Public Health England

Protecting and improving the nation's health

NHS Health Check content review form

1. Please tick the categories that apply to your proposal.
☐ It involves introducing a new component to the risk assessment.
2. Please provide a short summary describing your proposed change [*max 200 words*]
[*Please be sure to clearly state what your change or addition is e.g. to introduce a lung function test*] We propose addressing the lack of any reference to respiratory disease – the UK's third biggest killer – via the inclusion of an evidence-based short set of questions, similar to those used in dementia screening, to provide early indications of potential respiratory disease. This would include a question about the individual's smoking history, in addition to the question about their current smoking status, which is already a part of the Health Check. People taking part in the Health Check will also be asked several questions to assess the presence of any significant symptoms of respiratory disease such as breathlessness, chest infections, persistent cough or sputum production. The answers to these questions should be used to determine whether to trigger a referral for clinical assessment in primary care.
3. Please state which strategic health priority in the NHS outcome framework or the public health outcome framework the proposed change supports [*max 200 words*]
[*Please identify up to three priorities*] From the Public Health Outcomes Framework: • 4.7 Reducing premature mortality from major causes of death, in particular 'Under 75 mortality rates from respiratory disease'. • 2.14 Smoking prevalence – adults (over 18s). From the NHS Outcomes Framework: • 2 Health-related quality of life for people with long-term conditions

4. Please identify which of the programmes objectives the proposed change supports [*please tick*]

☐ To promote and improve the early identification and management of the individual behavioural and physiological risk factors for vascular disease and the other conditions associated with those risk factors.

☐ To support individuals to effectively manage and reduce behavioural risks and associated conditions through information, behavioural and evidence based clinical interventions.

5. How will the proposed change support the(se) objective(s)?

This change would support the above Health Check objectives regarding vascular disease in three ways.

Firstly, using simple questions as preliminary screening for COPD will help address the significant problem of under-diagnosis in COPD, which currently sees an estimated two million people living with undiagnosed COPD throughout the UK.[1] There is a strong inter-relationship between lung and heart disease.[2] Around 33% of COPD patients have hypertension, 19% have coronary heart disease and 6% have heart failure.[3] A 15-year follow up study has demonstrated that the presence of low lung function and a diagnosis of chronic obstructive pulmonary disease is strongly and independently related to the incidence of heart failure, even when all other risk factors like smoking were adjusted for.[4] The presence of lung disease is therefore also an indicator for vascular disease.

Secondly, questions relating to respiratory health will provide an additional opportunity to identify smoking. Although individuals are already asked about their current smoking status in the Health Check, studies have found inconsistencies between self-reported smoking levels and levels indicated through biochemical testing. This suggests that self-reported smoking status alone may not be sufficient assessment.[5,6] The link between smoking and both circulatory and lung disease is well-established: tobacco use contributes to 35% of all respiratory deaths and to 13% of all circulatory disease deaths.[7] Questions relating to respiratory symptoms such as breathlessness and persistent cough would help identify individuals displaying symptoms commonly associated with smoking but who have not self-reported tobacco use, thereby providing opportunities for smoking cessation interventions in smokers currently slipping through the net.

Thirdly, the identification of smoking related lung disease will provide additional incentive to smokers to quit as it identifies them as having a specific smoking related health problem rather than smoking being a risk factor. This emphasises the

concept of smoking cessation as treatment for disease not simply as prevention.

Finally, in addition to meeting existing objectives focussed on heart disease, the addition of this element would allow for a simple but crucial expansion of Health Check objectives to incorporate other key priority areas identified by the Secretary of State of Heath. The NHS Public Health Outcomes Framework includes an objective to reduce premature mortality from respiratory conditions. Given that respiratory disease is the third leading cause of death in the UK, after cancer and heart disease,[8] lung health should be recognised as an important priority in its own right.

COPD alone causes around 30,000 deaths per year in England and Wales, with nearly a third of these being premature deaths.[9] The percentage of deaths due to COPD compared to deaths from all causes has increased for both men and women between 2003 and 2013, meaning that mortality rate for COPD is not improving as quickly as that of other conditions.[10]

Earlier diagnosis and COPD management can slow disease progression and improve quality of life.[11] However, opportunities to diagnose and manage COPD effectively are routinely missed. A large retrospective study found that opportunities for diagnosis were missed in 32 900 (85%) of 38 859 patients in the 5 years immediately preceding a diagnosis of COPD and 42% of patients experienced symptoms between 11 and 15 years prior to a diagnosis being made.[12] This highlights the long time lag that most patients experience before getting a diagnosis, who would otherwise benefit from receiving NICE recommended treatments and interventions as well as information on how to manage their condition. Using the Health Check to identify and flag symptoms associated with COPD and respiratory disease will present opportunities for earlier diagnosis.

6. What is the evidence for the clinical effectiveness of the proposed change?

We propose to include questions in the Health Check to assess an individual's likelihood of having COPD. This would be in line with NICE guidance, which recommends that 'a diagnosis of COPD should be considered in patients over the age of 35 who have a risk factor (generally smoking) and who present with exertional breathlessness, chronic cough, regular sputum production, frequent winter 'bronchitis' or wheeze.' Other studies also support this shortlist of symptoms and risk factors as being indicative of COPD. A study of over 800 smokers found that eight items had a significant relationship to a diagnosis of COPD, including someone's age, pack-years smoked, body mass index, weather-affected

cough, phlegm without a cold, morning phlegm, wheeze frequency, and history of any allergies. The individual items yielded odds ratios ranging from 0.23 to 12. This questionnaire demonstrated a sensitivity of 80.4 and specificity of 72.0 at predicting whether someone had COPD.[13] This shows that a short questionnaire would be sufficient to design a reasonably accurate test in order to identify undiagnosed COPD.

There are significant numbers of people with undiagnosed COPD in the UK who may benefit from access to available treatments and interventions. Recent studies found that screening of smokers over 40 in general practice may yield up to 20% undiagnosed COPD cases, with a substantial proportion (42-70%) of those having moderate or severe disease stage.[14 15] According to the best estimates of the total size of the undiagnosed population, screening for COPD may result in as many as 400,000 extra diagnoses.[16] Another large scale study of 20,000 people, found 4.7% of the total over-30 population to have clinically significant COPD, with 80% of these having no previous COPD diagnosis.[17]

Whilst we are not recommending any one particular questionnaire to be included as part of the Health Check, we include some examples of specific questionnaires below to demonstrate that this can be an effective tool for finding COPD patients in practice. We would like the Expert Scientific and Clinical Advisory Panel (ESCAP) to consider the exact phrasing and questions as part of the Health Check content review process and would be happy to assist with identifying respiratory experts should ESCAP seek to design a pilot project to test the exact phrasing of the questions.

The COPD-Population Screener[18] has featured in several studies in recent years. With only 4 questions, it is the shortest questionnaire, which has produced accurate results indicating the presence of COPD. 2357 subjects aged between 40 and 79 were recruited into this study and 6.5% of these were found to have airway obstruction. The study recommended a cut-point of 4-points, resulting in a sensitivity of 67.1% and specificity of 72.9% with an area under the ROC curve of 0.70. The positive predictive value was 14.6% and negative predictive value was 97.0%.[19] Another paper, analysing the effectiveness of the same questionnaire found that a score on the COPD-PS of greater than five was associated with a positive predictive value of 56.8% and negative predictive value of 86.4%. Patients with spirometry indicative of AO scored significantly higher (6.8) than patients without AO (4). Higher scores were associated with more severe AO, bronchodilator use, and overnight hospitalization for breathing problems.[20]

Other questionnaires have been developed with similar sets of questions. CAP (developed by GSK) scores 0-20 with 11-20 being indicative of COPD. Smoking history, age of over 55 years and the presence of exertional breathlessness were

key elements of this simple model, which had reliable measurement properties when tested in a random population. The area under the receiver-operating characteristic curve for this model was 0.77, sensitivity was 77.6%, specificity was 64.9% and the positive likelihood ratio was 2.21.[21 22]

Two further questionnaires developed for primary care use had sensitivities of 54 to 82%, specificities of 58 to 88%, positive predictive values of 30 to 78%, and negative predictive values of 71 to 93%.[23] Whilst there will always be different accuracies associated with different questionnaires, this should not preclude the Health Check team from designing and testing the exact phrasing of questions, as some questionnaires listed here are also shown to be very effective.

Some of the symptoms being picked up by all the questionnaires, most notably in the presence of breathlessness, a persistent cough and smoking history, could also be indicative of other conditions, such as lung cancer, interstitial lung disease and tuberculosis. It is important that these symptoms are not missed and that the referral pathway from the Health Check reflects this.

It should be noted that the proposed change will be looking for individuals who are already showing some symptoms of disease and will not be effective at picking up individuals who may have COPD but are not yet displaying any symptoms. As new evidence becomes available, there may therefore be a case to be made in future for a different screening method, such as microspirometry, which would pick up individuals with a level of lung obstruction, who are not yet displaying symptoms.

7. What is the evidence of cost effectiveness of the proposed change?

Direct evidence of cost effectiveness is limited, but modelling from the Department of Health suggests that earlier diagnosis of COPD could save the UK National Health Service more than £1 billion over 10 years.[24] COPD is one of the costliest inpatient conditions treated by the NHS, making up over £800 million in direct healthcare costs.[25] These high costs stem both from the large numbers of people affected by COPD and from high levels of hospital admissions. COPD exacerbations are the second most common cause of emergency hospital admissions in the UK after ischaemic heart disease, with an estimated 94,000 admissions per year.[26,27]

Studies show that the greater the number of exacerbations, the faster the lung function decline in COPD patients, even when smoking status is adjusted for.[28] Exacerbations have a direct effect on a person's life expectancy: 50% of people with a severe COPD exacerbation will die within four years of an admission.[29] Yet, up to a third of people admitted to hospital with a COPD exacerbation for the first time do not have a previous COPD diagnosis.[30] There are a number of interventions

which can help to reduce the number of exacerbations of COPD, which are listed in response to Q9.

Full implementation of NICE guidance for COPD is estimated to result in an estimated 5% fewer admissions to hospital and around £15.5 million savings each year, but a higher use of prescribing, is estimated to cost the NHS slightly more overall. Nevertheless, the COPD Commissioning toolkit advises that if people remain undiagnosed until they are severely disabled by the condition, or are admitted to hospital as an emergency, the benefits of treatment to the individual are greatly reduced and the costs to the healthcare system greatly increased.[31]

8. Please provide an outline of how this would change current practice
i.e. what would frontline professionals delivering the NHS Health Check need to do that isn't already a part of the programme?

Healthcare professionals will need to ask a number of additional questions and make a calculation based on the risk factors. A referral to a clinician in general practice will need to be made for further testing for those people at high risk of lung disease. The proposal is intended not to place an extra burden on frontline staff delivering the health check. Staff will need very minimal training in order to carry out the new component.

9. If you are proposing a new component to the programme, please describe the effective treatment and management systems that are exist and are available.

A number of interventions are available for COPD patients, which can positively affect patients' quality of life and clinical outcomes. Most of these interventions are included in the NICE guidance for COPD. Some further studies are listed below.

Smoking cessation remains one of the most important interventions for everyone diagnosed with COPD.[32] A systematic review performed in 2010 showed that smoking cessation interventions were effective and cost-effective for people with COPD.[33]

A pneumococcal vaccination and an annual influenza vaccination are recommended by the Chief Medical Officer for all patients with COPD. Studies show that up to 64% of COPD exacerbations are preceded by colds and 16% are caused by influenza, suggesting that these periods of acute ill health are mostly initiated by viruses.[34] Access to a free vaccination, will therefore also have some effect on morbidity and mortality.

Pulmonary rehabilitation is a COPD treatment recommended by NICE and it should

be offered to "all appropriate people with COPD, including those who have had a recent hospitalisation for an exacerbation and those who consider themselves functionally disabled by COPD (usually MRC grade 3 and above)".[35] A Cochrane review of the effectiveness of pulmonary rehabilitation concluded that it "relieves dyspnoea and fatigue, improves emotional function and enhances the sense of control that individuals have over their condition. Rehabilitation therefore serves as an important component of the management of COPD and is beneficial in improving health-related quality of life and exercise capacity."[36] Furthermore, many studies have found that hospital admissions can be significantly reduced after a course of PR, showing the programme to be clinically significant in the treatment of COPD.

Physical inactivity is an important early feature of COPD which occurs commonly[37] and is associated with accelerated lung function decline.[38] Timely identification of COPD should provide incentive for patients to increase their physical activity levels. There is evidence that this can be accomplished with simple interventions such as pedometers and that this increase in activity may reduce exacerbation frequency.[39]

Addressing breathlessness and diagnosing COPD in a timely way is important to preventing disease progression and future disease burden, and thus has been proposed as a key element in developing a more sustainable health care system.[40]

Pharmacological interventions, such as the use of bronchodilators, are also a significant intervention for COPD patients, as these improve lung capacity, reduce the number of exacerbations and improve quality of life and mortality rates. The UPLIFT study was a double-blind, randomised, international, placebo-controlled clinical trial, which demonstrated these outcomes.[41] [42] [43] [44] Studies also show that the use of pharmacological interventions is more effective in the early stages of COPD. [45] Given that an admission to hospital for a COPD patient has an associated mortality rate of 13.9% within 3 months of the admission,[46] pharmacological interventions are particularly important at managing COPD effectively and are therefore prescribed to nearly every COPD patient who is diagnosed with the condition.

10. Please state whether you feel the change will have a negative, neutral or positive impact on health inequalities and on the nine protected characteristic groups and why.
[please tick, *max 200 words*]

☐ Positive

Overall, we would expect the effect on health inequalities to be a positive one. Social inequality causes a higher proportion of deaths in respiratory disease than any other disease area – 44% of all deaths from respiratory disease are associated with social class inequalities compared with 28% of deaths from ischaemic heart disease. Furthermore, men aged 20-64 employed in unskilled manual occupations

are around 14 times more likely to die from COPD than men employed in professional roles.[47] Diagnosing respiratory disease, such as COPD appreciably earlier and raising awareness of the symptoms via the Health Check is likely to have a positive effect on health inequalities.

9 protected areas:

- Age – some positive impact by identifying COPD cases in a timelier way. COPD predominantly affects the older age group: 1 in 8 people over the age of 35 are living with COPD.[48]
- Disability – some positive impact by enabling COPD patients to find out they have a chronic condition, which will lead to further disability, and enabling patients to get treatment earlier.
- gender reassignment - neutral
- marriage and civil partnership - neutral
- pregnancy and maternity - neutral
- race - neutral
- religion or belief - neutral
- sex - neutral
- sexual orientation - neutral

11. Please name a local authority that has already adopted this proposed change to their delivery of the NHS Health Check programme.

We are not aware of any local authority screening 40-74 year olds for COPD using a questionnaire.

12. Please list any relevant references

Please see a full list of references at the end of this document.

For completion by the ESCAP secretariat

13. Proposal shared with ESCAP

Yes.

14. ESCAP feedback

ESCAP members that it would be more appropriate to strengthen the clinical management section of the programme's best practice guidance to reflect NICE guidance on the diagnosis of COPD in people with a risk factor and presenting with symptoms. Therefore, ESCAP recommended that this proposal should not progress to stage 2.

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[2] http://www.sciencedirect.com/science/article/pii/S1047279705001055
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[5] Daly RJ et al. Self-reported smoking in vascular disease: the need for biochemical confirmation. Br J Biomed Sci. 1996 Sep;53(3):204-8 http://www.ncbi.nlm.nih.gov/pubmed/8914347
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[7] ASH Factsheet on Smoking Statistics http://ash.org.uk/files/documents/ASH_107.pdf
[8] Report on inquiry into Respiratroy Deaths, APPG on Respiratory Health, 2014.
[9] Calculation based on 2013 data, on the proportion of deaths from causes J40-J47 were in those under 75 years of age. Data souce: Table 5.10, Deaths by underlying cause – diseases of the respiratory system. ONS publications, 2014.
[10] http://www.ons.gov.uk/ons/rel/vsob1/mortality-statistics--deaths-registered-in-england-and-wales--series-dr-/2013/stb-deaths-registered-in-england-and-wales-in-2013-by-cause.html#tab-Comparing-Leading-Causes-of-Death-in-2003-and-2013
[11] Welte T et al. COPD: early diagnosis and treatment to slow disease progression. Int J Clin Pract. 2015 Mar;69(3):336-49. doi: 10.1111/ijcp.12522. Epub 2014 Oct 31. http://www.ncbi.nlm.nih.gov/pubmed/25363328
[12] http://www.thelancet.com/journals/lanres/article/PIIS2213-2600%2814%2970008-6/abstract
[13] http://www.ncbi.nlm.nih.gov/pubmed/16330875
[14] COPD screening efforts in primary care: what is the yield? Prim Care Respir J. 2007 Feb;16(1):41-8. http://www.ncbi.nlm.nih.gov/pubmed/17297526
[15] http://informahealthcare.com/doi/abs/10.3109/15412555.2012.727923 [Calculation: patients with moderate(II) or severe(III) stages=49; total patients with COPD=70]
[16] Calculation based on 2million people living with COPD undiagnosed - 20% of those is 400,000 people.
[17] http://thorax.bmj.com/content/65/6/492.full
[18] Scores range between 0-10, with 5 points and over being indicative of possible COPD. An example of the questions is available at: http://www.copdfoundation.org/Screener.aspx .
[19] Allergol Int. 2015 Jan;64(1):49-53. doi: 10.1016/j.alit.2014.06.002. Epub 2014 Dec 17. Validation of a COPD screening questionnaire and establishment of diagnostic cut-points in a Japanese general population: The Hisayama study.
[20] COPD. 2008 Apr;5(2):85-95. doi: 10.1080/15412550801940721.Development and initial validation of a self-scored COPD Population Screener Questionnaire (COPD-PS).
[21] http://www.ncbi.nlm.nih.gov/pubmed/22409441
[22] http://www.ncbi.nlm.nih.gov/pubmed/19720809
[23] http://journal.publications.chestnet.org/article.aspx?articleid=1084479
[24] http://www.hegalaxy.com/doctors-missing-chances-diagnose-copd-early-85-cases
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[26] Consultation on a Strategy for Services for Chronic Obstructive Pulmonary Disease (COPD) in England, page 18, Department of Health, (February 2010).
[27] An Outcomes Strategy for COPD and Asthma: NHS companion document, page 9, Department of Health (May 2012).
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[30] http://www.ncbi.nlm.nih.gov/pubmed/20299538
[31] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/212876/chronic-obstructive-pulmonary-disease-COPD-commissioning-toolkit.pdf
[32] van der Meer RM, Wagena E, Ostelo RWJG, Jacobs AJE, van Schayck CP. Smoking cessation for chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews 2001, Issue 1.

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[36] http://www.cochrane.org/CD003793/AIRWAYS_pulmonary-rehabilitation-for-chronic-obstructive-pulmonary-disease
[37] http://www.ncbi.nlm.nih.gov/pubmed/22362854
[38] http://www.clinsci.org/cs/118/0565/cs1180565.htm
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[41] http://www.ncbi.nlm.nih.gov/pubmed/19317104
[42] http://www.atsjournals.org/doi/full/10.1164/rccm.200906-0876OC#.VQmurI6sWSo
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[44] http://www.cochrane.org/CD010509/AIRWAYS_effectiveness-and-safety-of-inhalers-containing-the-drug-aclidinium-bromide-for-managing-patients-with-stable-copd
[45] http://respiratory-research.com/content/10/1/59
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[48] http://thorax.bmj.com/content/61/12/1043.full