

## **Taskforce for Lung Health**

Treatment, management and end of life call for evidence – Industry Forum submissions

AbbVie

AstraZeneca

GSK

Chiesi

Pfizer

AbbVie

Name *	Gary 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	AbbVie
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. *	Technology
Do you have evidence to support changes in respiratory policy or service interventions in the following areas: treatment and medicines, living with a lung condition, or end of life? 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 information submitted by AbbVie

**Real world examples of policy or practice which would improve outcomes for lung patients if introduced or replicated across the country.**

**The National Optimal Lung Cancer Pathway (NOLCP)**

- 34% of all lung cancer patients in the UK are currently diagnosed as an emergency<sup>1</sup>, a figure that is significantly higher than for other cancers. Many lung cancer patients

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<sup>1</sup> Public Health England. (September 2015). Routes to Diagnosis 2006-2013; preliminary results. A National Cancer Intelligence Network short report. Available at: <https://www.gov.uk/government/news/cancers-arebeing-diagnosed-earlier-in-england>. Accessed: October 2015.

face a lack of understanding of the signs and symptoms of lung cancer. They often attend a number of consultations before they finally receive a diagnosis, which often leads to a worse experience of care<sup>2</sup> and potentially worse outcomes.

- In August 2017, NHS England approved the Lung Cancer Clinical Expert Group's (CEG) National Optimal Lung Cancer Pathway (NOLCP). The purpose of these documents is to inform and support decision making by Cancer Alliances in relation to services and clinical pathways for lung cancer. The recommendations aim to address the whole cancer pathway from prevention, early diagnosis, treatment and care to living with and beyond cancer.
- This pathway has the potential to support the NHS to improve lung cancer services and we would like to see this promoted more widely by NHS England and others across the NHS. This includes NHS England working directly with Cancer Alliances to examine where the pathway could be implemented.

### **Government's Personalised Medicine Strategy**

- Cancer care is changing. Over the past 15 years or so there has been an increase in what is termed personalised medicine, whereby interventions are targeted at specific groups of patients based on genetic, physiological or other clinical factors.
- For patients with lung cancer, personalised medicine can mean monitoring or clinical intervention based on family history or evidence of inherited susceptibility mutations, or it could mean a therapy that targets tumours with specific genetic mutations. These targeted approaches can benefit patients by prescribing treatments that are more specific to their needs and increase overall- or progression-free survival with fewer side effects.
- AbbVie are encouraged that NHS England recognises the importance of these developments and has developed an ambitious strategy to embed the personalised medicine approach into mainstream healthcare. There is a great potential for personalised medicine to improve quality of life for patients in the coming years.
- However, in order for rhetoric to become reality for lung cancer patients we would like to see NHS England implement the Government's Personalised Medicines Strategy alongside investment in infrastructure, technology and capacity for the NHS to truly embrace personalised medicine. This includes largescale education within the NHS workforce on personalised medicine and support for multi biomarker panel testing becoming routine reimbursed practice in the NHS.

### **Biggest Barrier to Lung Health**

- Lung cancer is the second most common cancer in the UK, after breast cancer, with nearly 47,000 cases diagnosed and around 36,000 deaths per year. Despite progress

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<sup>2</sup> Mendonca, SC. et al. (2015). Pre-referral general practitioner consultations and subsequent experience of cancer care: evidence from the English Cancer Patient Experience Survey. *Eur J. Cancer Care*. Available at: <http://onlinelibrary.wiley.com/doi/10.1111/ecc.12353/abstract;jsessionid=4DA73BB7A83BE9C3471B0763AA16C170.f04t03>

made in diagnostics, surgical techniques, drug regimens and radiotherapy, only 5% of lung cancer patients survive for 10 years or more post-diagnosis, a figure that has remained relatively constant for the past 40 years.

- There is also a stigma attached to lung cancer due to the association with smoking. A survey by the Global Lung Cancer Coalition revealed one quarter of people in the UK have less sympathy for people with the illness than those with other forms of the disease .
- The UK's lung cancer outcomes compare poorly in relation to those of its European neighbours. The incidence rates for lung cancer in the UK are higher than in Europe - 45.1 per 100,000 people in the UK compared to a European average of 44.1 per 100,000.<sup>3</sup>
- The chances of survival for UK patients at five years after diagnosis are 4% lower than in Europe and the likelihood of them dying from the disease is also higher, with 38.8 per 100,000 people in the UK dying from lung cancer compared to a European average of 36.5 per 100,000<sup>4</sup>
- It is clear that a range of clinical approaches will be needed to improve lung cancer survival. Improved strategies for early detection will play a role, but it is also important that there is improvements in and access to treatments. Historically, the UK has been a relatively low user of newer cancer medicines in comparison with other countries<sup>5</sup>.
- When compared to other cancers, patient experience with lung cancer in England presents a mixed picture. According to the 2015 National Cancer Patient Experience Survey, which surveys over 100,000 cancer patients in England, lung cancer patients rated their speed of diagnosis and understanding of their condition as better than patients with other types of cancer. However, nearly two out of ten people with lung cancer stated that they were not aware of the treatment options available to them, suggesting that further improvements need to be made in increasing patient awareness of the advantages and disadvantages of different treatment options. <sup>6</sup>
- Currently lung cancer has the worst outcomes in the UK and the lowest treatment uptake<sup>7</sup>.
- Analysis has shown that the UK has increased its use of cancer medicines launched in the last five years (with the UK rising from 10th to 7th in the international rankings since 2008/09)<sup>8</sup>.

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<sup>3</sup> The Swedish Institute for Health Economics, *Access to cancer medicines in Europe revisited*, 2016 available at:

[http://ihe.se/wp-content/uploads/2016/08/IHE-Report\\_2016\\_4.pdf](http://ihe.se/wp-content/uploads/2016/08/IHE-Report_2016_4.pdf), accessed February 2017

<sup>4</sup> The Swedish Institute for Health Economics, *Access to cancer medicines in Europe revisited*, 2016 available at:

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<sup>5</sup> A report for the Secretary of State for Health by Professor Sir Mike Richards CBE, *Extent and causes of international variations in drug usage*, July 2010

<sup>6</sup> Quality Health, *Cancer Patient Experience Data (national)*, 2015, available at:

<http://www.ncpes.co.uk/index.php>, accessed February 2017

<sup>7</sup> Macmillan cancer support. UK Cancer Survival Rates "Stuck in the 1990s". March 2015.

[http://www.macmillan.org.uk/aboutus/news/latest\\_news/ukcancersurvivalratesstuckinthe1990ssayscharity.aspx](http://www.macmillan.org.uk/aboutus/news/latest_news/ukcancersurvivalratesstuckinthe1990ssayscharity.aspx)

<sup>8</sup> Nolte, E. and J. Corbett, *International variation in drug usage: an exploratory analysis of the 'causes' of variation*. 2014, RAND Europe

- In part, this is due to the establishment of the Cancer Drugs Fund (CDF), which has benefitted over 95,000 people with cancer since its launch in 2011<sup>9</sup>. Since 2000 the UK has approved sixteen treatments for different lung cancers through NICE and further treatments have been made available through the CDF.<sup>10</sup>
- But recent changes to the CDF and the failure to reform the National Institute for Health and Care Excellence's (NICE) approach for evaluating innovative cancer medicines to reflect trends in drug development mean this progress may be at risk.
- The CDF has resulted in significant amount of financial risk being placed on industry to provide short-term discounts while NICE's assessment criteria, which relies on survival data, makes it difficult to adequately appraise medicines when survival data can take many years to mature. As a result, there are challenges for companies in providing the data required by NICE to demonstrate cost-effectiveness, before the evidence base has matured.
- The CDF remains a short-term sticking plaster solution to what has long been acknowledged as a medicines appraisal system which has significant challenges in assessing the real clinical value of cancer treatments. NICE's assessment criteria, which relies on survival data, makes it difficult to adequately appraise medicines when survival data can take many years to mature
- Cancer medicines are effective for multiple diseases and in each of these different indications, the medicine will have a different impact and therefore a different value, but the current assessment system does not recognise this.
- Increasingly, regulatory agencies are approving highly promising new cancer drugs for use earlier in the development process, before the traditional range of clinical trials on their long-term benefits have concluded. In practice, this divide in perspectives between regulators and payers is resulting in, at best, delays before treatments can be approved for use in the NHS and, at worse, negative recommendations that mean that new medicines are not made available to patients.
- In order to overcome this NHS England and NICE should work with industry to ensure that people with cancer can access the best possible treatments, using a medicines evaluation system that is fit-for-purpose for modern cancer medicines. The appraisal process could be reformed to accommodate more sophisticated and complex treatment regimens (e.g. precision medicine, multi-indication and multiple-combination

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<sup>9</sup> NHS England, *Cancer Drugs Fund*, January 2018

<sup>10</sup> NHS England, *National Cancer Drugs Fund list*, 2017, available at: <https://www.england.nhs.uk/wpcontent/uploads/2017/01/national-cdf-list-v1-19.pdf>, accessed February 2017

treatments). This includes working to ensure there is a more consistent regulatory and reimbursement pathway for innovations in the NHS.

## 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: *	Policy professional? If so, what's your job title and the name of your employer?
Please provide any extra details	AstraZeneca
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 the following areas: treatment and medicines, living with a lung condition, or end of life?**

**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 oncology:

Five-year survival for adults diagnosed with lung cancer in England are lower than the European average (8.8% compared to 13.0%) (1). Survival rates for lung cancer are amongst the lowest of all common cancers (2).

Poor survival rates for lung cancer in England are due to a range of factors, one of which may be variation in the use of treatments. Research published earlier this year has shown that the extent of use of different treatment modalities varies between geographical areas in England, reflecting differences in clinical management between local multidisciplinary teams (3). The authors concluded that there is potential for further survival gains if the use of active treatments in all areas could be increased towards the highest current regional rates.

The UK has previously had some of the lowest levels of uptake of new lung cancer medicines out of the five largest EU states (4). Furthermore, access to some targeted treatments may be limited by a range of issues including access to diagnostic testing. 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 (5).

The importance of early diagnosis of lung cancer has been raised during the Taskforce's call for evidence on prevention and diagnosis, however it is also worth reiterating here that lung cancer outcomes are better for patients diagnosed at an earlier stage (one-year survival for men diagnosed at stage 4 is 15%, compared to 81% at stage 1, and 66% at stage 2 – 19% at stage 4, 85% at stage 1 and 69% at stage 2 for women) (6). This is because treatment at earlier stages can be given with curative intent. It is therefore important not only that patients with suspected lung cancer are identified at an early stage, but also that they move through the system and onto treatment before their cancer progresses. However, from October – December 2017 only 72.7% of lung cancer patients received first

definitive treatment within 62 days of being urgently referred for suspected cancer by their GP, compared to 83.0% for all cancers (7). The operational standard (target) for this waiting time is 85% (8). Implementation of the National Optimum Lung Cancer Pathway should support faster referral to diagnosis and treatment without compromising patient experience (9).

#### Severe asthma:

According to NHS England, severe asthma has an estimated prevalence of 140 in every 1 million people in England (10), while Asthma UK suggests that this disease could affect as many as 200–250,000 people in the UK (11). Evidence suggests that patients with severe asthma have more symptoms and exacerbations than those with a mild or moderate form of asthma, with a worse quality of life and higher levels of anxiety and depression (12). NHS England mandates that the disease receives systematic assessment and specialist care (10); such diagnostic assessments have demonstrated benefits in terms of quality of life, disease control and a reduction in unplanned healthcare use (13). However, patients describe waiting years to obtain a conclusive severe asthma diagnosis. Four years after the National Review of Asthma Deaths identified that severe asthma patients made up 39% of severity-assessed asthma deaths (14), Asthma UK states that “we can and must do better” to improve the treatment of people with severe asthma (11). Phenotypic heterogeneity is a feature of severe asthma at all ages, with numerous clinical phenotypes described (15, 16). New biological therapies for treatment of severe asthma, together with developments in biomarkers, present opportunities for phenotype-specific interventions and realisation of more personalised treatment. Improving methods to undertake the earlier identification of patients with potential severe asthma (such as the increased use and access to diagnostic markers, such as FeNO and eosinophil levels) alongside more rapid referral to specialist centres to diagnose and appropriately treat patients with novel medicines, provide an opportunity to improve severe asthma patients’ outcomes.

#### Smart inhalers:

Half of adults with asthma are not in full control of their condition, leading to unnecessary symptoms, limitations and impact on daily activities (17–19). Patients adherence and involvement in controlling their asthma are key drivers of treatment success (20–22). A NICE Medtech innovation briefing noted that Smart inhalers are more effective than current standard of care in improving respiratory treatment (23). Smart inhalers respiratory asthma patients to track the use of their medication to help them better manage their respiratory condition day-to-day. At the same time, Smart inhalers provide healthcare professionals with information on their patient’s adherence to their prescribed medicine, giving them a better understanding of how their patient is using their medication. Smart inhalers employ easy to use technology and according to Asthma UK this technology may result in fewer GP appointments, accident and emergency attendance (23). They have the potential to help patients engage with their treatment and better self-manage their condition. Several pharmaceutical manufacturers have market-ready Smart inhaler devices, but currently no universal funding mechanism exists for such technology to be readily provided to patients within the NHS.

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4. B Jonsson, T Hofmarcher, P Lindgren, N Wilking. Comparator report on patient access to cancer



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8. National Cancer Registration and Analysis Service. Cancer Waiting Times. Available from: [http://www.ncin.org.uk/collecting\\_and\\_using\\_data/data\\_collection/gfocw](http://www.ncin.org.uk/collecting_and_using_data/data_collection/gfocw). Last accessed 16/04/18.

9. Lung Clinical Expert Group 2017. National Optimal Lung Cancer Pathway.

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12. Shaw, DE et al. Clinical and inflammatory characteristics of the European U–BIOPRED adult severe asthma cohort. *Eur Respir J*. 2015 Nov;46(5):1308–21. doi: 10.1183/13993003.00779-2015

13. Gibeon, D et al. Dedicated Severe Asthma Services Improve Health–care Use and Quality of Life. *Chest*. 2015 Oct;148(4):870–876. doi: 10.1378/chest.14-3056.

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23. NICE Guidance: Smart inhalers for Asthma <https://www.nice.org.uk/advice/mib90/resources/smartinhaler-for-asthma-pdf-63499461673669> (Accessed 20 April 2018).

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

The National Cancer Patient Experience Survey (NCPES) highlights several areas in which the experience of lung cancer patients in England could be improved (1), including:

- Being given a care plan (32.7% of lung cancer patients responded positively).
- Being given enough information about whether radiotherapy was working in a way they could understand (58.2% of lung cancer patients responded positively).
- Once cancer treatment had finished, being given enough care and support from health or social services (42.7% of lung cancer patients responded positively).

#### References:

1. Quality Health 2017. National Cancer Patient Experience Survey 2016. Available from: <http://www.ncpes.co.uk/reports/2016-reports/national-reports-1>. Last accessed 16/04/18.

#### Rational

The National Review of Asthma Deaths (NRAD) 2014 highlighted that for many patients who die from asthma, across the disease severity, poor adherence to their maintenance anti-inflammatory preventer therapy and over-reliance on short acting beta-agonists (SABA) to control their symptoms is a major contributor.<sup>1</sup> The Lancet Commission statement on the future of asthma care has demonstrated that despite advances in inhaled therapies over the last 20 years, the initial improvements in mortality rate for asthma have plateaued, and suggests that this may be related to poor understanding and use of otherwise effective asthma therapies both by patients and healthcare professionals. This has been further highlighted by several authors suggesting that there are clinical management paradoxes in the current approaches to asthma care that result in conflicting and contradictory messaging, which may be contributing to inappropriate adherence and prescribing behaviours.<sup>3</sup>

The issue of SABA over-reliance by many patients with asthma is seen as a marker of this conflicting advice, and is associated with poor asthma control, tendency to exacerbations and impaired quality of life.<sup>3,4</sup> It is imperative that there is urgent action to minimise SABA over-reliance in the UK and to change the perceptions of what is optimal asthma care in order to improve the lives of patients with asthma, and minimise the risk of poor outcomes.

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**GSK**

Title	Mrs
Name *	Gill 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?
Are you responding as an individual or on behalf of an organisation? *	GSK
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 the following areas: treatment and medicines, living with a lung condition, or end of life? 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.	Refer to attachments – IMPACT & Salford Lung Study

Alternatively, upload your answer to this question here



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Additional information submitted by GSK on research paper 'A novel hybrid approach to real-world data capture in a mepolizumab study' available online at: <https://www.ers-education.org/events/international-congress/milan-2017.aspx?idParent=183161>



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## **Chiesi response to the Task Force for Lung Health – Second call for evidence**

### **1.0 Introduction**

Chiesi UK welcomes the opportunity to provide information to the *second call for evidence* from the Lung Health Task Force. This call for evidence is focusing on Treatment, Management and End of Life for patients with conditions of the lung. The Task Force is specifically calling for examples of ‘what needs to change’ to improve care and outcomes for patients. We are pleased to be able to respond with consideration for the treatment and management of patients with both Asthma and Chronic Obstructive Pulmonary Diseases (COPD).

As a pharmaceutical researcher and manufacturer, we have gained insights over recent years into the challenges faced by healthcare professionals working in respiratory care. We also believe there are many patient groups, clinical networks and charities that have supportive and compelling case studies, highlighting the areas where they believe change is most needed. In particular, we would cite the work of the National Asthma and COPD Audit Programme, including the National Review of Asthma Deaths (NRAD), published May 2014 and The Annual Asthma Survey Report 2017 that we believe provide strong overarching evidence and a compelling case for change.

### **2.0 Chiesi’s commitment to improving outcomes for patients**

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.

We have been committed to the work of the Task Force from the outset and submitted a case for change in the *first call for evidence* in February. Our first submission focused primarily on the NHS workforce challenges that seem apparent when we engage with healthcare professionals.

We recognise that this call for evidence from the Task Force is looking for specific aspects of the patient pathway that need to change, however, we firmly believe that without investing in and supporting the respiratory workforce, new initiatives to improve care may be difficult and slow to implement. We would therefore recommend that workforce development is included and prioritised within the Task Force report.

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### 3.0 Specific areas of focus

#### 3.1 Improving the management of patients with COPD to prevent exacerbations

##### Evidence:

It is estimated that COPD patients suffer one to four exacerbations per year. Studies show that severe acute exacerbations of COPD have an independent negative impact on patient prognosis with consequential healthcare burden and economic costs. Mortality increases with the frequency of severe exacerbations, particularly if these require admission to hospital<sup>1</sup>.

Of particular note, the course of COPD involves a rapid decline in health status after the second severe exacerbation and is associated with high mortality in the weeks following every severe exacerbation<sup>2</sup>.

##### Chiesi recommendations to reduce the potential risk of early mortality:

- Raise awareness across the range of healthcare professionals involved in respiratory care of the potential deleterious impact on prognosis resulting from severe acute exacerbations.
- Treatment plans for COPD management should ideally include strategies for delaying the second severe exacerbation.

#### 3.2 Access to pulmonary rehabilitation (PR) for COPD patients

##### Evidence

The report from the National COPD Audit provides a strong evidence base for the value of pulmonary rehabilitation for people with COPD. The report, published by The Royal College of Physicians (RCP) states that where good quality PR services are provided, patients who complete the treatment show considerable health benefits such as exercise capacity and quality of life<sup>3</sup>.

##### Chiesi recommendations to improve access to PR

- Increase knowledge and awareness of PR with primary and secondary care healthcare professionals to help encourage patients to access the service .
- PR services should ideally adapt their programmes to increase convenience and acceptability, to meet the needs of patients and carers and encourage participation and course completion.

#### 3.3 Patient experience – patients living with COPD

##### Evidence

The *Breathing New Life into COPD* survey of 500 people across Britain diagnosed with COPD was undertaken in 2017 by the research company, Opinion Health, funded by Chiesi Limited and was supported by the British Lung Foundation<sup>4</sup>.

The survey found that almost a third (31%) of respondents felt their treatment was not adequately controlling their condition while 60% felt there was not enough support available to help them manage it properly. The survey showed that almost half (46%) of patients used at least three inhalers to help keep their condition under control<sup>4</sup>.

Despite this, flare-ups, where the patient's condition suddenly worsened, led to a fifth (21%) of people visiting Accident and Emergency (A&E) up to twice a year and some patients (4%) had visited

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A&E three or more times in a year due to their lung health. Just under a fifth (18%) of those questioned said they had to stay in hospital overnight once or twice in the last year because of their flare-up<sup>4</sup>.

The survey also revealed a lack of awareness of the condition, with 37% of patients knowing nothing about it before they were diagnosed. COPD was also having a negative impact on the personal lives of people with the condition<sup>4</sup>.

Chiesi Recommendations to improve the patient experience:

- Patients and carers should be provided with adequate and appropriate information to help improve the patients' understanding of their condition and how best to manage their lung health.
- Information should be available in formats, languages and styles to ensure accessibility for all patients. Evidence shows that providing high quality health information is beneficial. It has a positive impact on service utilisation and health costs, patients' experience of healthcare and patients' health behaviour and status<sup>3</sup>.

### 3.4 Improving basic provision of care for patients with Asthma

The Annual Asthma Survey Report 2017 published by Asthma UK is a stark reminder that despite the publication of the NRAD report in 2014, there has been little or no decrease in the number of patients dying from asthma in the UK and around 70,000 patients each year experience the pain, upset and stress of an emergency visit to hospital. The report calls for emphasis on a need for basic care to be provided in every single case<sup>6</sup>.

The report indicates that nearly two-thirds of patients with asthma are not receiving basic levels of asthma care. The report also highlights significant variation in care provided across the UK.

Chiesi recommendations for standardised care

- Raise awareness with healthcare professionals of the potential for life-threatening asthma attacks if patients receive sub-optimal care.
- Good practice, where it is known, should be shared to help reduce unwarranted variation.

### 3.5 Use of technology to improve care for patients with Asthma

Evidence

The Annual Asthma Survey Report 2017 asked a number of questions to the respondents relating to patients' use of technology. The survey showed that technology is now playing a role in asthma care and there may be potential for expansion of this in the future<sup>6</sup>.

An analysis of *smart* inhaler devices undertaken by the Royal Pharmaceutical Society in 2017 identified that such devices have advantages in improving patient adherence and confidence in their treatment. Smart inhalers use Bluetooth technology to perform a range of functions that could include, detection of inhaler use, reminders for patients when to take their medication, gather data to help guide care. They have the potential to improve patients' adherence to asthma therapies, but they will need to be designed with health systems and patients in mind so that they can offer the best possible benefit<sup>7</sup>.

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#### Chiesi recommendations for improving the use of technology

- Patients, doctors, manufacturers and health systems should work together in the development of smart inhalers and asthma support apps.
- Investment in technology should remain patient centric to ensure the technology remains focused on improving the experience for the patient when using their inhaler.

#### 4.0 Conclusion

Chiesi welcomes the opportunity to provide this information and supports the work of the Task Force.

In addition to the information specific to treatments and the management of lung conditions, we have also included a recommendation for addressing workforce challenges. Chiesi believes that without a concerted effort to address these challenges first will result in many of the initiatives and service developments failing to gain the traction needed to deliver improved care for patients.

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<sup>7</sup> Smart inhalers: will they help to improve asthma care? *The Pharmaceutical Journal*, April 2017. <https://www.pharmaceutical-journal.com/news-and-analysis/features/smart-inhalers-will-they-help-to-improve-asthma-care/20202556.article> [accessed 05/03/19]

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**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	Pfizer UK
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? *	No
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 the following areas: treatment and medicines, living with a lung condition, or end of life?**

**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.**

Smoking Cessation – The following recommendations are based on available evidence that would support policy or service change interventions

#### 1) Treatment and Medicines : Models of Care

We recommend Staff in GP practices actively provide brief advice and medication as part of Long term condition management for patients who smoke, prior to onward referral for behavioural support. Studies examining onward referral for smokers demonstrate significant drop off in uptake(Lewis KE et al), and in many areas of the UK, services are being restricted for patients with specific co-morbidities. As such the ability to engage a smoker in a Quit is maximised by the HCP directly prescribing pharmacotherapy subsequent to VBA.

Public Health smoking services are being decommissioned/deprioritised and only help less than 2% of the smokers in the UK while 2M smokers with Long term conditions (QOF) are using NHS services every year but don't get the support around quitting.

There is a successful case study to demonstrate how GP practices have benefitted clinically and financially by prioritising smoking cessation among Long term condition patients(Primary Care Respiratory Update).

An additional study (Van Rossem et al) conducted recently supports the equal effectiveness of medication with brief advice in absence of behaviour support. This study could help develop and accelerate new ways of providing smoking cessation in GP Practices and increase access to patients to approved smoking cessation pharmacotherapy significantly



Supporting data :

Van Rossem et al, <https://www.ncbi.nlm.nih.gov/pubmed/28667826>;

Lewis KE et al, <https://www.ncbi.nlm.nih.gov/pubmed/19436042>;

Primary Care Respiratory Update <https://www.pcrs-uk.org/sites/pcrs-uk.org/files/QuittersSavesTime.pdf>

## 2) Treatment and Medicines: Data

Multimorbidity: Evidence for smoking cessation in patients with Long Term Conditions can be found at:

COPD: <https://www.ncbi.nlm.nih.gov/pubmed/20864613>;

Stable Cardiovascular disease: <https://www.ncbi.nlm.nih.gov/pubmed/20048210>;

Diabetes: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5217903/>

Acute Cardiovascular

disease: <https://www.ncbi.nlm.nih.gov/pubmed/26553744> & <https://www.ncbi.nlm.nih.gov/m/pubmed/29581161/>

## 3) Treatment and Medicines: Workforce

Quit at work Programmes – evidence to support can be found

at <https://academic.oup.com/occmed/article/63/8/526/1463858>

COPD – The following recommendations are based on available evidence that would support policy or service change interventions

## 1) Treatment and Medicines: Data

Implement GOLD positioning inhaled triple therapies – LAMA/LABA/ICS triple therapy for use in high-risk patients who continue to experience exacerbations whilst on bronchodilation therapies, providing incremental benefits in exacerbation risk management but with associated long-term steroid treatment risks. Recently published trial data for inhaled triple therapies support the GOLD positioning.

Supporting data can be found at:

GOLD 2018: [http://goldcopd.org/wp-content/uploads/2017/11/GOLD-2018-v6.0-FINAL-revised-20-Nov\\_WMS.pdf](http://goldcopd.org/wp-content/uploads/2017/11/GOLD-2018-v6.0-FINAL-revised-20-Nov_WMS.pdf)

IMPACT trial (triple therapy vs LABA/ICS vs LABA/LAMA in high-risk pts): [www.nejm.org/doi/full/10.1056/NEJMoa1713901](http://www.nejm.org/doi/full/10.1056/NEJMoa1713901)

TRIBUTE (triple therapy vs LABA/LAMA in high-risk

patients): [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)30206-X/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30206-X/abstract)

## 2) Treatment and Medicines: Data

Data from individual LABA/LAMA trials should not be applied across the class.

Evolving data suggesting that results from individual LABA/LAMA trials cannot be applied across entire class.

Indacaterol/glycopyrronium remains the only LABA/LAMA to have shown reduction in rate of exacerbation compared to both LAMA and LABA/ICS in prospectively designed clinical trials (SPARK, FLAME), whereas other medicines in the same class have either not carried out such trials or failed to show statistically significant reductions (DYNAGITO, IMPACT).

Direct head-to-head data for LABA/LAMAs is very limited, however one such trial did indicate that

measurable differences between individual treatments may exist (Feldman et al).

Supporting Data can be found at:

Feldman trial (umedclidinium/vilanterol v tiotropium/olodaterol; lung function crossover trial): <https://www.ncbi.nlm.nih.gov/pubmed/29094315>

Trials across LABA/LAMAs with similar design/populations but differing results:

SPARK (LABA/LAMA vs LAMA; high-risk patients; primary endpoint – exacerbation frequency; dual bronchodilation reduces exacerbation

risk): [http://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(13\)70052-3/abstract](http://www.thelancet.com/journals/lanres/article/PIIS2213-2600(13)70052-3/abstract)

DYNAGITO (LABA/LAMA vs LAMA; high-risk patients; primary endpoint – exacerbation frequency; no difference in exacerbation risk): [http://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(18\)30102-4/fulltext](http://www.thelancet.com/journals/lanres/article/PIIS2213-2600(18)30102-4/fulltext)

FLAME (LABA/LAMA vs LABA/ICS; high-risk patients; primary endpoint – exacerbation frequency; dual bronchodilation reduces exacerbation risk): <http://www.nejm.org/doi/full/10.1056/NEJMoa1516385>

IMPACT (LABA/LAMA vs LABA/ICS vs Triple therapy; high-risk patients; primary endpoint – exacerbation frequency; ICS-containing therapies reduce exacerbation risk): <http://www.nejm.org/doi/full/10.1056/NEJMoa1713901>

### 3) Treatment and Medicines: Data

Comorbidity: Patients with COPD and lung hyperinflation should be effectively bronchodilated – Recent evidence suggests this leads to improvements in cardiac function and output.

Data to Support:

CLAIM study full publication: <https://www.ncbi.nlm.nih.gov/pubmed/29477448>

### 4) Treatment and Medicines: Models of Care

Widespread application of the Primary Care Respiratory Society UK algorithm for the appropriate withdrawal of inhaled corticosteroids in patients with COPD.

This is in line with GOLD's 2018 treatment framework, which recommends bronchodilating therapies as first-line options in the majority of patients and real-world data which indicate significant percentages of patients at low risk of exacerbation are continuing to be treated with ICS-containing regimens (Price D et al 2014), despite long-term health risk associated with chronic steroid exposure (Price D et al 2013). The PCRS ICS step-away algorithm is informed by multiple studies (randomised controlled trials and real world studies) which have investigated switching patients from LABA/ICS or triple therapy to bronchodilation-only regimes (INSTEAD, OPTIMO, CRYSTAL, FLASH, WISDOM, SUNSET – see details to the right). One such study (SUNSET – randomised controlled blinded trial, Triple Therapy to LABA/LAMA switch in low-risk COPD patients) is still ongoing but the combined evidence of these trials suggests that, in appropriate patients, the withdrawal of steroid therapy is not associated with worsening symptom and exacerbation risk management, as long as patients continue to receive effective bronchodilation therapy.

Data to support can be found at:

PCRS ICS withdrawal algorithm: <https://www.pcrs-uk.org/stepping-down-ics-copd>

GOLD 2018: [http://goldcopd.org/wp-content/uploads/2017/11/GOLD-2018-v6.0-FINAL-revised-20-Nov\\_WMS.pdf](http://goldcopd.org/wp-content/uploads/2017/11/GOLD-2018-v6.0-FINAL-revised-20-Nov_WMS.pdf)

Price D et al, [www.ncbi.nlm.nih.gov/pubmed/25210450](http://www.ncbi.nlm.nih.gov/pubmed/25210450)

Price D et al, <https://www.ncbi.nlm.nih.gov/pubmed/23135217>

INSTEAD (Randomised controlled blinded trial, LABA/ICS to LABA switch in low-risk COPD patients, direct switch): <https://www.ncbi.nlm.nih.gov/pubmed/25359348>

OPTIMO (Open-label real world prospective study, LABA/ICS to long-acting bronchodilators in low-risk

COPD patients, switch at prescriber's discretion): <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4122053/>  
 CRYSTAL (Open-label pragmatic real-world study, LABA/ICS to LABA/LAMA switch in low-risk COPD patients, direct switch): <https://www.ncbi.nlm.nih.gov/pubmed/28720132>  
 FLASH (Randomised controlled blinded trial, LABA/ICS to LABA/LAMA switch in low-risk COPD patients, direct switch): [https://onlinelibrary.wiley.com/doi/full/10.1111/resp.13206\\_168](https://onlinelibrary.wiley.com/doi/full/10.1111/resp.13206_168)  
 SUNSET (Ongoing Randomised controlled blinded trial, Triple Therapy to LABA/LAMA switch in low-risk COPD patients, direct switch): <https://clinicaltrials.gov/ct2/show/NCT02603393?term=nct02603393&rank=1>  
 WISDOM (Randomised controlled blinded trial, Triple Therapy to LABA/LAMA switch in severe COPD patients with a history of exacerbations, gradual steroid dose reduction): <http://www.nejm.org/doi/full/10.1056/NEJMoa1407154>

### 5) Management: Models of Care

Regular monitoring of patients with COPD is vital to effective management (as is correct diagnosis). Real-world evidence (QoF, Dransfield) indicate that even patients diagnosed with COPD and receiving active therapy may still be symptomatic, with as many as 38% of patients on the COPD register still experiencing breathlessness.

Supporting Data:

COPD QoF: <http://digital.nhs.uk/catalogue/PUB30124>

Dransfield, real-world evidence <https://www.nature.com/articles/pcrj201059COPD>:

## Lung Cancer

### 1) Treatment and Medicines: Models of Care

Implement the NCAT approach to determine the costs of systemic anti-cancer therapy

Data to Support:

Central South Coast Cancer Network – Developing more efficient services for lung cancer patients. Applying the National Cancer Action Team (NCAT) approach helped to determine the costs of systemic anti-cancer therapy (SACT)

### 3) Treatment and Medicines: Models of Care

An increase in the number of Lung Cancer Clinical Nurse specialists

As diagnosis rates are increasing and as patient with Lung cancer are living longer, the case load for these nurses is growing. They provide valuable support to consultants and the numbers of patients that receive treatment is higher when LCNS are involved

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

Smoking Cessation – The full engagement of the NHS and CCGs in aiding smokers to quit (a National NHS Smoking Cessation plan) and a focus on quitting vs harm reduction

COPD – Regular monitoring of patients diagnosed with COPD is vital to effective management

Lung Cancer – access to the most effective  
therapy without delay