IMPRESS Guide to the relative value of COPD interventions
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IMPRESS was set up in 2007 as a joint initiative between the British Thoracic Society (BTS) and the Primary Care Respiratory Society-UK (PCRS-UK) to provide clinical leadership to the NHS to stimulate improvement and integration in respiratory services. The IMPRESS team now has representation from primary and secondary care, nursing and medicine, public health, social care, providing and commissioning and lay views. We have worked through many of the issues that local teams need to address to improve care across the system and provide practical and highly-regarded guidance through our website www.impressresp.com

The British Thoracic Society (BTS) has over 2,800 members who are actively working in a variety of healthcare professions to improve the standards of care for people with lung diseases. Sixty-five percent of members are secondary care physicians and doctors in training. The remainder are respiratory nurse specialists, respiratory physiotherapists, respiratory technical and physiological measurement professionals, smoking cessation practitioners and staff working in primary care settings. The society undertakes an ambitious programme of quality improvement activities, education and public awareness programmes, and publishes the journal Thorax. It also organises the largest single-society respiratory scientific meeting in Europe. BTS Guidelines are accredited by NHS Evidence. BTS national clinical audits are recommended by NAGCAE for inclusion in NHS trust quality accounts. BTS Care Bundles for both COPD and CAP are in development and the new series of BTS Quality Standards will be launched in 2012. Funding has been secured from HQIP to establish the BTS Lung Diseases Registry. The Society places great value on its work with strategic partners such as PCRS-UK and patient organisations, as it is these collaborations that help the over-arching strategic objectives of raising the profile of the specialty and working to improve standards of respiratory care.

http://www.brit-thoracic.org.uk/

The Primary Care Respiratory Society UK (PCRS-UK) is an independent charity representing primary care health professionals interested in delivering the best standards of respiratory care. It is dedicated to achieving optimal respiratory care for all through:
• Representing primary care respiratory health needs at policy level
• Promoting best practice in primary care respiratory health through education, training and other services
• Supporting the development of primary care health professionals in respiratory medicine
• Facilitating and leading primary care respiratory research

For further information and details of how to join the PCRS-UK http://www.pcrs-uk.org/

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IMPRESS Guide to the relative value of interventions for people with COPD

A population-based approach to improving outcomes for people with chronic obstructive pulmonary disease based on the cost of delivering those outcomes

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Introduction

This IMPRESS paper is produced by primary and secondary care clinicians with a respiratory interest, facilitated by a Health Foundation-supported London School of Economics team. It aims to guide commissioners working within the limits of respiratory programme budgets to allocate resources to the interventions for a population with COPD that offer the most value, defined as outcomes divided by cost. It also aims to introduce health economic concepts and literature that may be unfamiliar to many. It builds on our previous work on More for Less (Appendix 1) which was used by the London Respiratory Team and developed into a “value pyramid” that aimed to show the relative value of different interventions in COPD. IMPRESS has then taken back the work to develop further.

Our focus was on where there was scope to change. Our aim is not to suggest “switches” between particular drug therapies or to encourage either/or debates. We want to draw attention to what we know about where best value can be extracted from healthcare investment. We encourage clinical commissioners and clinical teams to collaborate to ensure that the investment is targeted to those populations or segmented populations that would benefit. The corollary of that is that we also encourage you to start to collaborate to withdraw investment in those interventions that do not yield value for a particular segment or population and to consider what should be substituted to improve outcomes. Like others, we argue that healthcare professionals have an ethical responsibility to avoid waste. This means taking steps to ensure that funds are spent on what improves a patient’s health, and to reduce expenditure on what does not, and to stop interventions that may cause harm.¹

¹. Brody M. From an Ethics of Rationing to an Ethics of Waste Avoidance. NEJM 2012: 2 May. DOI: 10.1056/NEJMp1203365
Background

The NHS is one of many national healthcare systems aiming to transform care delivery because of rising costs, increasing need and because it believes it can, and wants to, do better, for example by reducing unwarranted variation in care and outcomes. In the context of financial constraint, Porter argues healthcare commissioners have four basic choices:2

- Ration care or
- Reduce quality or
- Cut pay or
- Improve value

Of these, commissioning for value seems the one that can unite commissioners and clinicians and patients. Here value is defined as patient outcomes divided by the cost of producing these outcomes. This is the inverse of traditional economic evaluation methods and so not yet a familiar model. It also involves making explicit trade-offs between outcomes and resource use.

However, there is a lack of guidance about how we get best value for a population and how we address variation. IMPRESS has started to address this with these resources. It took as its starting point the IMPRESS work on misuse, overuse and underuse and under-coordination that led to our More for Less publication.

This highlighted interventions that were not used appropriately for patient benefit. However, it did not consider cost, or calculate the size of the benefit. This led to the NHS London “value pyramid” (Appendix 2) which is now reproduced in the NHS Companion Document3 and IMPRESS has therefore built on this, because it received immediate attention from a number of commissioners and traction with many policy makers and influencers. However, there were limitations to the pyramid:

- The data analysis needed peer review
- The visual explanation could be misinterpreted as offering either/or choices rather than less of this and more of that choices
- There were interventions missing
- It did not differentiate between the value of the interventions at different stages of disease
- It did not explain the “so what”. That is, if that’s the relative value, what does that mean for what I commission within finite resources and to best meet the needs of my local population?

We were also influenced by work by McKinsey’s for the DH England that aimed to prioritise interventions for congestive heart failure. (Appendix 3)

Therefore we aimed to produce some visual explanations of a complex analysis that reviewed cost-effectiveness data, considered what changes might be cost-effective and then applied those changes to an archetypal population of about 300,000 (Appendix 4). These numbers can be scaled as needed to match Clinical Commissioning Group sizes.

We have supplied the background thinking and analysis because there is a lot of useful analysis. Where we have identified disagreement or controversy, we describe the issues. We hope it creates purposeful discussions amongst commissioners, clinicians and patients, based on real local data and experience.

2. Porter ME. What is value in health care? NEJM 2010;363:2477-2481
Getting value from the Respiratory Programme Budget

Programme budgets

1. According to NHS Programme Budget data, the NHS in England spent £4.43 billion on respiratory care in 2010/11 of which £720 million was on COPD and £1.08 billion on asthma. The breakdown of cost for England and some illustrative PCTs is shown in the Appendix 5.*

2. Various public health tools demonstrate variability in healthcare outcomes, practice and costs in COPD. The Spend and Outcome Tool (SPOT) uses “z” scores to demonstrate distance from the mean and suggests commissioners lying outside the z score box may need to review spend, outcome or both.4

3. Rather than reducing costs, we suggest the perspective should be how to get the best value from this investment.

Population and individual health

4. This requires us to think about population health, and the relative value of the interventions we offer to local populations and segments of that population. The perspectives of the clinician and commissioner are not always the same, but need to align and inform each other. As an illustration, here is a potential population:

<table>
<thead>
<tr>
<th>Population</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>300,000</td>
<td>Population</td>
</tr>
<tr>
<td>Of those 80% adults = 240,000</td>
<td></td>
</tr>
<tr>
<td>Of those 20% smokers = 48,000</td>
<td></td>
</tr>
<tr>
<td>Of those 25% at risk (that is, 1:4 continuous smokers at risk of COPD) = 12,000</td>
<td></td>
</tr>
</tbody>
</table>

5. The choices a commissioner has to make relate to a defined population and are typically not either/or, but rather more of, or less of, to achieve the desired outcomes within a limited budget. They involve the concept of volumes of need and services.

6. The choices a clinician has to make typically relate to an individual, and may involve choices between options eg medicines, and about the combinations or sequence in which interventions are offered, given desired outcomes and a fixed budget.

Use of evidence

7. Both perspectives should be guided by the evidence base, but not accepted uncritically because the evidence may not represent the local situation/person.

8. We should also start from the knowledge that not every commissioner nor clinician applies the evidence-base systematically. For example, several studies have concluded that between 15% and 20% of those with a COPD diagnosis do not have COPD suggesting an alternative diagnosis (in our modelling we took a conservative figure of 10-15%).6,7 According to the national COPD audit 2008, of those discharged from secondary care the diagnosis is made despite only 55% of notes having evidence of spirometric confirmation within the last five years.8 Most of these patients are receiving some medication; some, maximal medication. This means that a substantial population is receiving medical interventions that will not benefit them, creating waste, and possibly harm.9 Others with correctly diagnosed COPD are receiving multiple therapies, some of which provide little or no value.

* The usual difficulty of separating drug spend between asthma and COPD means that other analyses also exist. The Economic Impact Assessment 2010 for the Outcomes Strategy for COPD and Asthma in England estimated £810m.

7. Audits in Leicestershire (D Ryan), Outer North East London (M Roberts)
9. Meanwhile, there are many people who are undiagnosed. Estimates of numbers vary considerably with some hospitals in London, for example, reporting as many as between 1/3-1/2 of admissions for acute exacerbation of COPD to be in previously undiagnosed patients. More published reports are needed about this, including whether these diagnoses are made by quality-assured spirometry.

Cost-effectiveness data

10. If we are to assess value, we need not just clinical effectiveness data but also cost-effectiveness data. The issue is not whether an intervention produces a statistically significant result but whether the difference, if significant, is big enough to be clinically useful. That is whether it has value. Ultimately, we should also be interested in incremental costs and value. That is, what is the extra value obtained from using multiple therapies compared with one or two?

QALYs

11. Cost per quality adjusted life year (QALY) is a standard, internationally recognised measure that uses validated quality of life measures, and costs. NICE currently uses cost per QALY although it is being reviewed. It sets the threshold for provision of medicines by the NHS at approximately £20,000-£30,000/QALY gained; where the probability is that treatments are cost-effective. Drugs with incremental cost-effectiveness ratios above this level are unlikely to be approved by NICE.

12. However, cost per QALY is not available for many interventions, including those for COPD, and when it is, there can be problems with the sample size, standardisation including period of time studied, the intervention studied, the service model in which it sits, the cost calculation methods and whether an absolute figure is given, or a more robust range of probabilities.

NNTs

13. Numbers needed to treat (NNTs) or harm (NNH) are familiar to many clinicians, useful and intuitive, but importantly are trial-specific and do not involve costs nor the size of the benefit. For example, one intervention might have a NNT of 2, and another of 10, but the impact can’t be compared: the intervention with a NNT of 2 might not achieve as big a benefit for the individual as the intervention with a NNT of 10. NNTs should not be used to compare results across trials unless this is done using standard statistical techniques.

Gaps

14. Not having a cost-effectiveness evidence base should not rule out an intervention and in some cases it would not be feasible to stop doing something, such as flu vaccination even though the evidence in COPD particularly is not strong. However, commissioners should understand where the gaps are.

15. IMPRESS advocates integrated care and supports the Future Forum and King’s Fund reports on integration, but the cost-effectiveness evidence for some key aspects of current policy such as risk stratification and integrated teams is not yet available.

Complex resource allocation decisions

Social process

16. Not only is the evidence lacking in many respects, but also healthcare decision-making and resource allocation is a social and complex process and requires judgements on many levels. For example, decisions on healthcare investment will depend on what conclusions commissioners reach about the need for equality, and how they define that. How analyses are interpreted and then applied often depends on discussion and debate among stakeholders with different agendas.

17. Then at the micro level, how decisions are implemented and their subsequent outcome depends on implementation by individual clinicians. For example, the success of a decision to spend more on pulmonary rehabilitation depends on referrers accepting the decision, choosing to use the service, and knowing how to do so. It also depends on how effectively they communicate this referral option to the patient in front of them.

18. The Kings Fund’s paper on rationing describes the problems at the macro level: “The notion that there is a neat, technocratic fix for taking decisions about resource allocation – as epitomised by NICE – therefore turns out to be a mirage. Indeed, NICE itself has recognised this in a variety of ways. It accepts that social value judgements are inevitably involved in the decision-making process.”

**Decision conferencing**

19. Recognising that developing a guide to the relative value of interventions in COPD would be one such social and complex process, IMPRESS used a method developed by the London School of Economics, supported by the Health Foundation, called decision conferencing.14 (Appendix 6) We acknowledge the expert facilitation that the London School of Economics gave us. Decision conferencing was designed to address the challenges we all face:

a. Many options are present,
b. Benefits and risks are rarely expressed as single objectives,
c. Multiple stakeholders with different agendas compete for limited resources,
d. Individually optimal resource allocations to organisational units are rarely collectively optimal, and
e. Those dissatisfied with the decisions taken may resist implementation.

20. In essence, decision conferencing requires the key players to work through a modelling process together, thereby ensuring shared ownership of the model and of its conclusions. It encourages communication throughout the group, develops shared understanding of the territory, and generates a shared direction. It has been used successfully by NHS Isle of Wight15 and other major policy areas.16,17 It aims to show people the effect of a change in investment. **When people are tired of change, it is imperative to show that the change will be worth the effort.**

21. In terms of cost-effectiveness analysis there are four possible scenarios if changes are made from the status quo. Here is an illustration of lung volume reduction surgery vs medical therapy for COPD.18

<table>
<thead>
<tr>
<th></th>
<th>Cost difference</th>
<th>Effect difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>LVRS more costly and less effective than MT (MT dominates LVRS)</td>
<td>+</td>
</tr>
<tr>
<td>B</td>
<td>LVRS less costly and less effective than MT</td>
<td>-</td>
</tr>
<tr>
<td>C</td>
<td>LVRS more costly and more effective than MT (LVRS dominates MT)</td>
<td>0</td>
</tr>
<tr>
<td>D</td>
<td>LVRS less costly and more effective than MT</td>
<td>-0</td>
</tr>
</tbody>
</table>

LVRS = lung volume reduction surgery; MT = medical therapy

22. The logical focus for a decision conference is the interventions in Quadrants C and D because in theory quadrants A and B provide a clear ethical and economic case for stopping an intervention (eg oxygen prescribed for breathlessness) or investing respectively. In COPD care, as in many specialties, there are areas of agreement and controversy and relatively few “low hanging fruit” in terms of A and B and therefore most of the debate will be about interventions in quadrants C and D.

The process

23. As we expect you will be unfamiliar with decision conferencing, and we hope you may want to try it, we describe the stages of our process. For those who wish to jump to our findings and conclusions; go here.

a. Agree on categorisations/segments of the population. We agreed on three pragmatic categories for which we expected to find evidence: eg undiagnosed, diagnosed with mild or moderate COPD or FEV1 >50% of predicted and diagnosed with severe or very severe COPD or FEV1 <50% of predicted. We rejected potentially more accurate categorisations based on smoking history or breathlessness because of a paucity of relevant evidence. (Appendix 7)

b. Produce a longlist of interventions by identifying all the possible interventions for those categories ranging from flu vaccination, stop smoking support, drug therapy, pulmonary rehabilitation, case management, to hospital based interventions including surgery.

c. Analyse, through desktop research, the cost-effectiveness data for these interventions, noting the cost per QALY and other measures, using a standard template (Appendix 8). In addition to standard searches and use of Cochrane reviews, there are some health economics databases such as The Center for the Evaluation of Value and Risk in Health (CEVR) is part of the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center in Boston, MA.

d. Challenge the studies’ validity for current practice (is that close enough to how we do that now; is it valid for the population we are considering?)

e. Agree on a written description of an archetypal population to which the interventions might be applied (Appendix 9). This should include real life practice: eg prescribing not in line with guidelines, and lower than guideline-advised referral to pulmonary rehabilitation. For example:

<table>
<thead>
<tr>
<th>Actual figures - applied on 300,000 population</th>
<th>Assumption Diagnosed Mild-Moderate (60% of diagnosed)</th>
<th>Assumption (Diagnosed Severe/Very Severe (40% of diagnosed)</th>
<th>Undiagnosed (Expected 3.6% - actual 1.6%)</th>
<th>Diagnosed Mild-Moderate (60% of diagnosed)</th>
<th>Diagnosed Severe/Very Severe (40% of diagnosed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPD population</td>
<td>6000</td>
<td>2880</td>
<td>1920</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smokers</td>
<td>2100</td>
<td>1008</td>
<td>672</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

f. At a decision conference, for each category of disease severity, describe how and how much an archetypal patient would benefit from an intervention (to create an index on the y axis). We scored the benefit using a visual analogue scale of 0-100 as used in economic evaluations, zero being no benefit, and 100 being maximum benefit. We also discussed the risk of harm in terms of side-effects and mortality and subtracted that but did not calculate disbenefits (ie use a negative number index). Note that because we used three categories of patients, and started with the most severe, the index did extend beyond 100 in the mild-moderate group for stop smoking: patient benefits are assessed on a scale where 100 is the benefit from smoking cessation to the severe category (smoking cessation for patients in the mild-moderate category is 130 because the patients will be younger and so will have greater residual life expectancy and fewer accumulated pack years).

g. Having got a number on the index, multiply that by the number who might benefit (the x axis) in order to calculate the size of the population who would benefit, represented by the size of rectangle. (See Figure 1)

h. We took the decision to start with a limited number of interventions in each category to keep it manageable. Therefore we chose those that we believed needed re-evaluation, based on our reading of the cost-effectiveness literature and our previous work on More for Less. That meant, for example, we did not include all drug therapies, but did include in our first analysis for people with severe or very severe disease, stop smoking support, pulmonary rehabilitation and triple therapy, (where single therapy is defined as treatment with a long-acting beta agonist (LABA) or a long-acting muscarinic antagonist (LAMA), double therapy is defined as LABA plus inhaled corticosteroid (ICS) and triple therapy is LAMA + LABA + ICS. (Appendix 10)

i. To see the rectangles we produced for each category, and all the assumptions we made on benefits and costs see Appendix 11.

Next steps

j. Using linked spreadsheets and formula supplied by the LSE team, apply our cost-effectiveness analysis to the rectangles to create cost-effectiveness triangles (Figure 2). These can be overlaid to show the relative value of different interventions for each category: the larger the volume, the greater the population to benefit; the steeper the hypotenuse, the greater the value.

Definitions of over-treated and unnecessarily treated (for full assumptions see Appendix 11)
Over-treated:
Assumed of the 3000 diagnosed patients, 15-20% have the right diagnosis but are over-treated. That is, 450-600 patients are over-treated. (We plotted 500 for whom a review of whether ICS/LABA therapy is appropriate might be warranted).

Unnecessarily treated:
Assumed 10-15% wrongly diagnosed with COPD and therefore wrongly treated = 300-450 patients are unnecessarily treated because COPD is a wrong diagnosis. Used a figure of 375 to plot the benefit.

Gave index of zero benefit, and made cost calculations (see Appendix 11) where a negative cost indicates a potential saving.
Definitions

**Pulmonary Rehabilitation** is a package of exercise/education and self-management. Note: costs of non-completion not fully counted. See the IMPRESS guide to pulmonary rehabilitation.

**Appropriate prescribing** defined as quality-assured diagnosis initiation and review of medicines - identifying those on both LAMA and LABA and deciding if triple therapy is appropriate.

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**Appendix 10** for a comparison of cost-effectiveness.

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k. Take stock of the results and decide if we needed to add more interventions into the analysis such as:

a. The cost-effectiveness of different ways of providing spirometry

b. The relative value of all the different pharmacological options

l. We concluded that the initial analysis gave some very powerful messages that wouldn’t, and shouldn’t, be diluted by adding in further interventions. In particular the messages about the balance between underused treatments such as stop smoking, pulmonary rehabilitation and overused and/or wasteful treatments such as some medicines.

m. We also all agreed that the hierarchy of medical treatments in the current NICE guideline was appropriate, given the evidence from National Institute of Clinical Excellence (NICE)\(^{20}\), Canadian Agency for Drugs and Technologies in Health (CADTH)\(^{21}\) and Belgian Health Care Knowledge Centre (KCE).\(^{22}\) We also noted that the actual costs would shift over time as a number of COPD medicines came off patent in the next 2-3 years. Our messages aren’t about switching, but about appropriate prescribing, and setting prescribing in the context of additional options.

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So what do these triangles and our analysis tell us?

a. They tell us that relative to our comparators, even with low (6%) one year quit rates in the undiagnosed population, stop smoking interventions provide great value in the diagnosed and undiagnosed populations and should be commissioned as a TREATMENT for COPD and be a priority for prevention in those not yet diagnosed.

b. Stop smoking interventions will, of course, benefit people at risk of developing or enduring a number of long term conditions including cardiovascular disease. In many places, they were set up initially as part of a cardiovascular disease strategy, in line with the National Service Framework for CVD. We are not suggesting that this is not important, but that we need to ensure that there is sufficient for people at risk of developing or suffering worsening COPD. Therefore investment in existing stop smoking services should be reviewed to ensure that they meet the needs of the local population. Where necessary, investment should be shifted to ensure that it does meet their needs. Where it is absent, for example, in settings such as hospitals or mental health units where the at risk population can be found, additional resource from the respiratory programme budget may be needed.

c. In the undiagnosed population the value of stop smoking support for smokers is greater than in comparison to case-finding in symptomatic smokers, but they both can be cost-effective and they are not mutually exclusive; a number of stop smoking services now use screening spirometry for smokers with symptoms, and practitioners using spirometers should also be trained in stop smoking counselling.

d. Particularly in severe disease, the steepness of the hypotenuse of the triangles is relatively similar for a number of interventions, but the population to benefit means that programmed pulmonary rehabilitation stands out as the one offering most value. The analysis of the cost-effectiveness data suggests the current sequence of management may need reordering so that interventions such as stop smoking and consideration for referral to pulmonary rehabilitation should happen before any trial of triple therapy because of the latter’s limited incremental cost-effectiveness. The message is patients should be optimised on treatment prior to pulmonary rehabilitation, not necessarily maximised.

e. Clinicians and commissioners should take much more note of the cost-effectiveness data of drug therapies, for which we used the NICE, Canadian and Belgian systematic reviews up to mid-2011, and that triple therapy should be reserved for patients for whom it is appropriate: for people with severe disease who have persistent exacerbations despite using either ICS/LABA or LAMA.

f. In the mild-moderate category there is substantial overtreatment and there is a negative value in some prescribing: the risk of harm can outweigh the benefits and therefore the prescriber should be aware of the financial and clinical costs and benefits. There are a number of clinical reasons why multiple treatments should be carefully considered before initiation, but there is also an economic argument that the incremental cost per QALY tends to be very high for multiple treatments – up to £130,000 (see Appendix 10).

g. There are gaps in the cost-effectiveness data on most service models, including traditional service provision, aspects of current integrated care policy such as risk stratification and integrated teams, and therefore local data and judgements will be required. IMPRESS would continue to advocate integrated care and shared records, to reduce under-coordination.21 It would also continue to argue for the guiding principle to be right services to be provided at the right time by the right person. The model of integrated care consultants and practitioners with a special interest should continue to be tested.24

h. Primary and secondary care specialists have a role with patients with complex respiratory problems including those who are acutely ill and they need the timely application of evidence-based interventions.

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23. Øvretveit J. Does improving quality save money? A review of the evidence of which improvements to quality reduce costs to health service providers. Sept 2009. Health Foundation

So what does this mean for you?

- Before the application of any value model, ensure it is applied to the right population. Ensure the basics are right every time: first think prevention. Then ensure accurate diagnosis, using quality assured spirometry of existing patients; and careful removal of medicines which are being misused including inhaled corticosteroids and oxygen. This is likely to need investment in capability and capacity. The costs of training, education and support are not included in this document, but are fundamental to it and we would strongly support investment, as argued in the Kings Fund document on integrated care.12

- Refer to our More for Less document that gives examples of ways to save money doing things more efficiently (Appendix 1 summarises)

- In our earlier work IMPRESS has argued that people admitted for an acute exacerbation of COPD should be seen by a specialist team, based on national audit work.25 We advise commissioners to specify that people admitted with a respiratory problem are seen by a specialist team within 24 hours as this will pick up any misdiagnosis or misuse of treatment. Patients should also be reviewed prior to discharge. We advise the use of an evidence-based care bundle.26

- Check if you commission stop smoking services in all settings including social care, and where you know significant numbers of people smoke locally. Ensure practitioners are trained in stop smoking counselling and using evidence-based formulary in all the services supporting sick smokers. Offer stop smoking professionals guidance on COPD and encourage case-finding by linking them into COPD pathways. This will help to tackle the problem of under-diagnosis. Consider engaging teams in mental health services and acute services such as ambulance services.27 Link up stop smoking and oxygen services.

- Do you commission pulmonary rehabilitation and in sufficient quantity to meet the need, where need is defined as ability to benefit from an intervention?28 Do you have a robust strategy for increasing appropriate referrals to it, as it is a skilled job to encourage breathless people to take exercise rather than to take more medicine? This should include early post-admission rehabilitation.29

- How are you ensuring that prescribing of inhaled medicine and oxygen is responsible? Do all prescribers know about the costs and the cost-effectiveness of the drugs they prescribe? The full NICE guideline and appendices would be useful to medicines management advisers,20 as are the NICE Medicines and Prescribing Centre bulletins. Are they making sufficient effort to ensure patients also understand their value and how best to use them?

- Waste is apparent in overprescribing and/or inappropriate prescribing that could be saved and reinvested in commissioning high value services such as pulmonary rehabilitation. NICE recommendations need to be read in full, as there are contradictions between the full document and the Executive Summary, which is often used in isolation.20 The full document agrees with other national appraisals.21,22 Taken with actual primary care prescribing figures there is likely to be a clear cost saving by reviewing pharmacotherapy in those patients with an FEV1 >50% predicted. In this patient group inhaled corticosteroids (ICS) are not cost effective using the NICE QALY cut-off, neither is a long-acting muscarinic antagonist (LAMA) cost-effective as the first line long-acting bronchodilator. In those with an FEV1 < 50% predicted, “triple” therapy should not be routine, but only used in those with persistent exacerbations despite using either long-acting beta agonist (LABA)/ICS or LAMA alone. In this group it would also be wise to review ICS/LABA preparations prescribed to ensure those that are used are the most cost effective.

- Be even-handed with the evidence. Apply what is known about cost per QALY; do not use lack of evidence as an excuse for not considering their value and finding ways to know it. We have provided our analysis. Consider plugging the evidence gap with your own studies if you are in a position to invest in improvement projects or research.

Further resources:

See resources on value at www.impress.com/

Limitations of the process

The IMPRESS group are experienced and practising clinicians and clinical leaders who are nationally recognised across primary and secondary care. The members do not have a pure academic background. IMPRESS is aware that this work is not straightforward or perfect, but in the absence of other work in this field, and in recognition of the scale of the challenge facing clinical commissioning groups, it believes it has a contribution to make. If it enables other clinicians to leapfrog over some of the analytical challenges needed, then it has been worthwhile.

We did not refer to original papers but used economic reviews where they existed from reputable national organisations such as NICE and its Belgian and Canadian equivalents or systematic reviews from Cochrane. We used clinical judgement and experience where evidence was lacking because lack of evidence is not the same as negative evidence.

Our selection of interventions was not done systematically, but based on previous analyses we have done for our publications
- IMPRESS Guide to pulmonary rehabilitation
- More for Less
- The London value pyramid
- How to improve quality and productivity by integrating COPD care
- Rationalising oxygen use to improve patient safety and to reduce waste 2nd Edition
- Guide to information about the use of medicines in the NHS
- Guide to information
- Commissioning a community COPD service

We did not explicitly discuss the selection or quality of papers during the decision conference but this was because it continued previous discussions and conversations about the best quality papers, and those describing interventions used in the NHS today. It represents a continuum in our work. We recommend that you read these other documents for further understanding.

Finally, we sought peer review from academic colleagues and have taken their comments on board.

S Williams
N Baxter
S Holmes
L Restrick
J Scullion
M Ward

July 2012

Summary of misuse, overuse, underuse and under-coordination that should be addressed in respiratory care

- Underuse of smoking cessation
- Rationalising oxygen prescribing (see IMPRESS separate guide to this)
- Reducing inhaler waste
- Overuse of high dose inhaled corticosteroids and/or combination products
- Underuse of inhaled corticosteroids for patients with asthma prescribed long acting beta agonists
- Underuse of reviews of patients with asthma requesting excess short acting beta agonists with no other treatments
- Underuse of audit of adverse effects eg percentage of children prescribed or using >800 micrograms per day of inhaled beclametasone who are not under the care of a specialist respiratory physician
- Overuse of enteric-coated prednisolone tablets for patients with COPD or asthma instead of uncoated prednisolone tablets. At the time of drafting (Jan 2010) there was a six-fold difference on the drug tariff
- Underuse of person-centred consultation and records review to identify and support people with poor asthma control
- Overuse of hospital beds (eg asthma admissions and COPD length of stay) and underuse of hospital respiratory specialist care
- Underuse of referral to pulmonary rehabilitation
- Underuse of psychological support
- Overuse of outpatients for common conditions
- Under-coordination with social care

Example of the implications in terms of cost for one of the changes:

One SHA: April to June 2010 compared to April to June 2011
Prednisolone prescribing, change from red to white tablets

<table>
<thead>
<tr>
<th>Priority area</th>
<th>Low cost prednisolone</th>
<th>Low cost prednisolone</th>
<th>Lost opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metrics</td>
<td>April to June 2010</td>
<td>April to June 2011</td>
<td>Prednisolone 5mg tablets as % of all prednisolone 5mg</td>
</tr>
<tr>
<td></td>
<td>(3 month average)</td>
<td>Prednisolone 5mg tablets as % of all prednisolone 5mg</td>
<td></td>
</tr>
<tr>
<td>Cluster 1</td>
<td>31.49%</td>
<td>55.8%</td>
<td>£85,673</td>
</tr>
<tr>
<td>Cluster 2</td>
<td>39.66%</td>
<td>71.2%</td>
<td>£52,168</td>
</tr>
<tr>
<td>Cluster 3</td>
<td>51.22%</td>
<td>66.4%</td>
<td>£22,956</td>
</tr>
<tr>
<td>Cluster 4</td>
<td>40.49%</td>
<td>66.6%</td>
<td>£41,581</td>
</tr>
<tr>
<td>Cluster 5</td>
<td>28.92%</td>
<td>56.2%</td>
<td>£66,426</td>
</tr>
<tr>
<td>Cluster 6</td>
<td>25.12%</td>
<td>60.9%</td>
<td>£89,825</td>
</tr>
<tr>
<td>SHA</td>
<td>33.92%</td>
<td>62.54%</td>
<td>£358,628</td>
</tr>
</tbody>
</table>
COPD ‘Value’ Pyramid
What we know so far.... Cost/QALY

2010
Value work now continued by IMPRESS
www.impressresp.com

References:
1. J Epidemiol Community Health. 1998 Feb;52(2):120-5 £50 saving for over 65
3. Thorax 2001;56:779-784 £0-1000 per QALY
4. Tiotropium in the treatment of COPD: Health technology Assessment KCE reports 108C Neyt M et al £7,456 per QALY
5. OBA Y Cost effectiveness of long acting bronchodilators for COPD. Mayo Clinic Proc 2007;82:575-582 £5,396 per QALY
6. CADTH. LABA plus Corticosteroids vs LABA alone for COPD. Issue 83 March 2007. Mayers I et al £130,000 per QALY and NICE COPD management of COPD in adults in primary and secondary care 2010 £131,000 per QALY

NHS London
Improving the experience of all Londoners with COPD and minimising the impact of the disease
### APPENDIX 3 – McKinsey analysis for DH

**It is feasible to prioritise interventions...**

*Example: congestive heart failure*

<table>
<thead>
<tr>
<th>Most effective Interventions</th>
<th>Eligible population</th>
<th>Current perf., %</th>
<th>Target perf., %</th>
<th>LYG*</th>
<th>Cost to PCT £k</th>
<th>Calculated cost/LYG*, £</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial treatment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 Diuretic</td>
<td>3,390</td>
<td>90</td>
<td>95</td>
<td>1,148</td>
<td>66</td>
<td>56</td>
<td>⭐</td>
</tr>
<tr>
<td>9 ACE inhibitor</td>
<td>3,390</td>
<td>78</td>
<td>90</td>
<td>808</td>
<td>152</td>
<td>188</td>
<td>⭐⭐</td>
</tr>
<tr>
<td>10 B blocker</td>
<td>3,390</td>
<td>55</td>
<td>75</td>
<td>1,501</td>
<td>327</td>
<td>218</td>
<td>⭐⭐</td>
</tr>
<tr>
<td><strong>Severe/ refractory</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 Spironolactone</td>
<td>407</td>
<td>85</td>
<td>95</td>
<td>111</td>
<td>-60</td>
<td>0</td>
<td>⭐</td>
</tr>
<tr>
<td>14 Digoxin</td>
<td>407</td>
<td>83</td>
<td>95</td>
<td>0</td>
<td>-53</td>
<td>0</td>
<td>⭐</td>
</tr>
<tr>
<td><strong>Secondary prevention</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25 Smoking cessation</td>
<td>1,468</td>
<td>10</td>
<td>50</td>
<td>2,166</td>
<td>390</td>
<td>180</td>
<td>⭐⭐⭐</td>
</tr>
<tr>
<td>26 Vaccination</td>
<td>6,118</td>
<td>75</td>
<td>95</td>
<td>4,296-5,949</td>
<td>227</td>
<td>38-53</td>
<td>⭐⭐⭐</td>
</tr>
<tr>
<td>28 Community monitoring</td>
<td>6,118</td>
<td>50</td>
<td>75</td>
<td>0</td>
<td>n.a.</td>
<td>0</td>
<td>⭐⭐⭐</td>
</tr>
<tr>
<td>29 Exercise</td>
<td>6,118</td>
<td>50</td>
<td>90</td>
<td>5,065</td>
<td>4,725</td>
<td>933</td>
<td>⭐⭐⭐</td>
</tr>
</tbody>
</table>

*Life years gained*

APPENDIX 4 – Archetypal population

TASK TO PREPARE FOR 18 NOVEMBER 2011

Imagine you are Chair of a Clinical Commissioning Group (CCG) responsible for a population of 300,000. Within this area there are estimated to be 6000 patients with undiagnosed COPD, 2880 with mild to moderate COPD, 1920 with severe or very severe COPD. Patients with undiagnosed COPD receive no treatment, by definition. On an annual basis these proportions of patients receive the following treatments.

Note: what we didn’t explicitly include, but discussions suggest was an important omission, were those misdiagnosed, but studies from Lung Health, Leicestershire and Outer North East London suggest that might be as many as 15%-20%.

<table>
<thead>
<tr>
<th>Actual figures - applied on 300,000 population</th>
<th>Assumption Diagnosed Mild-Moderate (60% of diagnosed)</th>
<th>Assumption Diagnosed Severe/Very Severe (40% of diagnosed)</th>
<th>Undiagnosed (Expected 3.6% - actual 1.6%)</th>
<th>Diagnosed Mild-Moderate (60% of diagnosed)</th>
<th>Diagnosed Severe/Very Severe (40% of diagnosed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPD population</td>
<td>6000</td>
<td>2880</td>
<td>1920</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smokers</td>
<td>35%</td>
<td>35%</td>
<td>2100</td>
<td>1008</td>
<td>672</td>
</tr>
<tr>
<td>Case finding</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment with Flu vaccination</td>
<td>92%</td>
<td>92%</td>
<td>2650</td>
<td>1766</td>
<td></td>
</tr>
<tr>
<td>Treatment with pneumococcal vaccination</td>
<td>70%</td>
<td>70%</td>
<td>1855</td>
<td>1344</td>
<td></td>
</tr>
<tr>
<td>Stop smoking support (treatment or referral rather than a gold standard)</td>
<td>75%</td>
<td>75%</td>
<td>1391</td>
<td>1440</td>
<td></td>
</tr>
<tr>
<td>Treatment with mucolytics</td>
<td>5%</td>
<td></td>
<td>96</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment with SABA</td>
<td>75%</td>
<td>75%</td>
<td>2160</td>
<td>1440</td>
<td></td>
</tr>
<tr>
<td>Treatment with LABA</td>
<td>20%</td>
<td>20%</td>
<td>576</td>
<td>384</td>
<td></td>
</tr>
<tr>
<td>Treatment with LAMA</td>
<td>35%</td>
<td>45%</td>
<td>1008</td>
<td>864</td>
<td></td>
</tr>
<tr>
<td>Treatment with ICS</td>
<td>30%</td>
<td>35%</td>
<td>864</td>
<td>672</td>
<td></td>
</tr>
<tr>
<td>Treatment with combined LABA+ICS</td>
<td>30%</td>
<td>40%</td>
<td>864</td>
<td>768</td>
<td></td>
</tr>
<tr>
<td>Course of oral steroids</td>
<td>20%</td>
<td>20%</td>
<td>576</td>
<td>384</td>
<td></td>
</tr>
<tr>
<td>Referral to pulmonary rehabilitation programme</td>
<td>5%</td>
<td>15%</td>
<td>144</td>
<td>288</td>
<td></td>
</tr>
<tr>
<td>Proportion of those referred assessed for pulmonary rehabilitation</td>
<td>50%</td>
<td>65%</td>
<td>72</td>
<td>187</td>
<td></td>
</tr>
<tr>
<td>Proportion of those accepted onto programme completing PR (note ave 77% range 40%-94% in post-exacerbation Cochrane review)</td>
<td>60%</td>
<td>50%</td>
<td>43</td>
<td>94</td>
<td></td>
</tr>
</tbody>
</table>

Data below are based on PEOPLE not spells or contacts

| Hospital admission in last 2 years (proportion of people) | 8% | 8% | 7% | 230 | 154 |
| Proportion of those admitted treated on specialist Respiratory wards (people not spells) | ?  | 55% | 10% | 127 | 84 |
| NIV for patients with persistent hypercapnic ventilatory failure during exacerbation despite optimal medical therapy (2011 Thorax paper) | 10% | 15 |
| People admitted who have early supported discharge (people not admissions) | 33% | 51 |
| Oxygen | | |
| End of life care planning | | |
| Access to respiratory nurse specialist | 80% | 123 |

### Aggregate PCT level expenditure (£million) 2010/11: Problems of the respiratory system

<table>
<thead>
<tr>
<th>PCT</th>
<th>Prevention &amp; Health Promotion</th>
<th>Primary care</th>
<th>Secondary care</th>
<th>Total gross &amp; emergency care</th>
<th>Community Care</th>
<th>Health &amp; social care provided in other setting</th>
<th>Non-health/social care</th>
<th>Total gross expenditure Emillion (Plus a proportion of GMS/PMS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENGLAND</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>England</td>
<td>0.2%</td>
<td>0.5%</td>
<td>25.4%</td>
<td>13.5%</td>
<td>27.7%</td>
<td>7.5%</td>
<td>10.3%</td>
<td>3.6%</td>
</tr>
<tr>
<td>Barking and Dagenham</td>
<td>0.8%</td>
<td>0.0%</td>
<td>28.9%</td>
<td>10.1%</td>
<td>36.3%</td>
<td>7.1%</td>
<td>1.5%</td>
<td>55.0%</td>
</tr>
<tr>
<td>Hammersmith and Fulham</td>
<td>0.1%</td>
<td>0.0%</td>
<td>16.7%</td>
<td>6.9%</td>
<td>32.1%</td>
<td>3.5%</td>
<td>14.2%</td>
<td>56.7%</td>
</tr>
<tr>
<td>Hull</td>
<td>0.0%</td>
<td>0.0%</td>
<td>32.1%</td>
<td>8.81</td>
<td>34.9%</td>
<td>6.4%</td>
<td>6.4%</td>
<td>54.6%</td>
</tr>
<tr>
<td>Leicester City</td>
<td>0.0%</td>
<td>0.0%</td>
<td>28.0%</td>
<td>7.58</td>
<td>40.4%</td>
<td>5.2%</td>
<td>6.0%</td>
<td>58.2%</td>
</tr>
<tr>
<td>Middlesborough</td>
<td>0.0%</td>
<td>0.0%</td>
<td>31.3%</td>
<td>4.74</td>
<td>39.5%</td>
<td>6.8%</td>
<td>11.0%</td>
<td>63.4%</td>
</tr>
<tr>
<td>Somerset</td>
<td>0.0%</td>
<td>0.0%</td>
<td>30.4%</td>
<td>12.04</td>
<td>38.6%</td>
<td>6.8%</td>
<td>3.1%</td>
<td>59.6%</td>
</tr>
<tr>
<td>Torbay</td>
<td>0.0%</td>
<td>0.0%</td>
<td>34.0%</td>
<td>3.93</td>
<td>30.4%</td>
<td>5.6%</td>
<td>7.3%</td>
<td>54.5%</td>
</tr>
</tbody>
</table>

APPENDIX 6 – Decision Conferencing

Larry Phillips (LSE)

Decision conferencing is a socio-technical process that combines working in groups helped by an impartial facilitator, on-the-spot computer-based modeling of data and participants’ judgments, and continuous visual display of the model and its results. The ‘socio’ aspect of the process relies on mobilizing the right people at the right time to give the right inputs to the model. The ‘technical’ part refers to the model itself. This is based on multi-criteria decision analysis, first introduced in 1976 by Keeney and Raiffa31, and now an accepted methodology for dealing with decisions that are characterized by multiple objectives.

The generic purposes of decision conferencing are: to achieve a shared understanding of the issues (though not necessarily consensus), a sense of common purpose (while preserving individual differences of opinion) and a commitment to the way forward (though allowing individual differences in the paths). The idea is to encourage individual creativity and use differences of perspective to find ways forward that will gain support from those implementing the actions. A key assumption of decision conferencing is the notion of ‘requisite modeling32: that a model should be just sufficient in form and content to resolve the issues at hand. The portfolio model need not be more complex than is needed to indicate relative priorities sufficiently to allow the head of commissioning to recommend the level of funding for each project that makes the best portfolio-wide use of the limited resource.

The modelling approach
The key idea behind the modelling approach is that every potential investment is characterized by its total cost and the overall risk-adjusted benefit expected from the investment. Investments can then be prioritized on by the ratio of the risk-adjusted benefit to the cost, the basis for establishing the cost effectiveness of a project, shown by the slope of the hypotenuse of the triangle. A weighting process ensures the units of benefit are equal from one area to the next, allowing priorities for investment to be compared across the entire portfolio.

This is typically accomplished in several stages. First, each project is assigned to a budget category, or area, to which resource is to be allocated. Next, investment options, or projects, are described, assessed for their costs and evaluated (scored) against benefit and risk criteria. Then, weights reflecting the relative benefits from one area to the next and from one criterion to the next are judged. Weighted scores are calculated, enabling the total benefit per unit cost to be shown for each investment option. Combining all investments into one overall curve of cumulative risk-adjusted benefit versus cumulative cost provides an ‘efficient frontier’ of the best portfolios for a given total cost.

The social process
Participation in decision conferences is carefully designed to ensure that all main perspectives on the issues are addressed. This may require several workshops, one for each investment area, and consultation with project teams and others, to provide a base of data and judgments. Peer review of the outputs from the workshops helps to ensure consistency and realism. In a final decision conference, with participants chosen to represent all perspectives, information about the projects is presented, and participants review the evaluations of the projects against cost, benefit and risk criteria, assess scores on the criteria, and participate in the process of assessing weights between areas and across the criteria.


APPENDIX 7 – Description of first workshop July 2011

Prior to the first scoping workshop, a briefing document was issued including a proposed list of cost effectiveness references (with no analysis of their robustness) that addressed the cost and outcome of all the interventions we knew were used regularly for COPD. These focused on secondary sources such as NICE, or other national equivalents, Cochrane and other systematic reviews. The aim of the first workshop was to begin the process:

To produce a guide for commissioners of services for people with chronic obstructive pulmonary disease (COPD) that focuses on the relative value (outcome divided by cost) of different interventions at different stages of disease severity. We expect that it would be used to stimulate discussion and to encourage commissioners to look at the balance of their investment. We want to explain it visually, potentially introducing unfamiliar concepts of health utility.

Participants:

Dr Louise Restrick (chair), IMPRESS Implementation Group, Respiratory Physician
Dr Steve Holmes, Co-chair IMPRESS, GP
Dr Mike Ward, Co-chair IMPRESS, Respiratory Physician
Ms Jane Scullion, IMPRESS Implementation Group, Respiratory Nurse Specialist
Dr Noel Baxter, IMPRESS Implementation Group, GP
Ms Siân Williams, IMPRESS Programme Manager (also took notes)
Dr Alec Morton, Lecturer, Management Science, London School of Economics & Political Science
Fleur Chandler, Health Outcomes specialist, GlaxoSmithKline
Dan Hudson, Health Outcomes specialist, GlaxoSmithKline

Note: All IMPRESS sponsors were invited to nominate health economists to attend, but only GSK accepted.

At that first meeting we confirmed that we would use existing systematic reviews such as National Clinical Guideline Centre (2010) Chronic obstructive pulmonary disease: management of chronic obstructive pulmonary disease in adults in primary and secondary care. London: National Clinical Guideline Centre. Including Appendix M (the NICE COPD Guideline 2010), Cochrane reviews; governmental or equivalent analyses; and evidence that has been regarded by peers as “practice changing”; supplemented by any data we knew was available from peer-reviewed audits.

Content
We discussed the interventions to be included and questioned where integrated care models/chronic care model fitted. We decided to include a category of integrated care in the analysis because some interventions – eg patient education by clinicians with specialist knowledge are typically provided as part of a chronic care model, and evaluated as part of a whole package, not as a discrete intervention. For example, we could find no evidence for the value of specialist nurse interventions in COPD, although there was some in lung cancer. This also illustrates an important caveat: no evidence does not mean the intervention does not have value, just that there is need for more cost-effectiveness evaluation.

The project scope
We considered whether we should consider mild disease and asked questions such as “what’s the QALY for getting the diagnosis right in the first place?” We debated the problem of comorbidities where people had multiple problems. We decided that a “pathway for people with significant pack years and still smoking” might be the most accurate way of thinking about the problem, but was probably too ambitious as our starting point. We agreed to consider a model for the person’s dominant condition and to take COPD as our starting point.

Categorisations
We concluded that a breathlessness score was probably the most useful discriminator rather than lung function. We also debated different exacerbation profiles because there was evidence suggesting anticipatory care might work for those who exacerbate. We also thought that smoking status might be another categorisation. However, in response to the question “Do you have the evidence to categorise in this way?” it was agreed best to use these three broad groups that would inevitably have some overlap. It was also agreed that our priority order for developing resources was as indicated by (n):

To produce a guide for commissioners of services for people with chronic obstructive pulmonary disease (COPD) that focuses on the relative value (outcome divided by cost) of different interventions at different stages of disease severity. We expect that it would be used to stimulate discussion and to encourage commissioners to look at the balance of their investment. We want to explain it visually, potentially introducing unfamiliar concepts of health utility.
• Undiagnosed (2)
• Diagnosed - Early (greater than 50% predicted), without hospital admission, MRC 1 and 2 (3)
• Diagnosed - Advanced (less than 50% predicted) (1)

Which measure of health utility?
The choice we made was between Cost per Quality Adjusted Life Year (QALY) and Number Needed to Treat. Numbers needed to treat (NNTs) or harm (NNH) are familiar to many clinicians, useful and intuitive, but importantly don’t involve costs nor the size of the benefit. For example, one intervention might have a NNT of 2, and another of 10, but the impact can’t be compared. The NNT of 2 might not achieve as big a benefit for the individual as the NNT of 10.

By contrast, QALYs do include cost and benefit using validated quality of life measures. NICE uses cost per QALY. NICE sets the probability that the treatment is cost effective at thresholds of £20,000–£30,000 per QALY gained. Therefore we concluded if we wished to address value, then we needed to prioritise QALYs. However, cost per QALY is not available for many interventions, including those for COPD, and when it is, there can be problems with the sample size, standardisation including period of time studied, the intervention studied, the service model in which it sits, the cost calculation methods and whether an absolute figure is given, or a more robust range of probabilities.

Therefore we agreed to use cost per QALY, but to use NNTs as a check for ordering any intervention for which there is no published QALY because we learnt that NNT analysis does correlate reasonably well to QALYs.

Understanding QALYs
The literature on cost-effectiveness of respiratory interventions is very heterogeneous and does not use comparable time periods, methods or costing methodologies. However, these are things to look out for in any cost-effectiveness study:

• The intervention being studied is described clearly so costs can be understood and compared to current practice
• The intervention reflects current practice and so is generalisable
• The quality of life (QoL) dimension is measured using a validated QoL measure eg EQ5D. There are look-up tables that calculate QALYs from EQ-5D scores. These are derived from public judgements, and therefore can vary between countries.
• Sensitivity analyses are useful to takes account of uncertainties. NICE uses the probability of cost effectiveness. This is, for example, how the Griffiths study on pulmonary rehabilitation is described: The probability of the true incremental cost/utility ratio of the programme being below £0 per QALY is 0.64. The probability that the true cost per QALY is below £3000 is 0.74, the probability that the cost per QALY is below £10,000 is 0.90, and the probability that the cost per QALY is below £17,000 is 0.95

We understood that the quality of life (QoL) dimension of a QALY can be obtained from one of a number of QoL measures eg EQ5D. These use databases to calculate the QALY. Sometimes researchers can ask people to say what values they want to attribute to what intervention which gets discussions started about what people value and why eg cancer survivors and hospital physicians disagreed about value of OP appointments- felt very valuable to patients for reassurance but diagnostic value low and therefore valued more lowly by physicians).

Generic QoL measures such as EQ5D might not have the resolution to pick up changes in chronic disease. Some less gross than others eg SF36. So a researcher might use a disease-specific tool too or instead. Some map across to QALYs. CAT can’t be mapped across yet but St Georges and CCQ can be.

Can risk adjust and inequality adjust

Can show cumulative costs (within a defined budget for example) and cumulative benefit by showing several triangles.

With any QALY calculation, you have to project their life course, which in a chronic condition like COPD can be uncertain. NICE uses QALYs and is becoming more nuanced, by building in uncertainty more.

What about societal cost?

Whilst it was acknowledged as relevant, we took the view that NIICE currently only takes account of direct healthcare cost at moment and so should we as it would be too ambitious to go further than NICE, particularly as NICE evaluations would form a core reference. NICE will take societal benefit into account and weighting for disease severity – prospectively for new analyses (after 2014). We did agree that if we did find relevant findings we could take these into account but didn’t expect to find much on societal impact. We also accepted that the findings would tend to accentuate rather than alter the direction of the findings.
How can analyses be adapted to local circumstance?

AM described how in Hampshire and the Isle of Wight where he had worked with PCTs needing to prioritise they had compiled data packs summarising evidence – health economics data plus public health evidence plus other local knowledge about inequity.

Choices relating to social welfare and inequalities

The starting point is that we care more about the worst off because they have worst health expectancy, but how do you take this into account in practical analyses?

AM described how he had tried to get PCTs to explicitly weight health benefits and the difficulty of pinning down answers to the question how much do you care about the worst off (by quintile)?

What about incorporating new data (especially on medicines)

We agreed we should take the prescribing references up to the date of the NICE guideline because our main purpose was to include in the same frame of reference stopping smoking, pulmonary rehabilitation and other elements not included in the NICE COPD guideline, rather than a detailed comparison between drugs. We also agreed that if papers on a new a new therapeutic class were published, this would be important, but it would be extremely unlikely that there would be mortality data available initially and so we decided to stick with the NICE guideline cut-off point.

It was agreed that for non-pharmacological interventions, we should be contemporaneous in terms of reference scope.

What about price inflation?

We agreed to use the prices and cost analysis as used in the original papers and not try to account for inflation. We noted that NICE sensitivity analysis does take account of pricing change. We also noted that NICE is introducing value-based pricing, but not until 2014 – too late for this work.

Interventions

During the meeting we came up with a full list of interventions in the three disease severity categories.

Discussion during the meeting about the end product

We were aware that we were stretching our knowledge and understanding in a new direction and experienced feelings of nervousness and uncertainty. As these are likely to be emotions that many clinical commissioning groups may have as they tackle difficult resource allocation decisions, we have recorded here some of our agreement about the end product:

• It should demonstrate the authors’ clear understanding of the concepts and build on previously tried and tested work that explains health economics to non-experts
• Must be practical
• Should provide commissioners with information to support decisions, and justification for trade-offs
• We should agree what we expect the powerful messages to be from our work so far (eg ensuring the rightful place for stopping smoking as an important treatment intervention) and testing the draft product against these
• It must emphasise that whilst McKinsey – type work uses average values for average patients that doesn’t mean that it is not appropriate for an individual clinician to prescribe other interventions
• It should explain that a good service provides people with packages of care along a pathway, not isolated episodic interventions
• We should highlight some general messages from the literature eg Purdy’s work on avoiding admissions showing the benefit of continuity of GP care
• We should try to answer a good commissioners’ question: can you stop people progressing?
• Standards of referencing should be used: eg always show the mean, range and confidence intervals
• Consider including aspirational measures in italics
• We should be sensible like NICE: recommend good practice. Some recommendations have no good evidence nevertheless we may have good reason [document what] to believe that they are worthwhile.

Action after the meeting

Different members of the task force took different interventions eg medicines, vaccination, stop smoking, and reviewed the literature using a standard template.
## Category of disease eg undiagnosed, mild-moderate or severe/very severe

<table>
<thead>
<tr>
<th>Intervention category eg Pulmonary rehabilitation</th>
<th>Full reference of article</th>
<th>DOI</th>
<th>Date published</th>
<th>If more than 10 years old, are there any caveats about its relevance today?</th>
<th>Cost per QALY</th>
<th>Range and confidence interval</th>
<th>What's the NNT particularly needed if no QALY calculation</th>
<th>What's the event for which NNT calculated eg 5 year survival or 2 year survival</th>
<th>Short description of the intervention</th>
<th>Population description including disease severity (MRC if used, otherwise FEV1)</th>
<th>Strengths of study - how archetypal/representative of real life populations and English interventions?</th>
<th>Weaknesses of study: how archetypal/representative of real life populations and English interventions?</th>
</tr>
</thead>
</table>

Worksheet completed by [Name]
APPENDIX 9 – Archetypal population and preparatory work for decision conference

TASK TO PREPARE FOR 18 NOVEMBER 2011

Imagine you are Chair of a Clinical Commissioning Group (CCG) responsible for a population of 300,000. Within this area there are estimated to be 6000 patients with undiagnosed COPD, 2880 with mild to moderate COPD, 1920 with severe or very severe COPD. Patients with undiagnosed COPD receive no treatment, by definition. On an annual basis these proportions of patients receive the following treatments:34

Note: what we didn’t explicitly include, but discussions suggest was an important omission, were those misdiagnosed, but studies from Lung Health, Leicestershire and Outer North East London suggest that might be as many as 15%-20%.

<table>
<thead>
<tr>
<th>Actual figures - before right care applied on 300,000 population</th>
<th>Assumption Diagnosed Mild-Moderate (60% of diagnosed)</th>
<th>Assumption Diagnosed Severe/Very Severe (40% of diagnosed)</th>
<th>Undiagnosed (Expected 3.6% - actual 1.6%)</th>
<th>Diagnosed Mild-Moderate (60% of diagnosed)</th>
<th>Diagnosed Severe/Very Severe (40% of diagnosed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPD population</td>
<td>6000</td>
<td>2880</td>
<td>1920</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smokers</td>
<td>35%</td>
<td>35%</td>
<td>2100</td>
<td>1008</td>
<td>672</td>
</tr>
<tr>
<td>Case finding</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment with Flu vaccination</td>
<td>92%</td>
<td>92%</td>
<td>2650</td>
<td>1766</td>
<td></td>
</tr>
<tr>
<td>Treatment with pneumococcal vaccination</td>
<td>70%</td>
<td>70%</td>
<td>1855</td>
<td>1344</td>
<td></td>
</tr>
<tr>
<td>Stop smoking support (treatment or referral rather than a gold standard)</td>
<td>75%</td>
<td>75%</td>
<td>1391</td>
<td>1440</td>
<td></td>
</tr>
<tr>
<td>Treatment with mucolytics</td>
<td>5%</td>
<td></td>
<td></td>
<td>96</td>
<td></td>
</tr>
<tr>
<td>Treatment with SABA</td>
<td>75%</td>
<td>75%</td>
<td>2160</td>
<td>1440</td>
<td></td>
</tr>
<tr>
<td>Treatment with LABA</td>
<td>20%</td>
<td>20%</td>
<td>576</td>
<td>384</td>
<td></td>
</tr>
<tr>
<td>Treatment with LAMA</td>
<td>35%</td>
<td>45%</td>
<td>1008</td>
<td>864</td>
<td></td>
</tr>
<tr>
<td>Treatment with ICS</td>
<td>30%</td>
<td>35%</td>
<td>864</td>
<td>672</td>
<td></td>
</tr>
<tr>
<td>Treatment with combined LABA+ICS</td>
<td>30%</td>
<td>40%</td>
<td>864</td>
<td>768</td>
<td></td>
</tr>
<tr>
<td>Course of oral steroids</td>
<td>20%</td>
<td>20%</td>
<td>576</td>
<td>384</td>
<td></td>
</tr>
<tr>
<td>Referral to pulmonary rehabilitation programme</td>
<td>5%</td>
<td>15%</td>
<td>144</td>
<td>288</td>
<td></td>
</tr>
<tr>
<td>Proportion of those referred assessed for pulmonary rehabilitation</td>
<td>50%</td>
<td>65%</td>
<td>72</td>
<td>187</td>
<td></td>
</tr>
<tr>
<td>Proportion of those accepted onto programme completing PR (note ave 77% range 40%-94% in post-exacerbation Cochrane review)</td>
<td>60%</td>
<td>50%</td>
<td>43</td>
<td>94</td>
<td></td>
</tr>
</tbody>
</table>

Data below are based on PEOPLE not spells or contacts

| Hospital admission in last 2 years (proportion of people) | 8% | 8% | ? | 230 | 154 |
| Proportion of those admitted treated on specialist Respiratory wards (people not spells) | ? | 55% | | 127 | 84 |
| NIV for patients with persistent hypercapnic ventilatory failure during exacerbation despite optimal medical therapy (2011 Thorax paper) | 10% | | | | 15 |
| People admitted who have early supported discharge (people not admissions) | | | 33% | | 51 |
| Oxygen | | | | | |
| End of life care planning | | | | | |
| Access to respiratory nurse specialist | 80% | | | | 123 |

Before the workshop

As preparation for the workshop, we would like you to think of some possible changes in provision you could commission for patients in the DIAGNOSED MILD TO MODERATE category. Now, please fill in, on the basis of your reading of the evidence, your BEST GUESS for the following.

In cases where there is a recurrent cost (e.g. prescribing), please estimate the annual cost and the annual benefit. In cases where there is a one-off cost (e.g. if you considered the severe/very severe category, surgery) please estimate the one-off cost and benefits which will accrue to the patient over the rest of his/her lifetime.

<table>
<thead>
<tr>
<th>Change in provision</th>
<th>How many patients will benefit?</th>
<th>Describe the typical patient who is affected</th>
<th>Describe how &amp; how much the typical patient benefit?</th>
<th>What would the cost be per patient?</th>
<th>What evidence supports these estimates?</th>
</tr>
</thead>
<tbody>
<tr>
<td>E.g. promote smoking cessation at every outpatient appointment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eg Reduce prescribing of ICS in mild-moderate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eg Stop LAMA where no benefit or evidence of poor compliance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Your idea will be crucial to make a good start on Friday. During the workshop we will assess the benefit on a common scale. We will do so in the following way (in preparation for the workshop, you might have a go at this using the list you generated above):

- For all of the changes in provision, for which change do you think the benefit received by the typical patient affected, will be greatest? Call the benefit received by this patient “100”;

- If there is no benefit to the typical patient say the patient receives “0” benefit.

- Now, for each change in provision, how big will the benefit to the typical patient affected by this change be, on this 0-100 scale? For example, if you think the benefit to the typical patient will be 25% of the most beneficial change, the benefit is 25.

Dr Alec Morton and Mara Airoldi
First table supplied by Siân Williams
11 November 2011
<table>
<thead>
<tr>
<th>Drug treatment</th>
<th>Cost per QALY (£)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>LABA alone</td>
<td>5,396</td>
<td>Oba Y. Cost effectiveness of long acting bronchodilators for COPD. Mayo Clinic Proc 2007;82:575-582</td>
</tr>
<tr>
<td>LAMA alone QALY cost per QALY (no data on FEV1 severity)</td>
<td>7,456</td>
<td>Neyt M et al. Tiotropium in the treatment of COPD: Health technology assessment KCE reports 108C</td>
</tr>
<tr>
<td>ICS/LABA +LAMA (FEV1 &lt;80%)</td>
<td>130,000</td>
<td>Mayers I et al. LABA plus Corticosteroids vs LABA alone for COPD. CADTH. Issue 83 March 2007.</td>
</tr>
</tbody>
</table>
APPENDIX 11 – Agreeing the index and population benefit

Working on a population of 300,000

The rectangles: definitions and assumptions

Rectangles demonstrate the population benefit by multiplying the number of patients who would benefit x benefit per patient

Severe and very severe COPD defined as FEV1 <50% of predicted
Assumed this represents about 40% of those diagnosed

Assumptions: severe and very severe disease

1. Stop smoking intervention
   a) Archetypal patient characteristics
      • Not working, routine and manual workers
      • Age: 68-70
      • 2/3 have a partner; have little social care and surrounded by smokers
      • History of CVD
   b) Number who benefit assumptions

35% of those with severe disease are smokers
Many (75%) of those smokers will have been told to stop/may have been given a referral (based on primary care registers)
NNT of 10 to achieve one year quit rate

Proportion who would take up referral: 70% patients. That is, of those who are current smokers, 7/10 will accept referral, and of those, one in who have an intervention will stop at 12 months

That is, 670 potential benefiers x 70% wish to quit = 470, of whom 10% quit at 12 months = 47-50 people.
c) **Benefit per person assumptions**

We are unable to describe the specific benefits on morbidity for patients with severe COPD because it has not yet been studied. This has been identified as an important research need: “We agree with Restrick *et al.* that evaluating the clinical efficacy of smoking cessation with the use of solid patient-relevant outcomes, such as exacerbations, could complement the already existing body of evidence in support of such an intervention.”

d) **Cost assumptions**

Smoking cessation clinic: NICE Woolacott: cost per lifetime quitter £196-£2683. We chose to use a conservative figure of £1400 based on the HTA 2002 appraisal and NICE (note that this 2002 study has been replaced by a 2010 study).

\[ £1400 \times 50 \text{ people who might benefit} = £70,000 \]

Note that there are alternative costings that we didn’t use but which could be substituted following local discussion/analysis: Van Schayck *et al.* says 1212-1906 Euros (Based on bupropion and nortriptyline and placebo drug costs with other detailed costs listed.) Hoogendoorn says intensive counselling and pharmacotherapy is 130-452 Euros and real life data from primary care trusts in NHS South Central shows £235 - £485 per quitter, with most £350-£400. These costs include nicotine replacement therapy. Our view is that evidence-based stop smoking support by competent practitioners with pharmacotherapy for people with severe/very severe COPD is currently very inconsistently provided.

2. **Pulmonary rehabilitation**

a) **Archetypal patient characteristics**

- 65 female
- Sociable
- Breathless on exertion
- Motivated
- Not housebound

b) **Number who benefit assumptions**

2000 diagnosed in a 300,000 population

15% currently referred. Appropriate referral should be 65% - i.e. 50% more. Assume of that additional 50%, only 90% of those additional patients turn up

Of those who start, 50% complete sufficient to benefit in some way

Increase in QoL, NNT of 2.

Assume 450 would benefit.

c) **Cost assumptions**

Cost: £500 per place, including those who drop out. Therefore place per completed = £1000.

---


40. Personal communication, Director of Public Health/Chief Medical Adviser, Isle of Wight NHS PCT, May 2012

41. IMPRESS Guide to Pulmonary Rehabilitation

42. DH Draft commissioning pack. Dec 2011.
3. Oxygen: Quality assured diagnosis, initiation and review (i.e. using pulse oximetry)

a) Archetypal patient characteristics

- Very breathless
- Close to housebound
- Not-smoking
- Previous admissions
- 70 years

b) Numbers who benefit assumptions

1920 would benefit from pulse oximetry because they have severe disease of whom 25% might be assessed as needing home oxygen. OR, and we used this, 10% of all those with COPD to be sufficiently severe to benefit from oxygen (10% hypoxic)

(95000 patients on oxygen nationally)

Benefit – more should benefit in future (expect within COPD 30% who are wrongly on it, 30% who would gain; 30% not using it in right way)

Assumed 170 would benefit.

c) Cost assumptions

Cost – may be neutral

Cost per patient: £1000 per year. Cost neutral for the oxygen, but cost of proper assessment.

[Note – we subsequently found an American cost-effectiveness study on LTOT calculating the incremental cost effectiveness ratio [ICER] for continuous oxygen therapy at $16,124 per QALY, and therefore could be deemed cost-effective, while the ICER of nocturnal oxygen therapy was $306,356/QALY and therefore not cost-effective.43]

4. Medication: Quality-assured diagnosis, initiation and review

a) Archetypal patient characteristics

- 68
- Smoking not yet hospitalized
- On triple therapy

b) Number who benefit assumptions

Of a population of 2000, currently 70% are on triple therapy but should be 10% i.e. 60% should not be on it because it should be targeted at those with repeat exacerbations despite treatment with either ICS/LABA or LAMA or who have demonstrated benefit from using triple therapy.

So, 10% of severe group should be on triple therapy and assumed 1200 would benefit from being taken off triple therapy.

c) **Cost assumptions**

Save £40 per month per patient (as tiotropium and inhaled corticosteroid both about same price) = £40 x 12 months = £500 per year per patient

---

Example of the discussion:

**4 patients**

- 70 year old smoker
- 65 year old sociable woman
- 70 year old very breathless
- 68 year old on triple therapy

Who will benefit most – ascribe them index of 100, compared to 0 = no benefit

Decided 65 year old woman stopping smoking =100

So, what weight do we assign to PR completion? Decided 80

Oxygen: decided 70

Medication = 0 (because of the assumptions above)

Next step is to agree on volumes of patients to which it applies

---

**Rectangles**

**Mild-moderate**

**Assumptions used**

Mild-moderate COPD, defined as FEV1 > 50% of predicted assumed this represents about 60% of those diagnosed

---

**Population health benefit**

Assumptions: diagnosed mild-moderate

Assume population of 3000

Focus is on areas to change (eg not single inhaled therapy with LABA)
1. Smoking cessation

a) Archetypal patient

- Routine and manual worker
- Younger than those with severe disease
- Surrounded by smokers

b) Assumptions about numbers who would benefit

That is, 3000 population of whom 35% are smokers = 1050 smokers
Of those, 70% accept referral = 70% x 1050 = 735
Of whom 18% quit at one year = 735 x 18% = 132

c) Assumptions of benefit

Gave it index of 130
Less likely to have cough
CVD risk reduced and reverts to non-smoker after 3 years
Rationale: Patient benefits are assessed on a scale where 100 is the benefit from smoking cessation for patients in the severe category. Smoking cessation for patients in the mild-moderate category is 130 because the patients will be younger and so will have greater residual life expectancy and less accumulated pack years.

d) Cost assumptions

Smoking cessation clinic: NICE Woolacott: cost per lifetime quitter £196-£2683. We chose to use a conservative figure of £1400 based on the HTA 2002 appraisal and NICE (note that this 2002 study has been replaced by a 2010 study).

Note that there are alternative costings that we didn’t use but which could be substituted following local discussion: Van Schayck et al says 1212-1906 euros (Based on bupropion and nortriptyline and placebo drug costs with other detailed costs listed.) Hoogendoorn says intensive counselling and pharmacotherapy is 130-452 euros and real life data from primary care trusts in NHS South Central shows £235 - £485 per quitter, with most £350-£400. These costs include nicotine replacement therapy. Our view is that evidence-based stop smoking support by competent practitioners with pharmacotherapy for people with severe/very severe COPD is currently very inconsistently provided.

2. Exercise programme – hire a person to take people on walks etc

a) Assumptions about numbers who would benefit

300-600 patients benefiting from exercise. Agreed on 450 for plotting the rectangle.
Gave an index of 78 of benefit.

b) Cost assumptions

Total cost (i.e. not per patient) would be about £50,000 on the basis of the cost of half an FTE health worker.

3. Medicines review – unnecessarily treated

a) Assumptions about numbers who would benefit

Assumed 10-15% wrongly diagnosed with COPD and therefore wrongly treated = 300-450 patients are unnecessarily treated because COPD is a wrong diagnosis. Used a figure of 375 to plot the benefit.

b) Cost assumptions

Savings could be £40 per month each for total annual saving of £480 pa pp = 375 x £40 x12 = £180,000. Assumed most on ICS/LABA and some on triple therapy.

c) Medicines review – over-treated

Assumptions about numbers who would benefit

In addition, of the 3000 patients, assumed 15-20% have the right diagnosis but are over-treated. That is, 450-600 patients are over-treated

Plotted 500

Gave index of zero.

Cost assumptions

Assumed savings could be from £40 per month to £80 per month so took average of £60 per month for total annual saving of £720 pa pp (those on triple therapy)

Need to deduct from saving the cost of monotherapy with LABA @ £140pa = £580

Undiagnosed COPD

Assumed population of 6,000

![Population health benefit diagram](image-url)
Assumptions
Reviewed two interventions: stop smoking and case-finding at risk patients.

1. Stop smoking
   a) Archetypal patient characteristics
      • 35
      • Smoker
      • Routine and manual worker, active and working

   Same intervention as for other patient archetypes: motivational interviewing + pharmacotherapy but applied to
   the general population.

   b) Number who would benefit assumptions

   Adult population = 300,000 x 80% = 240,000
   Population of smokers: 240,000 x 20% = 48,000
   Of these 70% wish to quit = 33,600
   Of whom 6% quit at 12 months = 1680
   Subtract the 670+1050 = 1720 with diagnosed COPD who smoke = 33,600-1720 = 31,880
   Multiply by the quit rate of 6% = 1900 (conservative)

   c) Cost assumptions

   Use a conservative figure of £1400 based on the HTA 2002 appraisal and NICE (note that this 2002 study has
   been replaced by a 2010 study). Note that there are alternative costings that we didn’t use but which could be substituted following local discus-
   sion/analysis: Van Schayck et al says 1212-1906 euros (Based on bupropion and nortriptyline and placebo drug
costs with other detailed costs listed.) Hoogendoorn says intensive counselling and pharmacotherapy is 130-452
euros and real life data from primary care trusts in NHS South Central shows £235-£485 per quitter, with most
£350-£400. These costs include nicotine replacement therapy. Our view is that evidence-based stop smoking
support by competent practitioners with pharmacotherapy for people with severe/very severe COPD is currently
very inconsistently provided.

   Agreed index of 200 relative to the index for general population because an inexpensive intervention with a rel-
atively low success rate can make an important difference if it has great potential to reduce mortality and is
applied early in the course of the diseases of interest. Over a 20-year horizon, the incremental cost-effective-
ness of varenicline in adult smokers in a Finnish study was estimated at 7791 euro over unaided cessation and
8791/QALY over buproprion.

2. Case finding at risk patients: Identifying those with more than 20 pack years
   a) Archetypal patient characteristics
      • 35
      • Smoker
      • Routine and manual worker, active and working

   48,000 smokers in general population undiagnosed
   Assumed the proportion who would have had 20 pack years = 10% = 4,800 (would need to check with local data)
   Not all will have COPD
   Assumed, 25% have COPD = 1200

   Add ex-smokers by picking up breathless people (proportion of breathless)

46. Anthonisen NR, Skeans MA, Wise RA, Manfreda J, Kanner RE, Connct JE; Lung Health Study Research Group. The effects of a smo-
b) Cost assumptions

Assumed additional £130.51 (2011/12 rate) per practice per QOF point per 1000 patients assessed

Average list size 5891 (Source GMC)

£130.51/5.89 = £22.16 per patient.

(Alternatively, this might be considered under a local enhanced service scheme (see example at www.impressresp.com/publications - other publications) in which case £175/5.89 = £30

Agreed index of 25 – to find 1200 people.

3. Quality-assured spirometry – could be added to this.

Could assume no additional cost as spirometry provided in general practice.
IMPRESS is supported by unrestricted grants from AstraZeneca, GlaxoSmithKline and Boehringer Ingelheim/Pfizer

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