Taskforce for Lung Health

Prevention and diagnosis call for evidence – Industry Forum submissions

Pfizer

AstraZeneca

GSK

Novartis

Sanofi

Chiesi

Pfizer:

Title	Mr
Name *	Andrew Jones
Are you happy for us to contact you by email about your submission to the Taskforce?	Yes
Are you a: *	Policy professional? If so, what's your job title and the name of your employer?
Please provide any extra details	Policy and Public Affairs Manager, Pfizer UK Ltd
Are you responding as an individual or on behalf of an organisation? *	Organisation
Is your organisation part of the tobacco industry? *	No
Does your organisation have any past or current, direct or indirect links with – or funding from – the tobacco industry? *	No
Are you happy for the taskforce to publish your response? *	Yes, and I'm happy to share my name and/or organisation
Please identify which theme, if any, your evidence falls under. This is so that we can easily identify which part of our final strategy your submission may relate to. *	Not sure/don't know
Do you have evidence to support changes in respiratory policy or service interventions in prevention and diagnosis? We are looking for up to three real world	

examples of policy or practice which would improve outcomes for lung patients if introduced or replicated across the country. If you have any costing evidence related to this, please include this too.	Pneumococcal disease prevention: Optimisation of the vaccination pathway for patients with COPD (data attached) Lung Cancer Diagnosis: Embedding of molecular testing early in pathways to enable appropriate diagnosis of disease sub-type and hence enable the use of the right targeted therapy (data attached). Smoking Cessation diagnosis and prevention: Identifcation of smokers via all frontline NHS staff - requires training (data attached) Smoking Cessation prevention: Delivery of smoking cessation interventions/services via GP practices (data attached) can result in the prevention of many smoking related conditions. COPD Prevention - GOLD guidelines good, but research needed on genetic factors. Further research needed on optimal prevention approaches (data Attached) COPD Diagnosis - Improvements in accurate diagnosis of airway disease needed, diagnosis needs to made in a specialist secondary care unit where appropriate training has been received (data attached)
What, in your experience, is the biggest barrier to improving lung health outcomes with reference to prevention and diagnosis?	Appropriately funded pathways of care at the point of contact with potential patients (i.e. Smoking cessation integrated into the NHS; COPD diagnosis in secondary care; Lung Cancer Molecular sub-typing; Pneumococcal disease optimised in COPD patients.

Further information submitted by Pfizer

Pneumococcal Disease Prevention

Pneumococcal disease in individuals with COPD

A study in the UK estimated the increased risk of invasive pneumococcal disease (IPD) among clinical risk groups and noted a particularly high risk in the immunocompromised and in individuals with chronic respiratory disease.[1] IPD mortality rates were 18.3% and 32.9% in 16-64 years and ≥65 year age groups with chronic respiratory disease – similar mortality rates to those observed in individuals who were immunocompromised. A recent British Thoracic Society (BTS) Adult Community Acquired Pneumonia (CAP) Audit reported that the mean age of CAP patients admitted to hospital was 74 years and that COPD was recorded in around a quarter of patients.[2] Pneumococcus continues to be a significant pathogen in hospitalised CAP, implicated in approximately 30% of cases.[3] Patients with COPD have an average of 3.7 to 9 chronic medical comorbidities[4 5] and the risk of CAP increases with increasing comorbidity.[6 7] Higher 30- and 90-day mortality, increased length of stay and admission to intensive care have also been reported for COPD patients hospitalised for CAP compared to those patients without COPD[8] and COPD also appears to be a risk factor for the development of severe CAP.[9] Pneumonia is often diagnosed in patients who are hospitalised with acute exacerbations of COPD (AECOPD) and has been reported to occur in 40% of all COPD admissions.[10] Inhaled corticosteroid use has also been reported to increase the risk of pneumonia in COPD patients.[11]

Pneumococcal vaccination in individuals with COPD

Pneumococcal polysaccharide vaccine (PPV) effectiveness for preventing adult IPD has been reported,[12-15] though duration of protection is short lived.[16] In addition, studies assessing PPV for preventing IPD in adults with compromised immune systems[12 17 18] and non-invasive pneumococcal pneumonia [12-15 17 19-22] have been inconsistent.[22] In the UK, the Joint Committee on Vaccination and Immunisation (JCVI) the expert body which advises UK health departments on immunisation, also acknowledge that PPV may fail to provide protection against pneumococcal infection in patients with COPD.[23] In 2011, the US FDA granted accelerated approval for the licensure of PCV13 in adults for prevention of vaccine-serotype (VT)-IPD and noninvasive pneumonia based on a potentially 'meaningful therapeutic benefit over existing treatments'. Approval in adults was contingent on proof of efficacy against pneumococcal pneumonia in adults ≥65 years of age and efficacy was demonstrated for pneumococcal pneumonia (including noninvasive pneumonia and IPD) in the CAPiTA study (Community-Acquired Pneumonia Immunization Trial in Adults).[24] The CAPiTA study included immunocompetent adults with risk factors/comorbidities aged ≥65 years and approximately 10% of subjects self-reported having lung disease.[24] A post hoc analysis of the CAPiTA data also reported significant and persistent efficacy of PCV13 against VT-CAP in at-risk adults.[25]

PPV is currently recommended in the national immunisation programme for persons aged ≥2 years with chronic respiratory disease,[26] however the role of PPV for protecting COPD patients from CAP is inconsistent.[27] Despite indirect protection afforded to non-immunised individuals by the childhood pneumococcal conjugate programme, serotypes in 13-valent

pneumococcal conjugate vaccine (PCV13) continue to cause cases of invasive pneumococcal disease in adults in the UK.[28] As PCV13 vaccine type pneumococci have not been completely eliminated from circulation, cases of noninvasive pneumococcal disease (i.e. nonbacteraemic pneumonia) will therefore continue to occur. In addition to severely immunocompromised adults for whom PCV13 is currently recommended,[26] there is a rationale for immunising elderly (≥65 years of age) persons with chronic obstructive airways disease (COPD) with PCV13 given that these individuals are at increased risk of pneumococcal infection. It is also likely that a review of the pneumococcal vaccination programme will need to be undertaken in the near future given recent changes in the epidemiology of pneumococcal infection in the UK[29] which will provide an excellent opportunity for stakeholders with an interest in COPD, such as the BLF to input their position on this important area of infection prevention.

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2. British Thoracic Society Adult Community Acquired Pneumonia (CAP) Audit Report
National Audit Period: 1 December 2014 – 31 January 2015 [Available from: https://www.brit-thoracic.org.uk/document-library/audit-and-quality-improvement/audit-reports/bts-adult-community-acquired-pneumonia-audit-report-2014-15/.
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14. Dear K, Holden J, Andrews R, et al. Vaccines for preventing pneumococcal infection in adults. *Cochrane Database Syst Rev* 2003(4):CD000422. doi: 10.1002/14651858.CD000422
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pneumococcal pneumonia. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America* 2006;43(8):1004-8. doi: 10.1086/507699
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29. Interim JCVI statement on adult pneumococcal vaccination in the UK
November 2015.

Lung Cancer – Diagnosis

For the **diagnosis** theme

We are particularly interested in

- Evidence relating to population level diagnosis interventions, such as screening
- Evidence on workforce training and upskilling to improve accuracy in diagnosis
- Evidence of how to embed diagnostic best practice, such as use of spirometry, across the health service
- Evidence of models of care which lead to higher and more accurate diagnosis rates
- How data collection could be improved to ensure we have accurate information on diagnoses of different lung conditions

Background

1. Lung cancer is increasingly being subdivided into molecular subgroups based on the evolution of our understanding of the complexity of the biology of the underlying disease and the concurrent development of targeted medicines which exemplifies the aims of personalised medicines
2. There is now a considerable evidence base that targeted therapies for such subgroups i.e. EGFR+, ALK+ driven disease responds more favourably to targeted therapies compared to standard chemotherapy or indeed the newer immunotherapy agents. It is important that pathological diagnosis is achieved quickly to enable these patients to get the right targeted therapy up front.
3. Other subgroups of lung cancer are being defined by novel biomarkers i.e. PDL1+, TMB which are helping us to understand which patients may benefit from immunotherapy
4. Recognition of the patients to access the right treatments in a timely manner is critical.
5. Quicker and more efficient diagnosis allows patients to be treated with target therapies which demonstrate improvement in OS. Despite this evidence access to new treatment is still an issue for rarer subtypes of lung patients.

Issues

1. Technical limitation of the small, and potentially low tumour cellularity NSCLC samples obtained from bronchoscopy and EBUS-TBNA means that the main challenge facing clinicians and pathologists is the need for ever greater amounts of information from diminishing amounts of tissue. It is therefore imperative that the quality of diagnostic samples in the advanced NSCLC setting is of the highest order.

How best to achieve this represents a challenge for health service providers that has received very little attention thus far.

2. Timely turnaround times for the appropriate molecular diagnostics testing need to be embedded in pathways for patients. There is enormous variation nationally between sites, diagnostic tests, the diagnostic pathways and the resulting timelines and outcomes for patients.
3. Discussion regarding medicines access ultimately depends on having robust data to support discussions around cost effectiveness. This requires robust data on the natural history of the disease, outcomes on standard therapies and outcomes on novel agents i.e. linking data sets on the molecular diagnostics and clinical outcomes. The UK at present does not have the ability to collect robust data in this regard. Data collection is considerably more rudimentary and does not link up molecular data and clinical outcomes to support.
4. Ensure all testing is linked to quality assurance schemes to maintain best practice.
5. Greater understanding of resistance mutations and potential sequencing of treatments is required to improve patients outcomes.

Opportunities

1. Workforce and training – to have sufficient workforce to support the delivery of timely molecular diagnostics **including sufficient administrative support with credible tissue tracking** to ensure turnaround times are achieved and to ensure the clinical workforce understand the importance of handling and managing tissue samples appropriately to address the challenges with limited samples in lung cancer and that they are supported in their delivery of this
2. Change the general culture regarding data collection and data quality – commissioners should recognise the importance of supporting robust data collection to help support better service delivery and improved patient outcomes and consider embedding dedicated data managers to support this
3. Molecular diagnostics need to be audited with other diagnostics outcomes as they form part of the fundamental diagnostic pathway for patients and there needs to be support to improve molecular diagnostics pathways when they are not delivering on expected turnaround times. Diagnostics best practice where turnaround times are shortest need to be applied nationally to reduce variation and improve overall outcomes.
4. Ensure all laboratories participate in quality assurance programs in relation to the delivery of the distinct molecular diagnostics.

Smoking Cessation – Prevention

Data:

Need to research evidence for e-cigarette users going on to smoke regular cigarettes? (Glantz SA, Bareham DW.

E-Cigarettes: use, effects on smoking, risks, and policy implications. Annu Rev Public Health. 2018 Jan 11. doi: 10.1146/annurev-publhealth-040617-013757)

Research Gaps:

Smoking Cessation in GP Practices. What are the clinical and financial benefits of delivering smoking cessation in GP practices and the in-year return on investment across the health system. Most commissioners are increasingly looking into ROI more than QALY for commissioning services and will be important to research how best we develop a strong case for CCGs to actively commission the service.

Models of Care:

GP practice actively providing smoking cessation support and medication as part of Long term condition management. Public Health England run smoking services are being decommissioned and only help less than 2% of the smokers in the UK while 2M smokers with Long term conditions are using NHS services every year but don't get the support around quitting. There are successful case studies where GP practices have benefitted clinically and financially by prioritising smoking cessation https://pcrs-uk.org/sites/pcrs-uk.org/files/QuittersSavesTime.pdf

Workforce:

All NHS frontline staff needs to be trained on NCSCT L1 Very Brief advice training which takes only 20 mins. It explains an evidence based way of initiating smoking cessation conversation with patients and takes less than 30 seconds to trigger a quit attempt. Every touch point in the system counts.

Smoking Cessation – Diagnosis

Models of Care:

VBA to be implemented for all current smokers: http://www.ncsct.co.uk/publication_very-brief-advice.php

Technology:

CO monitors should be provided to GPs and Nurses : https://pcrs-uk.org/sites/pcrs-uk.org/files/CarbonMonoxideTesting.pdf

COPD – Prevention

Data:

See GOLD statement 2018: Prevalence, causes and risk factors. Research still needed on influence of genetic factors

http://goldcopd.org/wp-content/uploads/2017/11/GOLD-2018-v6.0-FINAL-revised-20-Nov_WMS.pdf

Research Gaps:

Research still needed on influence of genetic factors

IMPRESS pyramid for showing value of COPD prevention/treatment interventions well established, but is based upon multiple data sources. Further research may clarify most effective options for lung health. https://www.networks.nhs.uk/nhs-networks/impress-improving-and-integrating-respiratory/documents/IMPRESS%20COPD%20Relative%20Value%20Main%20Report.pdf

Models of Care:

Much COPD prevention covered under Smoking Cessation, although see GOLD points above re: socio-economic burden, occupational exposure and genetic factors

COPD – Diagnosis

Data:

Increasing evidence from Real World sources showing inaccurate diagnosis of airway disease (partic. Differential diagnosis of COPD/Asthma): https://www.brit-thoracic.org.uk/pressmedia/2017/research-shows-inaccurate-diagnosis-of-chronic-lung-disease-in-primary-care/

Models of Care:

Knowsley CCG (Mersey area) – Central secondary care led COPD clinic. All patients with possible COPD sent to central clinic to be diagnosed and treated by specialists under oversight of secondary care clinicians https://www.lhch.nhs.uk/our-services/community-services/knowsley-community-respiratory-services/

See notes from BTS COPD audit about recording of spirometry results (bottom half of page: https://www.brit-thoracic.org.uk/standards-of-care/quality-improvement/copd-and-spirometry/)

Workforce:

See BTS/ARTP work on spirometry standards: http://www.artp.org.uk/en/spirometry/

AstraZeneca

Title	Mr
Name *	Ian Mullan
Are you happy for us to contact you by email about your submission to the Taskforce?	Yes
Are you a: *	Other? Please specify below
Please provide any extra details	Pharmaceutical company

Are you responding as an individual or on behalf of an organisation? *	Organisation
Is your organisation part of the tobacco industry? *	No
Does your organisation have any past or current, direct or indirect links with – or funding from – the tobacco industry? *	No
Are you happy for the taskforce to publish your response? *	Yes, and I'm happy to share my name and/or organisation
Please identify which theme, if any, your evidence falls under. This is so that we can easily identify which part of our final strategy your submission may relate to. *	Models of care

Do you have evidence to support changes in respiratory policy or service interventions in prevention and diagnosis? We are looking for up to three real world examples of policy or practice which would improve outcomes for lung patients if introduced or replicated across the country. If you have any costing evidence related to this, please include this too.

Lung cancer

a. Earlier diagnosis

There is a significant opportunity to improve outcomes through the earlier diagnosis of lung cancer. To illustrate this:
• 36% of England's lung cancer patients are currently identified via emergency presentation (14% higher than the average for all cancers) (1).
• 53% of lung cancers in England are diagnosed at stage 4 (2).
• One-year survival for men diagnosed at stage 4 is 15%, compared to 81% at stage 1, and 66% at stage two (19, 85 and 69% for women) (3).

Earlier diagnosis of lung cancer can be achieved through either raising awareness of lung cancer symptoms through public campaigns, or by using screening tests before symptoms arise. With regard to symptom awareness campaigns, we draw the Taskforce's awareness to the National Cancer Registration and Analysis Service (NCRAS)'s evaluation of the Be Clear on Cancer regional

and national lung cancer awareness campaigns (4).

There is not currently a national lung cancer screening programme in place in England, however there are ongoing and completed trials, set up to address issues including optimum screening strategy (eg the NELSON trial (5)), invitational methods (eg Lung Screen Uptake Trial (6)) and recruitment and design (UK Lung Screening Trial (7)).

We would also like to draw the Taskforce's attention to the pilots of lung health checks that have taken place, for example in:
• Manchester: https://www.macmillan.org.uk/_images/lung-health-check-manchester-report_tcm9-309848.pdf
• Liverpool: http://www.liverpoolccg.nhs.uk/media/2665/liverpool-healthy-lung-project-report_final.pdf
• Nottingham: https://www.roycastle.org/how-we-help/research/lung-cancer-screening-project

These pilots explore the potential for identifying lung cancer at an earlier stage, when outcomes are likely to be better, by inviting people who may be at high risk for a lung health check. The Manchester pilot resulted in a notable stage shift, with almost 8 out of 10 of the cancers identified though the pilot at early stage, and only 1 in 10 at stage 4.

In England, speed of diagnosis is being addressed through the implementation of a National Optimum Lung Cancer Pathway, the aim of which is to ensure a fast pathway from referral to diagnosis and then treatment without compromising patient experience (8).

b. Accurate diagnosis

It is important that lung cancer patients receive not just a timely confirmation of whether they have lung cancer, but also what type of lung cancer they have as this can inform prognosis and treatment decisions.

The National Lung Cancer Audit Report 2017 highlighted that only 72% of patients diagnosed in 2017 had a pathological diagnosis (9). In some cases, this may be due to unwillingness to perform a biopsy, for example in older patients. However, work has been done to develop an ambulatory technique for lung biopsy (10,11), which can be done with patients with poor lung function. As this can be conducted on an outpatient basis, this also reduces the need for beds and so has the potential to accelerate the time to diagnosis.

Patients should have access to appropriate molecular diagnostic testing at the point of diagnosis to support subsequent treatment decision making. However, Cancer Research UK have previously estimated that in 2014, 13,825 lung cancer patients missed out on molecular diagnostic testing, meaning that eligibility for some treatment options could not be explored (12).

In patients for whom a lung biopsy is not feasible, identification of mutations via circulating tumour DNA (ctDNA) analysis from a plasma sample can be used. The development of ctDNA testing services has been examined by the PHG Foundation (13), and the technology has been assessed in a NICE Medtech Innovation Briefing (14).

References
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4) National Cancer Registration and Analysis Service, 2018. Be Clear on Cancer: Regional and national lung cancer awareness campaigns 2011 to 2014 Final evaluation results – Executive Headlines.
5) See eg Yousaf-Khan U, van der Aalst C, de Jong PA, et al Final screening round of the NELSON lung cancer screening trial: the effect of a 2.5-year screening interval Thorax 2017;72:48-56.
6) Quaife et al The Lung Screen Uptake Trial (LSUT): protocol for a randomised controlled demonstration lung cancer screening pilot testing a targeted invitation strategy for high risk and 'hard-to-reach' patients BMC Cancer 2016;16:281
7) Field et al 2016 The UK Lung Cancer Screening Trial: a pilot randomised controlled trial of low-dose computed tomography screening for the early detection of lung cancer. Health Technol Assess. 2016 May;20(40):1-146
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11) Abdullah R, Tavare AN, Creamer A, et al. Lung cancer tissue diagnosis in poor lung function: addressing the ongoing percutaneous lung biopsy FEV1 paradox using Heimlich valve. Thorax. 2016 Aug;71(8):757-8
12) Cancer Research UK 2015. Molecular diagnostic provision in England for targeted cancer medicines (solid tumour) in the NHS. Available online at: http://www.cancerresearchuk.org/sites/default/files/policy_august2015_mdx_final.pdf
13) PHG Foundation 2017. Developing effective ctDNA testing services for lung cancer. Available online at: http://www.phgfoundation.org/documents/developing-effective-ctdna-services-for-lung-cancer.pdf
14) NICE 2018. Plasma EGFR mutation tests for adults with locally advanced or metastatic non-small-cell lung cancer. Available online at: http://nice.org.uk/guidance/mib137

Alternatively, upload your answer to this question here	
What, in your experience, is the biggest barrier to improving lung health outcomes with reference to prevention and diagnosis?	We are aware that challenges for the implementation of the National Optimum Lung Cancer Pathway will include capacity within radiology services. This will also be the case for

		the implementation of any future lung cancer screening programmes.

GSK

Title	Mrs
Name *	Gillian Ayling
Are you happy for us to contact you by email about your submission to the Taskforce?	Yes
Are you a: *	Policy professional? If so, what's your job title and the name of your employer?
Please provide any extra details	Director NHS Relations

Are you responding as an individual or on behalf of an organisation? *	Organisation
Is your organisation part of the tobacco industry? *	No
Does your organisation have any past or current, direct or indirect links with – or funding from – the tobacco industry? *	No
Are you happy for the taskforce to publish your response? *	Yes, and I'm happy to share my name and/or organisation
Please identify which theme, if any, your evidence falls under. This is so that we can easily identify which part of our final strategy your submission may relate to. *	Research
Do you have evidence to support changes in respiratory policy or service interventions in prevention and diagnosis? We are looking for up to three real world examples of policy or practice which would improve outcomes for lung patients if introduced or replicated across the country. If you have any costing evidence related to this, please include this too.	n/a
Alternatively, upload your answer to this question here	

What, in your experience, is the biggest barrier to improving lung health outcomes with reference to prevention and diagnosis?

Prevention

Smoking cessation, avoiding starting smoking & avoiding maternal smoking in pregnancy & avoiding second hand smoke.

I think that we also need more evidence on how the shift to vaping will impact lung disease, and there's also a potential impact of cannabis smoking on lung health as well.
Tashkin DP (June 2005). "Smoked marijuana as a cause of lung injury". Monaldi Arch Chest Dis (Review). 63 (2): 93–100..
Lutchmansingh, D; Pawar, L; Savici, D (2014). "Legalizing Cannabis: A physician's primer on the pulmonary effects of marijuana". Current respiratory care reports. 3 (4): 200–205. doi:10.1007/s13665-014-0093-1..

Air pollution, particles from diesel in particular (I understand BLF have a campaign around this already)

Diagnosis (apologies more questions than answers)
Early diagnosis of COPD – people present late. (may have lost 50% LF before they present – Sutherland et al. NEJM 2004. Does early diagnosis and Rx lead to better outcomes? Does screening of at risk patients (e.g, >40 and smokers) help?

Diagnositic spirometry – quality in primary care very variable. Is it better to provide rapid access to diagnostics in hospital instead?
Screening in Primary care – review attached.

Diagnosis of asthma, particularly in children. No simple test available – should we use eosinophils/FeNO ? Impact of diagnosis, (especially if incorrect) – uneccessary Rx and avoidance of exercise by children and adults. Should we have rapid access hubs – see NICE and BTS letter.

Alternatively, upload your answer to this question below

btssignasthma.pdf 2.36 MB · PDF

The SIGN 153 guideline on the management of asthma submitted alongside GSK's submission is available online at: https://www.sign.ac.uk/sign-153-british-guideline-on-the-management-of-asthma.html

Novartis

Title	
Name *	
Are you happy for us to contact you by email about your submission to the Taskforce?	
Are you a: *	Other? Please specify below
Please provide any extra details	Novartis

Are you responding as an individual or on behalf of an organisation? *	Organisation
Is your organisation part of the tobacco industry? *	No
Does your organisation have any past or current, direct or indirect links with – or funding from – the tobacco industry? *	No
Are you happy for the taskforce to publish your response? *	Yes, but only anonymously
Please identify which theme, if any, your evidence falls under. This is so that we can easily identify which part of our final strategy your submission may relate to. *	Models of care

Do you have evidence to support changes in respiratory policy or service interventions in prevention and diagnosis? We are looking for up to three real world examples of policy or practice which would improve outcomes for lung patients if introduced or replicated across the country. If you have any costing evidence related to this, please include this too.

NRAD found that the UK has one of the highest asthma death rates in the world, with the majority of these avoidable, and put forward a clear set of recommendations on how asthma services could be improved and how those diagnosed with asthma could be supported to manage their condition appropriately.

However, the NRAD recommendations have not been implemented and recent reports continue to highlight the significant variation in the commissioning of asthma services across the country, and the fact that levels of uncontrolled asthma appear to be increasing.

At present, the NICE Quality Standard for Asthma (2013) includes 11 Quality Statements shaped around the five domains of the NHS Outcomes Framework. There are three asthma

indicators in the Quality and Outcomes Framework (QOF) and two relevant CCG Outcome Indicators (below) that were introduced in 2015:

Under 75 mortality rates from respiratory disease (Domain 1: Preventing people from dying prematurely)
Unplanned hospitalisation for asthma, diabetes and epilepsy in under 19s (Domain 2: Enhancing quality of life for people with long-term conditions)

Beyond the current Asthma Audit Development Project led by the Royal College of Physicians (RPS), there appears to have been limited progress on wider NRAD recommendations being implemented. There is, therefore, a compelling case to be made for the implementation of further policy levers to deliver the recommendations of NRAD, in line with the NHS policy cycle.

Alternatively, upload your answer to this question here	

Sanofi

Title	Mr
Name *	Harry Thurston-Smith
Are you happy for us to contact you by email about your submission to the Taskforce?	Yes
Are you a: *	Policy professional? If so, what's your job title and the name of your employer?
Please provide any extra details	Sanofi
Are you responding as an individual or on behalf of an organisation? *	Organisation
Is your organisation part of the tobacco industry? *	No
Does your organisation have any past or current, direct or indirect links with – or funding from – the tobacco industry? *	No
Are you happy for the taskforce to publish your response? *	Yes, but only anonymously
Please identify which theme, if any, your evidence falls under. This is so that we can easily identify which part of our final strategy your submission may relate to. *	Not sure/don't know

What, in your experience, is the biggest barrier to improving lung health outcomes with reference to treatment, managing lung disease, and end of life?

Diagnosis

1. Need for clinical trials to include different asthma phenotypes e.g. patients with irreversible airway obstruction, obese- asthma, COPD-asthma, smokers etc.
2. The conflicting BTS/SIGN and NICE guidelines may be causing confusion in asthma clinics.
3. Evidence for the length of time between diagnosis of severe uncontrolled asthma and patient's achieving control with new therapy
4. Examination of the need for asthma severity and exacerbation risk scoring system – currently severity is derived from current treatment intensity and level of control, but could instead be based on all relevant clinical parameters, quality of life and patient reported outcomes, and biomarkers. A severity score could be used to determine response (depth of response) and change of treatment criteria, as well as being useful as clinical trial inclusion criteria

Management

1. Evidence for the number of patients dependent on OCS, yet not referred to an asthma specialist
2. The ERS Severe Asthma group, Setting the Agenda for Future Research, identified that there is a lot of relevant data held within industry clinical trial databases that could be more generally useful to the community. Even the placebo-only arm data would be useful (to exclude commercially sensitive data). Perhaps the Taskforce should be lobbying for access to our data….!

Seqirus

Title	Global Director, Public Health Policy
Name *	Aaron Thomas Rak
Are you happy for us to contact you by email about your submission to the Taskforce?	Yes
Are you a: *	Other? Please specify below
Please provide any extra details	Global Director of Public Health Policy, at Seqirus Vaccines, a CSL Company

Are you responding as an individual or on behalf of an organisation?

Is your organisation part of the tobacco industry? *	No
Does your organisation have any past or current, direct or indirect links with – or funding from – the tobacco industry? *	No
Are you happy for the taskforce to publish your response? *	Yes, and I'm happy to share my name and/or organisation
Please identify which theme, if any, your evidence falls under. This is so that we can easily identify which part of our final strategy your submission may relate to. *	Technology
Do you have evidence to support changes in respiratory policy or service interventions in prevention and diagnosis? We are looking for up to three real world examples of policy or practice which would improve outcomes for lung patients if introduced or replicated across the country. If you have any costing evidence related to this, please include this too.	

Additional evidence submitted by Seqirus

Question 1: Do you have evidence to support changes in respiratory policy or service interventions in prevention and diagnosis. We are looking for up to three real-world examples of policy which would improve outcomes for lung patients if introduced or replicated across the country. If you have any costing evidence related to this, please include that too.

As stated by the British Lung Foundation, "Lung disease is one of the top 3 killers in the UK, with the number of people dying from lung disease in the UK failing to improve over the past decade". One substantial contributor to this statistic is influenza, an acute viral infection of the respiratory tract characterised by the sudden onset of fever, chills, headache, myalgia and extreme fatigue. For otherwise healthy individuals, influenza is an unpleasant but usually self-limiting disease. However, the risk of serious illness from influenza is higher amongst children under six months of age, older people, and those with underlying health conditions and pregnant women.[1] Estimates of excess winter deaths attributable to influenza in the last decade in England and Wales range up to 10,351 (in 2008-9), and the highest estimate in the past two decades was 24,797 for the 1999-2000 influenza season.[2]

Influenza immunisation has been recommended in the UK since the late 1960s, with the objectives of protecting those who are most at risk of serious illness or death, and to reduce transmission contributing to the protection of vulnerable patients who may have a suboptimal immunisation response. In 2000, the policy was extended to include all people aged 65 years or over, and has further been extended by the Joint Committee on Vaccinations and Immunisation (JCVI) to people in clinical risk groups, children 2 to less than 17 years of age, and pregnant women.[3] Additionally, the influenza season is the key driver of antibiotic use, and vaccination could have a major impact.[4] Increasing immunisation rates, using enhanced products, and the immunisation of healthcare workers and carers could help to reduce influenza-related morbidity and mortality amongst vulnerable populations. Recommendations and funding already exist so that enhancements could achieve broad reach and impact in a cost-effective and feasible way.

1. Improved vaccine coverage amongst at risk groups: The UK has some of the highest immunisation rates across Europe,[5] yet most recommended groups have not yet met the UK Department of Health (DOH) target of 75% vaccination.[6] JCVI recommends that people who are at increased risk of influenza complications, such as those with chronic heart, kidney, liver or respiratory disease, those with diabetes, immunosuppression, asplenia/spleen dysfunction, morbid obesity, or who are pregnant[7] are vaccinated, and the vaccine is paid for by the National Health Service (NHS). Despite recommendations, the immunisation rate for this population for 2016/17 was only 48.1%. Since tracking started in 2004/05, uptake has ranged from 39.9% to 52.3%, has plateaued, and fallen short of targets of 75%. Also, there is a geographic disparity in uptake from 34.3% in the Leeds West Clinical Commissioning Group (CCG) to 61.2% in the Stockport CCG. Overall, of the 6.2 million people who fall into these clinical risk groups, only 3.0 million are vaccinated.[8]

Since 2000, the vaccination rate for the 65+ population has risen slightly from 65.4% but has plateaued in recent years, and was 70.5% in the 2016/17 season.[9] There is also a sizeable geographic disparity between CCGs ranging from 48.6% (Waltham Forest) to 78.7% (Rushcliffe).[10] For the 65+ population, 3 million people are not regularly vaccinated.[11] Due to suboptimal immunisation rates, improved uptake of vaccines for already recommended populations could substantially increase respiratory health.

2. Increase use of available and recommended enhanced vaccines: Immune responses to vaccination decline with age, and antibody responses in the elderly are lower than in younger adults, which

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[1] *Influenza: The Green Book* Chapter 19. Page 1 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/663694/Greenbook_chapter_19_Influenza_.pdf

[2] Ibid p. 2

[3] Ibid p. 4

[4] "Value of Vaccines in the Avoidance of Antimicrobial Resistance" Report of the Workshop 29-30 March 2017: Centre on Global Health Security: Chatham House: http://www.who.int/immunization/research/meetings_workshops/PDVAC_2017_AMR_Clift.pdf Slide #6

[5] Technical Report: Seasonal Flu Vaccination in Europe 2007/2008 to 2014/2015. Pages 1, 14, 15, and 16. https://ecdc.europa.eu/sites/portal/files/documents/influenza-vaccination-2007%E2%80%932008-to-2014%E2%80%932015.pdf

[6] "National Flu Immunisation Programme 2017/2018 Pages 2-3. https://nhs-digital.citizenspace.com/rocr/r01193-17a/supporting_documents/R01193annual_flu__letter_2017to2018.pdf

[7] *Influenza: The Green Book* Chapter 19. Pages 13-14

[8] Seasonal Influenza Vaccine Uptake GP Patients: Winter Season 2016/2017: Pages 13-15 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/613452/Seasonal_influenza_vaccine_uptake_in_GP_patients_winter_season_2016_to_2017.pdf Pages 13-15.

[9] Ibid p. 13-15

[10] Ibid Pages 13-15

[11] Ibid p.13-15

translates into lower effectiveness, known as immunosenescence. During the 2016/17 UK influenza season, the effectiveness of standard vaccines against medically attended, laboratory -confirmed influenza in primary care in the elderly could not be demonstrated.[12] This was also studied in a meta-analysis of data between 2004 and 2015 that was unable to show efficacy for the influenza vaccine in the elderly against the A(H3N2) influenza virus[13].

In August 2017, an adjuvanted trivalent inactivated vaccine (aTIV) Fluad® was licensed for those aged 65 years and older in the UK. aTIV has been licensed in some European countries since 1997 and in the USA since 2015. [14]I n June 2017, JCVI reviewed published data that aTIV has higher vaccine immunogenicity and effectiveness than non-adjuvanted vaccines in the elderly.[15] Mathematical modelling by PHE indicates that, even under quite conservative estimates of effectiveness, aTIV would be highly cost-effective in both the 65-74 and 75 year and over age groups. [16] Given the low influenza vaccine effectiveness seen in those in seasons dominated by A(H3N2), JCVI agreed that use of aTIV in those aged 65 years and over would be both more effective and cost-effective than the non-adjuvanted vaccines currently in use.[17] NHS has subsequently issued a preferential recommendation for the use of aTIV for all over 65 in the UK, and has provided additional funding to do so. [18] Other immunisation options had sub-optimal results, and this new enhanced, recommended, and financed option has the potential to reduce disease further for this vulnerable population, yet multi-disciplinary education and coordination is necessary to achieve uptake and impact health.

3.Improved immunisation of Health Care Workers (HCW): It is estimated that up to 1 in 4 HCW may become infected with influenza during an influenza season – a higher incidence than in the general population.[19] Additionally, the patient population found in hospitals is much more vulnerable and HCW may transmit the illness to patients even if mildly or sub-clinically infected, and there are reports of influenza outbreaks within hospitals.[20] Every year, the influenza vaccination is offered to frontline HCW in the NHS as a way to reduce the risk of staff contracting the virus and transmitting it to their patients.[21] For the upcoming (2018/19) season, NHS has recommended that, "the quadrivalent vaccine will then be likely offer clinical benefit with improved protection to the health care worker themselves in terms of reduced absence and illness, and also indirectly to their vulnerable patients as well." [22] The 2016/ 2017 season saw 63.2% of all direct patient care HCWs to have received influenza vaccine, an increase from previous seasons, [23] but below the 75% goal, and it varies across healthcare trusts from 53.0% to 78.2.% [24] This is despite the JCVI recommendation and its encouragement by the General Medical Council and the British Medical Association (BMA) as part of good medical practice.[25] NHS has also recommended the vaccination of social care staff as part of their occupational requirements to protect vulnerable patients. [26]

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[12] *Influenza: The Green Book* Chapter 19. Page 9
[13] JCVIL Minutes of the Meeting 4 October 2017 Page 11
[14] *Influenza: The Green Book* Chapter 19. Page 9
[15] JCVI: Minutes of the Meeting 4 October 2017: Page 11
[16] JCVI: Minutes of the Meeting 4 October 2017: Page 12
[17] JCVI: Minutes of the Meeting 4 October 2017: Page 12
[18] NHS England Gateway Reference 07648: Vaccine Ordering for the 2018/2019 Influenza Season https://www.england.nhs.uk/wp-content/uploads/2018/02/vaccine-ordering-18-19-influenza-season-gp-pharm.pdf
[19] Health Care Worker Vaccination. Clinical Evidence. Page 3: http://www.nhsemployers.org/~/media/Employers/Publications/Flu%20Fighter/flu%20fighter%20clinical%20evidence%20Aug%202016.pdf
[20]Ibid Health Care Worker Vaccination. Clinical Evidence. Page 3: http://www.nhsemployers.org/~/media/Employers/Publications/Flu%20Fighter/flu%20fighter%20clinical%20evidence%20Aug%202016.pdf
[21] Ibid p. 3
[22] NHS Gateway Reference 07683 "Vaccine Ordering for the 2018-2019 Influenza Season". Available at: https://www.england.nhs.uk/wp-content/uploads/2018/02/vaccine-ordering-18-19-influenza-season-nhs-trusts.pdf
[23] Seasonal Flu Vaccine Uptake in Health Care Workers (HCW) in England; Winter Season 2016/2017 Page 4. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/613450/Seasonal_influenza_vaccine_uptake_in_HCWs_2016_to_2017.pdf
[24] Ibid p. 4.
[25] Health Care Worker Vaccination. Clinical Evidence. Page 4:
[26] Flu Immunisation for Social Care Staff Page 2. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/643609/Flu_social_care_staff_leaflet.pdf Page 2.

In summary, enhancing influenza immunisation in recommended groups (including HCW and carers) and using enhanced vaccines is a key avenue to improve respiratory outcomes. This is a feasible avenue as recommendations have existed for decades and products are available, and has broad reach and impact based upon the size of recommended populations and the annual burden of disease.

Chiesi

CHIESI LIMITED
Manchester Green
333 Styal Road
Manchester M22 5LG
Tel: 0161 488 5555
Fax: 0161 488 5566

Chiesi submission to the Task Force for Lung Health – First call for evidence

Purpose of this paper

This paper is provided to the Task Force for Lung Health established by British Lung Foundation (BLF) July 2017, as the Chiesi UK contribution to the evidence for chapters one and two (prevention, diagnosis). We welcome the opportunity to provide this information to support the work of the Task Force.

Chiesi overview

Chiesi is a global pharmaceutical company. In the last 30 years, we have grown to be one of the leading manufacturers and suppliers of medicines for respiratory conditions. Our medicines are used by many patients in the UK with asthma and Chronic Obstructive Pulmonary Disorder (COPD), helping them to manage their lung health.

As part of our work we provide educational support for healthcare professionals to enable them to provide quality care for their patients.

Our approach to developing this submission

As a consequence of our activities with healthcare professionals, we believe we have helpful insights into the healthcare environment in which patient care is delivered. The information provided in this paper is based on that insight.

What needs to change?

We believe that there are two significant challenges for the diagnosis of lung disease:

- Encouraging national policy development to promote public awareness and patient activation to seek help for their lung condition
- Ensuring there is a sustainable and well supported workforce for the delivery of respiratory care.

Patient awareness

As a potential consequence of low awareness, patients with Chronic Obstructive Pulmonary Disease (COPD) in particular, may present late with symptoms that have been ignored for some time[1]. The earlier the diagnosis of COPD is made, the greater the potential to reduce damage to the lungs through addressing lifestyle factors such as smoking, lack of physical activity and the prevention of COPD exacerbations, which are associated with disease progression[2].

Workforce

Whilst we take our commitment to supporting the workforce very seriously, as an industry, we are unable to directly address the perceived shortages of skilled and competent healthcare professionals and, in particular, respiratory nurse specialists.

We are now seeing an increased awareness within the NHS of digitally enabled disease support tools, using Bluetooth and Smartphone technologies. These innovations have the potential to help patients manage their disease, but will require interaction from a variety of healthcare professionals in order to improve asthma care at a population level[3]

Our field teams regularly meet front line staff who are approaching retirement. The respiratory nurse workforce is an ageing population. Approximately half of respiratory specialist nurses are aged between 45 and 54 years and a further 18% are aged between 55 and 64 years[4].

Summary

Chiesi remains committed to supporting this important initiative. We believe that as a matter of urgency the key focus for change needs to be the raising of patient awareness to seek treatment for lung conditions early and to actively address the workforce challenge.

Chiesi also believes that a well-resourced, competent NHS respiratory workforce is critical for the provision of good quality care for patients. Without this, there is a potential risk that levels of unwarranted variation across the UK may continue.

References:

[1] Chronic Obstructive Pulmonary Disease (COPD) Clinical Presentation. *Medscape*. September 2017 https://emedicine.medscape.com/article/297664-clinical (accessed 18-03-19)

[2] Opportunities to diagnose chronic obstructive pulmonary disease in routine care in the UK: a retrospective study of a clinical cohort. *The Lancet Respiratory Medicine*. Lancet Respir Med; 2: 267–76. February 2014 https://www.thelancet.com/action/showPdf?pii=S2213-2600%2814%2970008-6 (accessed 02-04-19)

[3] Howard, S. et al. 2016. What are the pros and cons of electronically monitoring inhaler use in asthma? A multistakeholder perspective. *BMJ Open Respiratory Research*, 3(1). November 2016 https://bmjopenrespres.bmj.com/content/bmjresp/3/1/e000159.full.pdf (accessed 18-03-19)

[4] Yorke, J. et al. Evaluation of the current landscape of respiratory nurse specialists in the UK: planning for the future needs of patients. *BMJ Open Respiratory Research*, 4(1). https://bmjopenrespres.bmj.com/content/4/1/e000210 (accessed 12-04-19)

Registered Office:
333 Styal Road, Manchester M22 5LG
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WWW.CHIESI.UK.COM

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