settings where NHS healthcare is provided or commissioned	There was consensus that these settings are appropriate to include. One group advised that pharmacist-prescribing will be important to consider.
Section 1.3 Key areas that will be covered: 1 Pharmacological management of chronic asthma 2 Non-pharmacological management of chronic asthma 3 Assessing risk of exacerbations	Overall there was general agreement that these are the key areas to include. One group felt that there are current concerns about overtreatment due to the current structure of the patient care pathway in the BTS/SIGN guideline. Conversely there was a view from another group that the BTS/SIGN guidance covered pharmacological management sufficiently. A number of groups had strong views that self-management should be included. It was felt that the NICE guideline should put a greater emphasis on patient-centred asthma management, for example patient self-management, patient self-care plan (including effectiveness of mobile phone apps) and planned review. One group also thought that education of healthcare professionals providing asthma care (assessment on a competency basis) and patient education should be considered, for example education on asthma, inhaler techniques,

	etc.
Areas that will not be covered: 1 Omalizumab 2 Comparison of inhaler devices 3 Allergen avoidance devices (for example Airsonett air filter) 4 Thermoplasty 5 Severe, difficult to control asthma 6 Acute asthma 7 Service delivery for acute asthma attacks 8 Complications of smoking in the management of people with asthma	There was a range of opinions on the appropriate areas to exclude. Some groups agreed that omalizumab, should be excluded whereas others thought it should be included. One group suggested it should be re-worded more generally to 'biologics'. Some groups agreed that comparison of inhaler devices should be excluded on a practical basis (new inhaler devices appear on the market every few months), whereas some groups felt inhaler devices should be covered as new developments in technology might not be covered by a NICE Technology Appraisal and that a clear comparison between inhaler devices is needed. One group suggested 'inhaler devices' should be re-worded more generally to 'drug-delivery' devices. Some groups agreed that allergen avoidance devices should not be covered whereas other groups thought that they are an important part of allergen avoidance and need to be considered if covering a question on allergen avoidance. There was consensus from all but one group that thermoplasty should be excluded. There was consensus from all but one group that severe, difficult to control asthma should not be excluded and should be covered as guidance is needed on how best to identify this population/what are the referral criteria. This is currently a 'hot topic' with a lot of big drug trials in the pipeline which NICE should not miss out on. Some groups agreed that acute asthma should be excluded whereas other groups felt that it should be included. One group noted that it may be

	difficult to draw a line between chronic and acute asthma. Some groups agreed that service delivery for asthma attacks should be excluded if this area is sufficiently covered in the NICE Acute Medical Emergencies guideline. However, other groups thought it should be covered in the Asthma Management guideline as the seriousness of asthma needs to be highlighted and also that follow-up after discharge needs to be considered. It was noted that management after discharge is included in the NICE Quality Standard for Asthma; stakeholders advised that NICE should ensure that management after discharge is not deleted from the Quality Standard if there is a future update based on the guideline. There was a range of opinions about whether the complications of smoking should be excluded or included. Some groups agreed that smokers with asthma are more likely to have poor control and poor compliance and need to stop smoking before any other advice can be given. Whereas other groups felt that smokers with asthma are an important group to include because people who smoke are over-represented in hospital admissions. Smoking cessation could impact a person's stepped-approach management and so this aspect cannot be excluded. Other stakeholders felt that the problems of smoking are general and not specific to asthma and therefore should be addressed by other means. However, there are concerns about the effect of passive smoking which should be covered. Stakeholders suggested that smokers should be added as subgroup and other relevant guidance should be cross-referred to if possible. Stakeholders felt that the existing guidance on smoking cessation is not utilised or implemented enough. Regarding non-pharmacological management of occupational asthma, there was agreement that this area could be excluded but that the guideline

	should link to the BTS/SIGN for awareness of occupational asthma. One group thought that an 'all or nothing' approach was best so if the guideline is not covering everything, then it should be excluded. Regarding pregnant women with asthma, there was consensus from all groups that this should be covered because there is a clear need as currently it is poorly managed and there is a lot of room for education. Stakeholders felt that this is an area that the NICE guideline could add value. In addition, there were very strong arguments from some stakeholders for inclusion of smoking in pregnancy and asthma, because the current guidance is very vague and ad hoc and GPs would welcome concrete guidance on this.
Section 1.5 Key issues and questions **Pharmacological management of chronic asthma** ***Mild intermittent asthma*** 1 What is the most clinical and cost effective drug or combination of drugs for the management of mild intermittent asthma: • SABA alone • SABA + regular/continuous low dose ICS • SABA + intermittent ICS • SABA + intermittent ICS + LABA • SABA + leukotriene antagonists • Long-acting muscarinic receptor antagonists.	In general, all groups agreed that this question was important to include but strong concerns were raised about the stratification of asthma as mild/moderate (according to GINA). Stakeholders suggested that mild/moderate needs to be replaced by controlled/uncontrolled. There was concern that drawing this dichotomy ignores the BTS/SIGN stepwise programme, also that people can be on many drugs but considered 'mild'. It was noted however that stratification was not done on the basis of the BTS/SIGN steps as these may not be correct. Some stakeholders suggested that the stratification can be based on ICS and driven by the evidence. There were differing views on whether LAMAs should be included; most stakeholders thought it should be removed whereas a few felt it should be included. Many stakeholders agreed that LAMA alone would never be used. One group noted that 'leukotriene' on its own is incorrect.

	Also that there is good evidence for sodium cromoglycate and nedocromil, so these should be considered. One group raised that 'intermittent' and 'low dose' need to be defined. One group expressed concerns about the use of SABA as step 1; people often over-rely on SABA which quickly deals with immediate symptoms but not long-term ones and suggested that this question should not refer to SABA as a starting point.
Mild persistent asthma 1 What is the most clinical and cost effective drug or combination of drugs for the management of mild persistent asthma: • SABA + regular/continuous low dose ICS twice daily • SABA + intermittent ICS • SABA + intermittent ICS + LABA • SABA + leukotriene • SABA + frequent low dose ICS + rapid onset LABA • SABA + oral theophylline • Long-acting muscarinic receptor antagonists	In general, all groups agreed that this question was important to include but again strong concerns were raised about the stratification of asthma as mild/moderate dichotomy. One group felt that SABA + oral theophylline should be excluded as this is the next step of severity and is not currently done in practice. Also that LAMA alone should be removed as this would never be used alone but maybe with ICS.

Moderate persistent asthma 1 Which is the optimum sequence in which to add agents to low dose ICS when these fail to provide adequate control: • LABA • long-acting muscarinic receptor antagonists • leukotriene receptor antagonists • oral theophylline/aminophylline?	In general, all groups agreed that this question was important to include but again strong concerns were raised about the stratification of asthma as mild/moderate dichotomy. One group suggested adding to the sequence a high dose of ICS alone. Some groups also suggested adding sodium cromoglycate. One group advised that low dose ICS and high dose ICS need to be defined. Also that people starting on high dose would need to be considered in a separate review from people starting on low dose. Stakeholders advised that LABA alone would never be used.
All symptom levels of severity 1 In people who are not on ICS treatment who present with an exacerbation, is initial high dose ICS more clinically and cost effective than initial low dose ICS? 2 Do leukotriene receptor antagonists, LABA, sodium cromoglycate, oral beta-2-agonists and oral theophylline reduce asthma symptoms during exercise in people with exercise-induced asthma?	There was general agreement from all groups that both questions may be a lower priority for inclusion. Some groups agreed that the alternative question *"Are you better to start with low dose ICS, high dose ICS, or LABA/ICS*?" would be better. One group advised that for people with exercise-induced asthma LABA alone would never be used. One stakeholder had the view that monitoring of exercise-induced asthma should be included. Another group pointed out that there is already a Cochrane review on treatment for exercise-induced asthma which shows most treatments work and questioned if this doing this review would add value.
Adherence to pharmacological therapy 1 What are the most clinically and cost effective strategies to improve medicines adherence using inhaler devices in asthma (for example structured patient information and education)?	There was universal consensus from all groups that adherence is a very important question to include. Some groups suggested adding adherence to self-management, but some

	stakeholders acknowledged that this would perhaps make the review question too large. Another group wanted a review of adherence strategies to all asthma medication, not just inhalers, but acknowledged that inhalers are probably the biggest issue regarding poor adherence, but that pill burden is also a barrier to adherence in acute asthma. One stakeholder felt that smart inhalers and counters should be considered in this review question. One group felt that a preceding question was needed "*How do you recognise poor adherence*?" and then a follow-up question "*What is the effect of different devices on adherence*?" One group thought that the question "*Does once or twice daily make a difference to adherence*?" should be reviewed. One group felt that strategies to improve medicines adherence to inhalers are not 'structured patient information and education' as these are separate issues and that self-management interventions should be included here. Another group wanted poor adherence in smokers and people with co-morbid mental health conditions to be included.
Review of pharmacological therapy 1 What are the clinical features (symptoms and/or objective measurements) which indicate that a step up or step down in treatment is appropriate?	There was agreement from all groups that this is an important question to include, but there was a range of views on whether this question should be confined to only looking at indications for stepping down treatment. Some groups agreed that advice for stepping down is currently needed and may be prioritised over stepping up. However, other groups felt there are concerns that patients are often unnecessarily stepped up and that clearer guidance is needed to help decisions about stepping up.

	Furthermore that this question should look into the magnitude of the step up (e.g. is more than twice better than twice?). Also, that the guideline should be clear about if the GP or the patient themselves are making the change. Stakeholders raised concerns about the amount of evidence that would be available to give guidance on stepping down.
Non–pharmacological management of chronic asthma 1 What is the clinical and cost effectiveness of allergen avoidance (for example, elimination of house dust mites) to improve asthma control? 2 What is the clinical and cost effectiveness of breathing retraining in people with asthma +/- dysfunctional breathing (for example cognitive behaviour therapy or psychological support)?	There was a range of opinions about whether this is an important area to include. Some groups agreed that neither question are a priority, in particular, the first question on allergen avoidance is well covered in the BTS/SIGN guideline. Other groups agreed these two questions are important to include and also should be expanded to include other aspects of non-pharmacological management, for example diet, nutrition and lifestyle as factors because in one stakeholder's opinion some people are self-managing effectively with omega 3 fatty acid, vitamin D and vitamin E supplements. This stakeholder also advised that confining non-pharmacological management to 'chronic' asthma should be deleted because this is managed in secondary care; however other group members disagreed with this view and advised that much of chronic asthma is dealt with in primary care. Another group felt that this guideline should be a non-pharmacological guideline as the BTS/SIGN guideline is too drug-focused. It was suggested that the NICE guideline should focus on non-pharmacological management i.e. training, assessing risk, how to engage with asthma patients. Another group felt that an 'all or nothing' approach was best and that if covering non-pharmacological management all strategies would need to be

	reviewed and not just these two areas. Furthermore that the question on breathing retraining would need rewording for clarity because the examples given are not breathing retraining. In reality, patients would go straight to physiotherapy.
Assessing risk of exacerbations 1 What is the clinical and cost effectiveness of asthma care (for example referral) delivered according to stratification of risk of exacerbations in a risk register to improve outcomes for people with asthma?	There was universal consensus from all groups that this was an important question to include because this is not covered in the BTS/SIGN guideline and the NICE guideline has potential to add value here. Stakeholders felt that risk scores would be very powerful, and would move away from just a stepped ladder approach like in the BTS/SIGN guideline. A severity score might actually aid the understanding of the stepped approach. One group wanted the question to be expanded to address organisational care. Another group felt this question should be linked to strategies for differential management of higher risk patients including earlier referral to specialist care. Another group advised that validated risk tools should be included. One stakeholder advised the question needed re-wording for clarity. Another group expressed the need for guidance on how to address patients with different levels of risk. They mentioned the following high risk patients: • Patients with use of high quantity of steroids • Patients with exacerbations • A&E admissions • Hospital admission

	• Obese people.
Section 1.6 Main outcomes 1 Quality of life (both health- and social-related quality) 2 Asthma control assessed by a validated questionnaire (for example the Asthma Control Questionnaire) 3 Exacerbations 4 Unscheduled healthcare utilisation 5 Mortality	There was general consensus from all groups that these are the main outcomes. One group wanted lung function to be added. It was also noted that the definition of exacerbations will vary between the trials. Two groups pointed out that safety should be an outcome, such as specific adverse events (cardiovascular events), hospital admissions, safety of steroids in adolescents, etc. Another group suggested the following additions: • Lung function • Airway inflammation • Inhaler technique • Overprescribing e.g. excessive beta-2 use, antibiotics and oral corticosteroids
Section 2.1 Related NICE guidance • Patient experience in adult NHS services (2012) NICE guideline CG138	Two groups agreed that the patient experience for children will be different from adults and so should be included if the patient experience guideline covers adults only. The child and family's quality of life are important considerations.
Are there any critical **clinical** issues that have been missed from the Scope that will make a difference to patient care?	One group raised the importance of looking at the best way of managing medicines and other forms of support; self-management (and possibly psychological support) should be included in the guideline; even if action plans are covered by the BTS/SIGN guideline, they should be considered in this guideline too - either as an assumption underpinning all questions, or as a separate review question. One group wanted the management of asthma while breastfeeding to be included in relation to drug issues.

	One group wanted clear guidance on when to refer to specialist care (and when they feedback from this), as this may not be picked up by exacerbations. One group wanted level of skills/knowledge of healthcare professionals providing asthma care, including the role of the pharmacist in ensuring correct use of inhalers, providing information etc to be included, as well as self-management and patient education, the role of asthma charities which are important to help to create self-management plans and run patient support groups.
Are there any areas currently in the Scope that are **irrelevant** and should be deleted?	One group advised that the following areas are irrelevant and should be deleted from the scope: 1. Allergy avoidance 2. Occupational Asthma 3. Organisation of care 4. Exercise-induced asthma 5. Pregnancy
Are there areas of **diverse or unsafe practice** or uncertainty that require address?	One group advised that when to step up/down is currently diverse and unsafe clinical practice. The NICE guideline should focus on the frequency of symptoms and specific symptoms as an indicator.
Which area of the scope is likely to have the most marked or biggest health implications for patients?	One group advised adherence would have the biggest impact on patient health.
Which practices will have the most marked/**biggest cost** implications for the NHS?	One group advised that breathing retraining would represent the biggest cost impact on the NHS, as it is currently under-funded and under-staffed.
Are there any **new practices** that might **save the NHS money** compared to existing practice?	One group advised that improved adherence would save the NHS money on resource use and also patient education indirectly through, for example, reduced exacerbations.
If you had to delete (or de prioritise) two areas from the Scope what would they be?	One group suggested the following areas should be de-prioritised and deleted from the scope:

	1. Allergy avoidance 2. Occupational Asthma 3. Organisation of care 4. Exercise- induced asthma 5. Pregnancy One stakeholder felt that pharmacological interventions could be de-prioritised and removed, but the rest of the group did not agree with this view.
As a group, if you had to rank the issues in the scope in order of importance what would be your areas be?	One group suggested the order of importance as: 1. Aspects of service delivery/delivery of care including knowledge and skills of healthcare professionals and patients in inhaler training, structured annual review, self-management plan, clinician training 2. Adherence 3. Use of stepwise approach. Another group felt that adherence, especially in young people, was the number one priority.
Any comments on guideline committee membership? **Full members** Chair x1 Adult Respiratory Physician x2 Paediatrician in Respiratory Medicine x1 Adult Specialist Respiratory Nurse x1 Paediatric Specialist Respiratory Nurse x1 Practice Nurse x2 General Practitioner x2 Pharmacist x1 Patient/carer member x2 **Co-opted expert witnesses**	There was general agreement with the guideline committee composition. One group suggested that a psychologist should be recruited for the non-pharmacological, adherence to therapy, patient information and education aspects of the guideline. One group wanted an equal balance between paediatric and adult members, and primary and secondary care and suggested recruiting four patient members to represent the adolescent patient and/or parent. Also that the emergency medicine physician and acute physician could be removed if not covering acute asthma.

Emergency Medicine Physician x1 (If covering acute asthma) Acute Physician x1 (If covering acute asthma) Allergologist/Allergist x1 (If covering allergen avoidance) Physiotherapist x1 Mental Health Professional x1 Service transformation/Change management/Implementation science Expert x1	One group felt that two practice nurses were too many and one would suffice. One group thought that the pharmacist should be specified as 'non-retail', and should be a medicine-management pharmacist. One group suggested the following additions: • A member of the BTS/SIGN guideline • A member from industry • A charity representative • A community representative.
Are there any areas that you think should be included for the purposes of the quality standard? Are there any service delivery or service configuration issues that you think are important?	One group advised that this will be unknown until the evidence is clear.
Other issues raised during subgroup discussion for noting.	One stakeholder queried why the guideline would look at the same combinations across different steps and severity of asthma? How long should therapy be trialled for, before moving onto different treatment? Two stakeholders stressed the importance of including observational studies in providing 'real world evidence' that they felt RCTs could not, due to natural variation in patient inhaler capabilities and lack of/poor training.

A representative from each subgroup fed back the key points discussed. The workshop was closed with an outline of the next steps. Attendees were reminded of the dates for consultation on the draft scope and GC member recruitment. Further written comments on the draft scope and applications for GC membership were encouraged.