

These guidelines have been replaced by [NICE Guideline Chronic Obstructive Pulmonary Disease CG101](#)

Superseded By NICE Guideline Chronic Obstructive Pulmonary Disease CG101:
Chronic Obstructive Pulmonary Disease. National clinical guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care. Thorax 2004 Mar; 59(Suppl 1): 1-232.

COPD Evidence Tables

The evidence tables are presented in section order.

The methodological quality of each paper was rated using the Scottish Intercollegiate Guidelines Network (SIGN) system (Scottish Intercollegiate Guidelines Network. SIGN 50 Guideline Developers Handbook, 2001; ID 19457):

++	All or most of the SIGN methodology checklist criteria were fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought very unlikely to alter.
+	Some of the criteria were fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.
-	Few or no criteria were fulfilled. The conclusions of the study are thought likely or very likely to alter.

COPD Guideline

Health Economics Evidence Tables

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***Note:** These tables were put together informally for the purposes of presenting key information clearly to the GDG. They are not intended to be a comprehensive reference source.*

Smoking Cessation

Specific Area	Study Type	Economic Analysis	Authors	Location	Year
	(letter)	Letter to Chest journal arguing that we should spend money on smoking cessation interventions.	Grannis	US	2001
	Model	Projections for the Netherlands – the impact smoking behaviour has on COPD health care costs. Prevalence based approach. Projects from 1994 to 2015. Costs increase by 90% of which, smokers cause approximately 90%. Total life years lost increase more than 60%. The model demonstrates an increase in the burden of COPD. The major causes of this increase are past smoking behaviour and the aging of the population; also changes in smoking behaviour will have only a small effect in the nearby future.	Feenstra	Netherlands	2001
	Guidance	This is not COPD specific, it is general guidance published in Thorax. Outlines the costs to the NHS caused by smoking, estimates the CE of smoking interventions. This guidance was aimed at those involved in planning health services locally and other health professionals who will advise and deliver the services. There is a wealth of economic information in this guidance, however it is for smoking as a whole in the UK and is not specific to COPD	Parrot et al	UK	1998

	HTA	<p>Review of economic evidence on smoking cessation. Concluded that different studies use different methodologies etc.</p> <p>Decision analytic model built to compare the CE of 4 smoking cessation interventions.</p> <ul style="list-style-type: none"> • Advice or counselling only • Advice plus nicotine replacement therapy (NRT) • Advice plus bupropion sustained release (SR) • Advice plus NRT and bupropion SR <p>The incremental cost per life year saved is about £1000-2400 for NRT, £640-1500 for bupropion and £900-2000 for NRT plus bupropion.</p> <p>The estimated cost of the smoking cessation programme to the NHS in England and Wales would be about £67 to £202 million p.a.</p> <p>The incremental CE of bupropion is generally better than that of NRT. This should be interpreted cautiously because of the very limited available data on the relative efficacy of bupropion and because the cost of adverse effects of bupropion were not considered in the analysis.</p> <p>They conclude that irrespective of the method used or the assumptions involved, the results of existing economic evaluations and the model developed in this report consistently suggest that smoking cessation interventions, including the use of NRT and/or bupropion are relatively CE in terms of the cost per life-year saved.</p> <p>This HTA is not COPD specific, and is looking at 2 specific smoking cessation interventions for the smoking population as a whole.</p>	Woolacott et al	UK	2002
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Bronchodilators

Specific Area	Study Type	Economic Analysis	Authors	Location	Year
Ipratropium bromide, albuterol Separate inhalers and combined inhaler	Retrospective cohort using health care database.	Overall costs associated with inhaled bronchodilators were reduced with the use of the combination inhaler. The rate of use of other respiratory drugs and antibiotics was similar. The combined inhaler is cheaper to purchase than the separate inhalers	Benayoun S, Ernst P, Suissa S	Canada	1997
Ipratropium plus albuterol vs ipratropium alone and albuterol alone	RCT n=1067 85 day study period	CEA – post hoc pharmacoeconomic evaluation. Cost per mean change in FEV1 and cost per exacerbation free and hospital free days. Both treatment arms containing Ipratropium were associated with a lower TC and were more effective with regard to bronchodilation than albuterol alone. (Dominant). Inclusion of ipratropium is associated with a lower rate of exacerbations hence lower treatment costs and improved CE. Combination of ipratropium. and albuterol. Produced statistically significant results in peak FEV1 over either agent alone.	Friedman M, Serby C et al	US	1998
Delivery methods- Metered Dose Inhalation vs nebulized. Salbutamol, ipratropium bromide	6 week audit 4 hospital wards n=67 nebulizer n=6 MDI n=22 both	CMA – equal effect demonstrated in RCTs previously. Hospital viewpoint. MDI least expensive therapy when self administration possible and for all levels of supervision if more than 4 minutes needed to administer nebulizer treatment. Time and motion study to estimate staff costs. MDI \$1.27 for 200µg and \$1.73 for 400 µg doses Wneb. \$2.62 for 2.5mg dose	Turner M O, Gafni A, Swan D, Fitzgerald M	Canada	1996
BA+CS (Terbutaline 250µg and beclomethasone 100µg) BA+AC	RCT 2.5 years. N=274 3 arms Study addressing whether the additional	EEACT (CEA) Societal viewpoint Costs based on 1989 Dutch prices, converted to US\$. Study stopped earlier than planned due to highly selective treatment related withdrawals and significant differences in primary physiologic endpoints.	Rutten-Van Molken M, Van-Doorslaer E K et al	Netherlands	1995

(Ipratropium bromide 20µg) BA+PL (placebo)	treatment costs of the combination therapies are outweighed or justified by the additional clinical benefits and reduced utilization of other health care services	ICER of BA+CS compared to BA+PL ≈ \$200 per 10% increase in FEV1 (95%CI \$57-\$450) Also, \$5.35 per symptom free day gained (95%CI \$1-\$127). Compared to BA+PL, BA+CS led to significant improvements in FEV1 and symptom free days. BA+AC did not differ from BA+PL in this respect. BA+CS costs \$376 more than BA+placebo, but led to statistical significance. Savings in other health care costs of about \$175. The addition of a corticosteroid to a Beta2 agonist leads to significant benefits in respiratory function and restricted activity days and a relatively low additional cost. Addition of an anticholinergic agent appears expensive and of no long term value. In order to reach net societal savings, the economic benefits of increased productivity due to inhaled corticosteroids have to be valued higher than \$42 per day.			
Ipratropium bromide	Retrospective study using data from the computer archive of a network model HMO. Looked at expenditure during the first 6 months post diagnosis	No clinical effectiveness data. Use of multivariate regression analysis to look at the effect of age, sex, FEV1 and pharmacotherapy on health service expenditure. Results: Significant increase in expenditure for patients prescribed theophylline (corticosteroid) or albuterol compared to ipratropium bromide. Initial therapy using ipratropium bromide and subsequently adding albuterol leads to a decrease in use of health care services compared to all other combinations.	Sclear D A, Legg R F et al	USA	1994
Theophylline, ipratropium bromide	3 centre study. n=311 theophylline n=289 Ipratropium bromide. Use of a Markov model for CEA. Data from chart review	CEA of theophylline (T) and ipratropium bromide (IB) Perspective is 3 rd party payer. Overall costs for theophylline = \$121.40 per patient per therapy month, vs \$84.56 for ipratropium bromide. Marginal cost of Theophylline over IB from extrapolation over 1 year using the Markov model = \$366. The Markov model also predicted that patients receiving IB had a greater number of complication free therapy months than T. Therefore, IB is less costly and more CE than T. Sensitivity analysis carried out and IB still remained dominant	Jubran A, Gross N, Ramsdell J et al	USA	1993

Inhaled formoterol dry powder vs ipratropium bromide vs placebo	Randomised trial QoL secondary outcome	<p>Quality of life measured using the St Georges questionnaire. Measured before the first dose of study medications and at the end of the treatment period. A difference of 4 points or more was considered clinically relevant.</p> <p>Results: F12 and F24 both had statistically significant increases in total scores on the SGRQ compared to placebo. F12 gave an increase of greater than 4 points. There was no difference between Ipratropium Bromide and placebo. These results are different to other studies which is noted by the authors.</p>	Dahl R, Greefhorst L et al	Denmark	2001
Ipratropium and salbutamol vs salmeterol alone and ipratropium alone. Salmeterol vs ipratropium and salmeterol vs placebo	Based on existing data – 2 multicentre efficacy and tolerability trials.	<p>Review of literature and update on the pharmacoeconomics with new drugs. Concluded that the severity of COPD and the type of drugs used in the management of COPD influences the subsequent cost of treatment. Ipratropium/salbutamol combination \$788 per patient p.a. Salmeterol \$1059 per patient p.a. (1999 values)</p>	Friedman M, Hilleman D E	US	1999
Ipratropium	Retrospective cohort study N=413 Patients from 1993/94	<p>COI evaluation. Health care utilization and costs identified through chart review. In stage I (American Thoracic Society stratification), ipratropium has lowest total cost. In stage II and III, ipratropium and beta2 agonist have lowest total cost. This is mainly due to lower add-on drug costs, fewer diagnostic and lab test and lower utilisation rates for clinic visits, emergency department visits and hospitalisation.</p>	Hilleman D E, Dewan N, malesker M, Friedman M	US	2000

		<p>Other results- interventions that reduce or prevent hospitalisation in patients with COPD will have the greatest potential impact on cost. (Hospitalisation is most important cost variable).</p> <p>The use of ipratropium leads to a decrease in health care resource use vs other therapies.</p> <p>This work supports that of Jubram et al. in that theophylline had higher total treatment costs than other monotherapies.</p> <p>Other result: Use of a larger number of drugs is not associated with lower treatment costs.</p>			
Salmeterol 50µg vs theophylline	<p>Open label study 3 months Extra 9 months for QoL using SF-36 and safety. N=178 Randomised Patients had a mild/moderate clinical history of chronic bronchitis</p>	<p>Quality of Life was measured using the SF-36 at 3,6,9 and 12 months.</p> <p>Mean changes between visits for each dimension looked at.</p> <p>Both drugs gave a statistically significant increase in quality of life compared with baseline measurements as measured by the SF-36.</p> <p>Salmeterol gave a statistically significant increase over theophylline in 3 dimensions (physical functioning, changes in health perception and social functioning).</p> <p>Salmeterol also shown to be more effective than theophylline, as measured by morning peak expiratory flow rate % of symptom free days and nights and FEV1.</p>	Di Lorenzo G, Morici G, Drago A et al	Italy	1998

Corticosteroids

Specific Area	Study Type	Economic Analysis	Authors	Location	Year
Inhaled corticosteroids	Randomised, double-blind, placebo controlled study. Part of the Copenhagen City Heart Study. N=290 Budesonide 800µg am + 400 µg pm for 6months, then 400 µg twice daily for 30 moths vs placebo for 36 months.	There was no formal economic analysis. The authors are pointing out that the results of their study indicate no benefit of this drug for COPD patients and that this is an unnecessary cost. The study was based on a select group of COPD patients – it excluded patients who had any evidence of airway hyperactivity, by excluding patients if they responded acutely to inhaled terbutaline or more chronically to a course of oral prednisolone for 2 weeks. The patients included had mild disease and primarily had emphysema. These results may not be applicable to the general COPD population as some patients have a significant inflammatory component.	Dragonetti M E, Groth M L	Denmark	1999

Inhaled	<p>Cost effectiveness analysis of Fluticasone propionate (FP) in patients with moderate to severe COPD.</p> <p>Fluticasone propionate 1000 µg daily in addition to regular bronchodilator therapy vs placebo.</p> <p>N=281</p> <p>International, double blind, randomised study over 6 months.</p>	<p>Perspective: NHS and societal.</p> <p>Outcome measures: achieving a $\geq 10\%$ improvement in FEV1 and remaining exacerbation free throughout the study (6 months).</p> <p>Both groups were costed prospectively and costs included use of inpatient, outpatient and primary health-care services and medication. Time lost from usual activities and paid employment was also recorded.</p> <p>Results: From an NHS perspective, the mean incremental cost to improve FEV1 by $\geq 10\%$ over 6 months is £45.50 per patient. From a societal perspective, the incremental cost effectiveness ratio was negative (i.e. improvement in lung function achieved a net cost saving).</p> <p>Cost effectiveness acceptability curves were generated and showed that from an NHS perspective, FP is cost effective for more than 80% of the time if decision makers are willing to pay an additional £5.00 per day to improve FEV1 by $\geq 10\%$.</p> <p>No significant differences between groups in terms of the proportion of patients remaining free of an exacerbation of any severity at the end of treatment. However, significantly more patients in the FP group were free of moderate/severe exacerbations at the end of the study.</p> <p>Sensitivity analysis showed that the incremental cost effectiveness ratios are generally robust.</p>	Ayres J G, Price M J, Efthimiou J	UK	2003
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Inhaled	<p>Cost effectiveness analysis 1 year, randomised, double blind trial.</p> <p>Fluticasone propionate (FP) 250 µg twice a day vs placebo.</p> <p>Population: Subjects who were undiagnosed prior to the study with objective signs of obstructive airway disease. Salbutamol allowed as rescue medication.</p> <p>N=82</p>	<p>Main outcome measures: postbronchodilator FEV1. QALYs. and direct medical cost.</p> <p>ICER US\$ 13,016 per QALY for early treatment and US\$33,921 per QALY for the combination of detection and treatment.</p> <p>In summary, early treatment with fluticasone propionate 250 µg twice a day in subjects with objective signs of obstructive airways disease resulted in increased medication costs, but also improvements in lung function and quality of life.</p> <p>The treatment is relatively cost effective, but this cost effectiveness ratio was only achieved by identifying subjects early on by detection. When the costs of detection are factored in, the cost effectiveness ratio becomes much less favourable. In comparison to other early treatment strategies, e.g. smoking cessation the cost effectiveness ratio for fluticasone propionate is a lot higher.</p> <p>(estimated between £212 and £873 per life year saved – Parrot et al 1998, Thorax).</p>	Van den Boom G, Rutten-Van Molken M et al	Netherlands	2001
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<p>NB this paper already reviewed for bronchodilators.</p> <p>Combined bronchodilator and corticosteroid.</p>	<p>BA+CS (Terbutaline 250µg and beclomethasone 100µg) BA+AC (Ipratropium bromide 20µg) BA+PL (placebo) RCT 2.5 years. N=274 3 arms Study addressing whether the additional treatment costs of the combination therapies are outweighed or justified by the additional clinical benefits and reduced utilization of other health care services</p>	<p>EEACT (CEA) Societal viewpoint Costs based on 1989 Dutch prices, converted to US\$. Study stopped earlier than planned due to highly selective treatment related withdrawals and significant differences in primary physiologic endpoints. ICER of BA+CS compared to BA+PL ≈ \$200 per 10% increase in FEV1 (95%CI \$57-\$450) Also, \$5.35 per symptom free day gained (95%CI \$1-\$127). Compared to BA+PL, BA+CS led to significant improvements in FEV1 and symptom free days. BA+AC did not differ from BA+PL in this respect. BA+CS costs \$376 more than BA+placebo, but led to stat. sig. Savings in other health care costs of about \$175. The addition of a corticosteroid to a Beta2 agonist leads to significant benefits in respiratory function and restricted activity days and a relatively low additional cost. Addition of an anticholinergic agent appears expensive and of no long term value. In order to reach net societal savings, the economic benefits of increased productivity due to inhaled corticosteroids have to be valued higher than \$42 per day.</p>	<p>Rutten-Van Molken M, Van-Doorslaer E K et al</p>	<p>Netherlands</p>	<p>1995</p>
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Oxygen Therapy

Specific Area	Study Type	Economic Analysis	Authors	Location	Year
	Mechanical ventilation of patients on LTOT with acute exacerbations Prospective cohort study F/U at 1 and 5 years CUA N=20 Setting: ICU in a university hospital Study carried out 1992-1994	This study is evaluating mechanical ventilation and not LTOT. Very small sample size. Does not contribute to evidence on oxygen.	Anon, J M, Garcia de Lorenzo A G et al	Spain	1999
		This is not evaluating oxygen therapy, it is evaluating the impact of a hospital-based home-care program on the management of COPD patients receiving long term oxygen therapy. (NB Excluded from hospital at home review)	Farrero E, Escarrabil J et al	Spain	2001
Domiciliary liquid oxygen vs. concentrator treatment	Domiciliary liquid oxygen vs. concentrator treatment in chronic hypoxaemia CUA Prospective randomised trial F/U at 6 months N=51 (multicentre trial)	Costs were measured in both arms, including use of other services and the cost of the oxygen. Outcomes were measured using two quality of life instruments – the sickness impact profile (SIP) and the Euroqol. The main finding was that liquid oxygen treatment was more expensive than concentrator treatment, but had a better impact on QoL. This was demonstrated through the SIP, but the Euroqol showed no significant differences. The total cost of treatment using liquid oxygen was US\$4,950 ± 2,340 and the cost of concentrator treatment was \$US 1,310 ± 650. (1996 prices) Significant differences were found between the two groups in four dimensions of the SIP and in the total SIP score. Study carried out 1993/4	Andersson A, Strom K et al	Sweden	1998

Oxygen at home	CMA of provision of oxygen at home	<p>This study is a cost analysis of providing oxygen by concentrator or cylinder.</p> <p>They assume no difference in efficacy or other resource use (i.e. frequency of visits to GP etc).</p> <p>Their conclusion is that as long as more than three cylinders a month are being used, independent of flow rate or duration of prescription, it is always cheaper to prescribe a concentrator.</p> <p>If the duration of prescription is likely to be 12 months or longer, it is always cheaper to prescribe a concentrator when two or more cylinders are being used per month whatever the flow rate.</p> <p>Although this was based on data from Northern Ireland, they state that the cost of contracts for provision of concentrators are similar throughout the UK and are equivalent to other European countries.</p>	Heaney L G, McAllister D, MacMahon J	Northern Ireland	1999
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Non Invasive Ventilation

Specific Area	Study Type	Economic Analysis	Authors	Location	Year
NIV	Economic evaluation based on a theoretical model Setting: tertiary care teaching hospital. Study from a hospital perspective Comparing standard therapy (oxygen, bronchodilators, steroids, antibiotics) with standard therapy plus NIPPV	They build a decision tree using data on effectiveness from a meta analysis and use the literature for other parameters. They demonstrate that adding non-invasive positive pressure ventilation in the setting of a severe, acute exacerbation of COPD is more effective and less expensive than standard therapy, when viewed from the perspective of the hospital. Under baseline assumptions, the mean cost for patients NIPPV in addition to standard therapy was \$7,211 (1996 Can\$). Standard therapy alone costs \$10,455. This results in a cost saving of \$3,244 per patient. Sensitivity analysis demonstrated that the findings were sensitive to some of the assumptions: If the location for NPPV was the ICU rather than an intermediate care unit, the estimated savings were less, but still favoured NIPPV. They caution that these results are applicable to patients with severe exacerbation, those with mild exacerbations would probably show no difference and this needs formally evaluating.	Keenan S P et al	Canada	2000
NIV	Editorial referring to Keenan paper	Criticises the meta analysis used in the model. They have a few concerns over the methodologies of some of the studies that are included in the meta analysis and say that the benefit may not be as large as the meta analysis shows. Also, they warn against making broad conclusions from this work, as this is a select patient group. They suggest more work is needed to establish the effectiveness.	Jasmer R M, Matthay M A	US	2000

Non-invasive mechanical ventilation	Prospective trial n=10 non invasive n=6 invasive Setting: a respiratory ICU	This is a limited study – they did not evaluate outcomes, they just looked at resource use in 48 hours following ventilation. Sample is very small. The patients who had invasive mechanical ventilation had previously had non invasive mechanical ventilation, which was unsuccessful.	Nava S et al	Italy	1997
NIV for acute exacerbations	Cost effectiveness analysis alongside an RCT. Standard treatment with and without the addition of ward based NIV. N=236 Hospitalised patients, with an exacerbation of COPD and mild to moderate respiratory acidosis.	Economic analysis compared the costs of treatment patients received after randomisation. Outcome: Incremental cost per in hospital death. Perspective: NHS, hence direct costs only Results: NIV group associated with a reduction in costs of £49,362 (mainly through reduced use of ICU). Incremental cost effectiveness ratio -£645 per death avoided (95%CI -£2310 to £386) Dominant strategy (more effective and less costly) Modelling of results showed that providing a NIV service will avoid 6 deaths and 3-9 admissions to ICUs p.a., with an associated cost reduction of £12 000-£53 000 p.a. It is noted that although there is a cost saving overall, costs are increased on the respiratory wards, but these are offset by savings in the costs of ICUs. Cost effectiveness acceptability curves were created and showed that at a cost of £5,000 per death prevented, there is a 95% probability that NIV is more cost effective than standard treatment.	Plant P K, Owen, J L, Parrott S, Elliott M W.	UK	2003

Non-invasive mechanical ventilation	Book chapter. Small review	<p>No new empirical work here, this is a summary of the literature on the costs incurred by the use of non invasive mechanical ventilation.</p> <p>It concludes that the economic literature is scarce, but there are a few studies which look at workload and length of stay in the ICU.</p> <p>Problems are that charges are often used instead of costs and workload is difficult to measure and there is no consensus on it.</p> <p>The real cost consequences from using NIMV remain largely unknown.</p> <p>It is possible you may get a reduction in the length if ICU and hospital stay when NIMV is used, but this may mean a higher workload for staff. Staff will need to be skilled in the use of it.</p> <p>Chevrolet et al (1997) found that for COPD patients, >90% of the ventilation time had to be monitored by a nurse. However, this study was performed when NIMV in the ICU was new and there is probably a learning curve.</p> <p>Bott et la (1993) noted that nursing workload was not different between COPD patients treated with nasal volume controlled NIMV and standard treatment.</p> <p>Kramer et al (1996) report similar findings in COPD patients and non-COPD patients, using NIPSV, delivered by nasal mask.</p> <p>Confalonieri et al (1999) found that for COPD patients with severe community acquired pneumonia, nursing workload was no different for NIPSV compared to standard treatment on the first day. After 3 days of treatment, workload was lower with NIPSV. The authors attributed this to their large experience with the technique.</p>	Chevrolet	Switzerland	2001
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Pulmonary Rehabilitation

Specific Area	Study Type	Economic Analysis	Authors	Location	Year
Hospital based PR	DEC Report	<p>The report cites systematic reviews of trials that give evidence that hospital outpatient based PR programmes are effective in improving QoL for patients for up to 18 months. However, the patients in the trial were very heterogeneous.</p> <p>There is too little evidence about home based PR and no evidence beyond 18 months.</p> <p>A cost utility analysis was described.</p> <p>Costs were £200-£400 per patient (excluding overheads)</p> <p>Utility was measured by asking a clinical expert to rate how a patient would score on each of the 3 dimensions of the Index of health related quality of life before and after a pulmonary rehabilitation programme. These health states were then valued using the tariff for the instrument.</p> <p>A pulmonary rehabilitation programme that includes at least 4 weeks gives an estimated QALY gain of 0.1.</p> <p>Cost per QALY ranges from £2,000 to £8,000</p> <p>If all patients over 45 with COPD participated in a PR programme, the cost to a typical health authority would be £600,000 to £1,200,000.</p> <p>There may be some resource savings due to reduced GP consultations and hospital admissions, but there was no evidence given to quantify this.</p>	McBride A, Milne R The Wessex Institute	UK	1999

Outpatient	Observational before and after study. 1993-1996 7 week based programme n=267	Quality of life was measured using the CRDQ and the Breathing Problems Questionnaire (BPQ). Rough estimates were also made of set up costs The setting was a DGH in Leicester. CRDQ showed a significant increase in all domains in a sub set of 57 patients who completed it (n=57). Longer term follow up at 10 months (n=49) still showed a continued improvement in a small number of patients. BPQ showed no overall change. Rough estimate of set up costs £7,870 and an annual cost of £1,574	Singh S J, Smith D L, Hyland M E, Morgan M D L	UK	1993-1996
Private hospital	Observational at a private hospital outpatient PR programme. Chart review and survey N=72	Following PR, there was a significant decrease in hospitalisation and length of stay for up to 4 years. Average cost per day in hospital for a patient with COPD is approx \$515. Cost to run the PR programme is \$1,500-\$2,000 per patient.	Scherer Y K, Schmieder L E	US	1998
Outpatient based	Before and after trial N=46	Cost data (minimal) Cost of 10 outpatient sessions= \$650 They cite 12 studies that have reported reductions in hospitalisation rates for patients undergoing PR. They suggest that the decrease in need for health care can more than offset the cost of PR, but they give no new evidence for this, just cite various pieces of information from various sources.	Rosenbaum R R, Bach J R, Penek J	US	1997

Medical Centre	Observational 3 week PR n=37 1 centre	Quality of life was measured using the SF-36 pre and post PR. There was an increase in 5 of the QoL subscales of the SF-36 following PR. No cost data Also looked at correlations between QoL and functional capacity. No correlations between FEV1 and improvement in walk distance, but there was a correlation between FEV1 and an increase in SF-36 physical function and energy/fatigue subscales.	Boueri F M V, Bucher- Bartelson B L, Glenn K A	US	2001
Study of use of SF-36 for this purpose	Observational N=22	This study was a test of the use of the SF-36 summary scores as outcome measures. Also used St Georges Respiratory Questionnaire. Results found that the SF-36 was sensitive.	Benzo R, Flume P A, Turner D, Tempest M	US	2000
PR and lung volume reduction	Prospective cohort study N=19 (who underwent PR in preparation for lung volume reduction surgery)	Quality of life was measured at baseline, after PR and 6 months after LVRS. Results: No significant change from baseline in any of the 8 domains after PR. They cite Ries et al. N=119 for 6 years. Following RCT of PR, they found no significant change in HRQL using the generic quality of well being scale. The 2 RCTS that have found an increase in HRQL after PR used the CRDQ.	Moy M L, Ingenito E P, Mentzer S J	US	1999
Inpatient PR	Observational study conducted between 1992-95 N=77	Aim was to see which patients sustained HRQL benefits from in patient pulmonary rehabilitation. Looked at HRQL using the St Georges Respiratory Q. Results: the beneficial effects on HRQL gained during inpatient PR decreased 9 months post discharge.	Ketelaars C A J, Huyer H et al	Netherlands	1997
Outpatient	Observational N=17	Quality of life was measured before and after the programme using the CRDQ. There was a significant improvement in mood 1 month after the program.		?	2000

Lung volume reduction surgery vs PR	Prospective randomised trial N=200 with severe COPD N=37 met study criteria	Quality of life measured using the sickness impact profile (a generalized measure of QoL). This was significantly improved after 8 weeks of rehab and maintained after 3 months of additional rehab. LVRS+PR greater effect than PR alone. Small study, small follow up. Cites several studies that have shown a statistically significant increase in QoL after PR vs standard medical therapy.	Criner G J, Cordova F C, Furukawa S et al	US	1999
BTS statement	Summary	Useful for background. PR can take place in the hospital outpatient setting, the community or the home. Majority use hospital facilities. Some experience with outpatient programmes, but only limited experience of providing inpatient, home or community rehab. Potential impact on resource use: hospital admissions frequency; duration of stay; exacerbation rate; GP home visits; bronchodilator usage. Cost of programme will depend on size and scope as well as personnel costs. In the UK in 1998, annual programme cost estimated at £20,000 and £400-£700 per patient.	BTS	UK	2001
Primary care	Pilot study, n=14, 13 completed.	Pilot study to see if PR performed by the primary health care team in 1 practice was feasible. 14 patients recruited, 13 completed. Estimated costs of running the programme £1410 (£113.07 per completed patient). Set up costs including equipment and training were £1391.35. Total rehab costs were £220.10 per patient. Analysis of use of primary and secondary care services and drug prescribing was performed for 12 months before and 12 months after rehab. No important differences were found, although there was a reduction in GP visits after the programme (13 before compared to 2 after). Results indicate that it is feasible for a multidisciplinary primary health care team to establish a programme in 1 practice. This was a much less intense programme (14 hours compared to 28-100 hours in a typical hospital)	Jones et al	UK	2002

Outreach respiratory care	Economic evaluation	Not relevant to this area, is a CEA of a different service	Gordois et al	UK	2002
Home based	Review	This is not an economic evaluation and contains no empirical data on costs. It cites a few studies that suggest that home based rehab is cheaper than outpatient based, but these studies are US based and are of little use in applying the results to the UK	Wijkstra et al	Netherlands	2000

Outpatient	CUA N=200	<p>Randomised controlled study of PR. 18 visit, 6 week outpatient rehab programme or continue standard medical management. CUA of the programme. Costs were those borne by primary and secondary health services. SF-36 at baseline, at end of 6 week intervention perode and 12 months after entering the study. Used SF-6D (pilot study valuation) to calculate single index. Combined with survival data to produce QALYs. Costs – from NHS trusts. Analysis based on the basis of 17 patients per programme. TCs per programme were divided by 17 and allocated to each patient randomised to the rehab group. Calculated cost per QALY. Bootstrapping and CEACs undertaken.</p> <p>CUA is on the addition of PR to standard care, although the patients were chronic disabling lung disease patients, they were primarily COPD patients. This paper gives the most comprehensive description of costs and is the only study to contain utility data.</p> <p>Also compared their results to those of Goldstein et al in Canada (this was an inpatient setting). Converted costs to UK£. Outpatient is much cheaper.</p> <p>Each rehab programme costs £12,120 for up to 20 patients. Mean incremental cost of adding rehab to standard care was -£152 (95% CI -881 to 577) per patient. Incremental utility of adding rehab was 0.03 (95%CI 0.002 to 0.058) QALYs per patient</p> <p>Dominant (i.e. less costs and increase in QALYs)</p> <p>Bootstrapping demonstrated that there was a high likelihood of generating QALYs at negative or relatively low cost. The probability of the cost per QALY generated being below £0 was 0.64</p> <p>A very thorough and detailed EEACT. Detailed costing and analysis. This study is UK based, recent and relevant</p>	Griffiths et al	UK (Wales)	2001
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Immunisation

Specific Area	Study Type	Economic Analysis	Authors	Location	Year
Immunisation	Cost effectiveness analysis Of OM-85 BV vs placebo N=381 (190 placebo, 191 OM-85 BV)	The CEA was carried out in conjunction with a placebo controlled randomised clinical trial. Effectiveness was defined as the difference in the number of severe acute exacerbations. Results: The risk of being hospitalised for a respiratory cause was 30% lower in the OM-85 BV treated group than in the placebo group. The length of hospital stay for a respiratory problem was much shorter in the group treated with OM-85 BV (mean 6.5 days) than placebo (mean 11.3 days). The median cost to prevent one day of hospitalisation for a respiratory condition was CDN\$45 (95%CI CDN\$18 to CDN\$210).	Collet J P et al	Canada	2001
Immunisation	NICE Technology Appraisal	Guidance from the NICE technology appraisal recommends routine immunisation of people of any age with chronic respiratory disease, where it is known that either influenza A or influenza B is circulating in the community. “Vaccination offers a very cost effective first line of defence against influenza.” “The Committee concluded that the evidence indicated that, when influenza is circulating, it would be both clinically effective and cost effective for at-risk people with influenza-like illness to be treated with zanamivir or oseltamivir if they can begin their course of medication within 48 hours of the appearance of symptoms.” People who have chronic respiratory disease (including COPD) are considered to be at risk.	NICE TAG no. 58	UK	2003

Immunisation	<p>Cost effectiveness analysis of OM-BV (Broncho-Vaxom)</p> <p>Hypothesis: The preventive use of Brocho-Vaxom for the reduction of infections in CB patients is more cost-effective than the sum of all costs for the diagnosis and therapy of each single infectious episode.</p>	<p>A decision analytic model was built, based on expert opinion. Many of the parameters of the model were also based on expert opinion.</p> <p>The effectiveness comes from a meta analysis of placebo controlled, randomised, double blind trials conducted in private practice settings in different European countries. All the cost data is based on the Swiss health care system.</p> <p>Assuming the decision tree structure shown (which is the diagnosis and treatment of acute exacerbations in chronic bronchitis patients consulting a physician in Switzerland), the effectiveness of OM-BV as being 0.5 prevented acute exacerbations per six months per patient and all the probabilities shown for the parameters of the model, this resulted in cost savings for those patients treated with OM-BV of CHF 688.16 including both inpatient and outpatient care.</p> <p>The most sensitive parameters of the model are:</p> <ul style="list-style-type: none"> • The success rate of the first antibiotic treatment • The sensitivity factor for the 2nd diagnostic process • The effectiveness of Broncho-Vaxom 	Grove A K, Bergeman R, Keller R	Switzerland	1996
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Immunisation	<p>Cost effectiveness analysis N=1,696 453 not vaccinated 1,243 vaccinated</p>	<p>This is a prospective cohort study assessing the cost effectiveness of influenza vaccination in preventing complications in a cohort of adults with a chronic lung disease.</p> <p>Comparator: no vaccination.</p> <p>The study was carried out in 1995-96, in a single network centre that consisted of six computerised primary care group practices.</p> <p>The cohort was split into 2 age groups: 18-64 and 65 and over.</p> <p>Results:</p> <p>The effectiveness of the programme could only be established for patients over 65. After adjusting for confounding variables, it was found to reduce the occurrence of any complications by 50%. (95%CI 17-70), acute LRTI by 46%, and cardiac disease by 57% (not statistically significant).</p> <p>Net savings produced by the programme were calculated as immunisation costs-cost of medical care averted.</p> <p>The cost analysis was only undertaken for those aged 65 and over.</p> <p>The estimated net saving was £50 per elderly person vaccinated.</p> <p>Conclusion:</p> <p>‘This study suggests that, in the Netherlands, immunisation of elderly patients with chronic lung disease against influenza is effective and cost saving, therefore these patients should be given high priority.’</p> <p>Notes:</p> <p>This paper has been excluded from the clinical review, due to it being a heterogeneous population.</p> <p>This paper was not also included in the HTA review.</p>	Hak E, van Essen G A et al	The Netherlands	1998
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Lung Volume Reduction Surgery

Specific Area	Study Type	Economic Analysis	Authors	Location	Year
Lung volume reduction surgery	Cost and outcomes comparison of sternotomy versus thoracoscopy	<p>This is an observational study, which compares two methods of lung volume reduction surgery: video assisted thoracoscopy (VATS) and sternotomy.</p> <p>All patients from 1995-97 from 1 surgeon were assessed. 19 had sternotomy, 23 had thoracoscopy.</p> <p>Both groups were comparable pre-operatively.</p> <p>Results: VATS takes longer to perform</p> <p>Postoperatively, the sternotomy patients had more days on the ventilator, more days in the ICU, more days with an air leak and longer hospital stays.</p> <p>Average hospital costs and charges were reduced in the VATS group.</p> <p>Notes: Small sample Observational US based Single site (and 1 clinician)</p>	Ko C Y, Waters P F	US	1998

Alpha 1 Antitrypsin

Specific Area	Study Type	Economic Analysis	Authors	Location	Year
a1 – antitrypsin replacement therapy	Model Of the cost effectiveness of alpha1 antitrypsin (AAT) replacement therapy	<p>At the time of publication, the efficacy was unknown. Therefore a model was constructed, using epidemiological and disease cost data from published sources. They estimated the expected cost of disease treatment under a range of possible efficacy and other parameter values to estimate the cost effectiveness.</p> <p>At an efficacy of 70%, the cost per life year saved would be between \$28,000-\$72,000 (1990), depending on patient age, sex and smoking status.</p> <p>At an efficacy of 30%, the cost per life year saved would be between \$50,000-\$128,000 (1990).</p> <p>Issues:</p> <ul style="list-style-type: none"> • Small number of potential beneficiaries • High cost and unknown benefit • Model uses change in survival as efficacy outcome and disregards QoL. • Costs of therapy and treatment may now be outdated. <p>This paper is of limited use, as there are many assumptions and uncertainties and it is US based and outdated.</p>	Hay J W, Robin, E D	US	1991

Mucolytics

Specific Area	Study Type	Economic Analysis	Authors	Location	Year
Oral N-Acetylcysteine (NAC)	Cost effectiveness analysis Based on retrospective analysis of studies.	<p>The aim is to estimate the cost effectiveness of using NAC as a preventive treatment for exacerbations of bronchitis. They build a deterministic model based on assumptions and secondary analysis of clinical data from prospective studies.</p> <p>The perspective is the payer (i.e. Swiss healthcare system)</p> <p><u>Data used for model</u></p> <p>Medline searched and checked the references from the resulting papers.</p> <p>Included prospective, double-blind placebo controlled NAC trials. (These studies are shown below)</p> <p>All 9 studies included</p> <p>Only 2 of the studies reported on hospitalisations.</p> <p><u>Results</u></p> <p>The pooled data show that continuous administration of 400 mg day per os of NAC leads to a significant reduction in the number of exacerbations. (NAC: 16.2 vs 25.2 % exacerbations per month).</p> <p>Also, a significantly smaller percentage of days of sick leave (NAC: 3.6 vs 5.3%) and a lower rate of hospitalisations. (NAC 1.5 vs 3.5% over a six month period).</p> <p>For the model, they assumed a compliance rate of 80%.</p> <p>The mean direct costs of an untreated patient were CHF 869 vs CHF 700 in the NAC treated patient.</p> <p>The direct costs included:</p> <ul style="list-style-type: none"> • NAC treatment • Management of an exacerbation • hospitalisations <p>Sensitivity analysis showed that cost neutrality is reached at 0.6 exacerbations per 6 months. i.e. would occur in an untreated patient</p> <p>These results suggest that this is an effective and cost effective treatment, as reductions in exacerbations and hospitalisations translate into reduction in resource use.</p> <p>Indirect costs (based on sick leave) were also significantly different:</p> <p>Treatment: CHF 779</p> <p>No treatment: CHF 1324</p>	Grandjean E M, Berthet P H et al	Switzerland	2000

Other notes

They randomly eliminated single trials used in the meta analysis and showed that the results and their significance do not depend on a particular single study.

None of the 9 studies used considered hospitalisations as a study endpoint and only 2 of them reported on it.

The most important source of cost variation is the percentage of hospitalised patients.

Of the 9 studies used, 7 were published in the 1980s, one in 1976 and one in 1994:

Grassi and Morandini (1976)

Grassi et al (1980)

Boman (1983)

Jackson (1984)

Macfarlane and The BTS (1985)

Meister (1986)

Parr and Huitson (1987)

Rasmussen and Glennow (1988)

Hansen et al (1994)

Patient Education

Specific Area	Study Type	Economic Analysis	Authors	Location	Year
'Personalised hospital practice' (PHP) intervention: attended by 1 nurse and 1 doctor.	RCT with 1 year f/u N=100 1988-1990 1990 prices used	Objective was to evaluate the effect on health service use of educating patient with COPD about their illness The suggestion was that the intervention personalised hospital practice led to a reduction in the consumption of health services by patients with COPD, probably by increasing their knowledge of the disease and hence their ability to manage themselves. The aim is to educate, which will hopefully help to prevent and treat exacerbations and consequently lead to a decrease in resource consumption. Main effect were fewer consultations of GPs and fewer readmissions to hospital by patients who have had PHP The authors note that teaching patients with COPD about their disease will probably influence patterns of consumption differently in other health systems. Not really useful paper, but useful to know that in this study there was an impact on resource use. Patient education : different behaviour : impact on resource use	Tougaard et al	Denmark	1992
Experimental behavioural program	General health policy model to determine the CE of an experimental behavioural program N=76	CUA. Collected info on health status 'well year equivalents' over 18 months. QWB used \$24,256 per well year gained. Some assumptions used, but sounds methods and explicit. Although old, demonstrated reasonable CE of behavioural programs in COPD. May be of limited relevance here however	Toevs et al	US	1984
Measuring outcomes of a COPD disease management program	Review of the program	This study is US based and is of little relevance for our purpose. The costs are also irrelevant.	Zajac	US	2002

Hospital at Home

Specific Area	Study Type	Economic Analysis	Authors	Location	Year
Hospital at home	RCT (Part I of II) Hospital at home vs inpatient care COAD patients: n=32	This is the clinical paper (3 month follow up of outcomes) At f/u there were no major differences in outcome for COAD patients. However, they did not prefer hospital at home care. Conclusion: as few differences in outcome were detected, cost becomes a primary concern.	Shepperd S, Harwood D, Jenkinson C et al	UK (Northamptonshire)	1998
Hospital at home	Cost minimisation analysis (CMA) (Part II of II) COAD patients: n=32	Hospital at home significantly increased healthcare costs for patients with COAD. Hospital at home significantly increased GP costs for those with COAD. (p=0.02) There was some evidence that costs were shifted to primary care for COAD patients. “patients with COAD in the hospital at home group spent significantly fewer days in hospital, but this reduction was offset by the time spent in hospital at home care so there was no significant difference between the 2 groups for the total days of health care” Sensitivity analysis: ‘costs remained significantly more expensive for patients for COAD when duration of hospital at home care was reduced by 1 day, but a reduction of 2 days resulted in a non significant difference between the two groups.’	Shepperd S, Harwood D, Gray A et al	UK (Northamptonshire)	1998

Hospital at home	RCT Supported discharge vs standard hospital care N=184	Not an economic evaluation, but does give the costs of the 2 arms of the trial. 1997/8 costs. Inpatient costs based on length of stay and average cost (AC) per bed day in the respiratory unit. Due to using AC, overstates the value of reduction in bed days. Little details given on the costing methods. Median time to discharge was 7 days for the home support group and 5 for admitted group. 25% of home group and 34% admitted group were readmitted before the final assessment at 8wks. No significant dif in attendances by GPs and carers or in health status at 8 wks between the two groups. Mean total health service cost per patient estimated at £877 for home support group and £1753 for admitted group. Very little detail given on the costing, therefore difficult to judge.	Skwarska E, Cohen G et al	UK (Edinburgh)	2000
Hospital at home	RCT Early discharge with domicillary respiratory nurse support vs conventional hospital management N=81	Outcome measures: readmission, additional hospital days, death within 60 days of admission. Results: early discharge reduced inpatient stay from a mean of 6.1 to 3.2 No formal economic evaluation, so they are cautious, but they reduced the length of stay by approximately half and found no sig. dif in readmission rate. They did not measure the number of nurse visits for the early discharge patients and did not measure any consequent resource use effects (e.g. GP visits).	Cotton et al	UK (Glasgow)	2000

Hospital at home	RCT Hospital at home vs inpatient care 3 months f/u n= 100 home care n=50 hospital	Main outcome measures: Readmission rate, changes in FEV1, mortality No significant difference in FEV1 at f/u 37% home care and 34% hospital care readmitted at 3months. No significant difference in mortality. Conclusion: hospital at home care is a practical alternative to emergency admission in selected patients with exacerbations of COPD. No economic evaluation.	Davies et al	UK (Liverpool)	2000
Hospital at home	RCT Early discharge, hospital at home scheme vs acute hospital care N=241 (medically stable, elderly patients taken from general medical, orthopaedic, elderly and general surgical specialties). These are not COPD patients	Main outcome: QoL, satisfaction, physical functioning at 4 wks and 3 months. LOS in hospital/hospital at home, mortality at 3months. Results: No significant differences in patient mortality, QoL and physical functioning at 4 wks or 3months. LOS for hospital was 62% of LOS in hospital at home schemes. Conclusion: Schemes similar in terms of acceptability and effectiveness. Increased LOS of home scheme must be interpreted with caution because of different organisational characteristics of the services. This is the first paper of 2. The second is a CMA (Coast et al)	Richards et al	UK (Bristol)	1998
Hospital at home	As above Cost minimisation analysis (CMA) These are not COPD patients	These are not COPD patients. CMA found a mean cost to the NHS and social services of £2516 per hospital at home patient and £3292 per hospital patient. Costs to the patient similar in the 2 arms. This was patient level costing and fairly rigorous and well reported, however it is not very generaliazable to different patient groups. COPD patients may be completely different.	Coast et al	UK (Bristol)	1998

Antibiotics

Specific Area	Study Type	Economic Analysis	Authors	Location	Year
Antibiotics	Pharmacoeconomic review	<p>This paper is a review of antibacterial use in acute exacerbations of chronic bronchitis. They review current evidence on the cost of chronic bronchitis and acute exacerbations, the cost effectiveness of antibacterials and the factors affecting the cost effectiveness.</p> <p>There are very few economic evaluations in this area, only one is a prospective economic evaluation based on a clinical trial. The rest are decisions analysis based modelling studies or retrospective database studies.</p> <p>Key findings:</p> <ul style="list-style-type: none"> • A key factor affecting the cost effective use of antibacterials is the definitive diagnosis of the condition, to avoid unnecessary prescribing. • Current evidence suggests, but does not prove that use of more effective, but costly first line antibacterials may be relatively cost effective and may minimise overall expenditure by reducing the high costs associated with treatment failure. • Chronic bronchitis and AECB have a significant and negative physical and psychological effect on health-related quality of life. <p>They conclude that due to the small number of economic evaluations and the nature of the designs, they cannot give a definitive statement recommending which specific antibacterial should be preferred on cost effectiveness grounds for the management of acute bacterial exacerbations of chronic bronchitis and they suggest future research. They cite the paper by McGuire et al, which suggests that by reducing AECB treatment failures and subsequent hospital admissions, substantial healthcare costs to the UK NHS could be saved.</p>	Morris S et al	Various (due to papers in review)	2002

			<p>They also cite the economic evaluation by Torrance et al (a prospective, randomised, non blind study) which estimates an incremental cost per QALY (quality adjusted life year) of ciprofloxacin vs usual antibacterial care as \$Can 18,600 from a societal perspective and \$Can27,000 from the third party payer perspective. They also conducted a subgroup analysis, which indicated that for patients with severe chronic bronchitis, ciprofloxacin may dominate usual antibacterial care.</p> <p>They cite Backhouse et al who constructed a model to compare the cost effectiveness of amoxicillin, amoxicillin/clavulanic acid, ciprofloxacin and cefaclor for the treatment of AECB in the general practice setting in the UK from the perspective of the UK NHS. The results indicate that amoxicillin/clavulnic acid as first and second line therapy was most cost effective, dominating amoxicillin. Even though this has a higher drug acquisition cost, its higher efficacy rate was found to reduce the cost of treatment failure.</p>			
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Paper reviewed following comments from GDG5.

The use of antibiotics for acute exacerbations Q109/110

Backhouse et al 1995, British Journal of Medical Economics

Economic evaluation of alternative antibiotic regimens in the management of acute exacerbations of chronic bronchitis

Model

- General practice setting.
- NHS perspective
- Direct medical costs of treatment. Impact of the disease and its treatment on patients and their families and other societal costs are excluded.
- Patient group – those with chronic bronchitis and other medical problems, moderate to severe airflow obstruction and chronic bronchial sepsis.

Testing hypothesis that because of differences in drug efficacy, it is not always the case that the least expensive drug is the cheapest form of therapy in terms of overall use of healthcare resources.

Outcome measure is the number of successfully treated patients following two courses of antibiotic therapy.

- Model compares amoxycillin, co-amoxiclav, ciprofloxacin and cefaclor.
- Baseline model – assumed that the same drug is given on 2 consecutive occasions.
- Sensitivity analysis used to investigate the effect of using co-amoxiclav and ciprofloxacin as second line therapies following amoxycillin failure.
- Side effects are not included as those that are likely to have an impact are believed to be extremely rare.
- The analysis focused on patients with chronic bronchitis and moderate to severe airflow obstruction and chronic bronchial sepsis.
- Combination of data from published trials and clinical opinion

- Initial model produced with information obtained from a review of published literature and from a group of clinical experts with a known interest in the treatment of this patient group.
- Draft model reviewed by a further group of GPs who were asked to comment on its appropriateness as a representation of clinical practice rather than an exhaustively detailed description of every eventuality.
- Emphasis has been placed on the events most likely to lead to significant resource use such as medical consultations, extra drugs and hospitalisation.
- Cost effectiveness was measured as the incremental cost per successfully treated patient.

Health Economics Evidence

Summary of Health Economics papers found after rerunning clinical searches and search of DARE, NHSEED and HTA 07/07/03.

6 papers were found that were included for review:

- | | |
|-------------------------|---------------------------------------|
| 1. Jones et al 2003. | Salmeterol |
| 2. Hogan et al 2002 | Formoterol |
| 3. Gallefoss et al 2002 | Patient education and self management |
| 4. Carlucci et al 2003 | NIV |
| 5. Gildea et al 2003 | alpha 1 antitrypsin deficiency |
| 6. Ramsey et al 2003 | Lung volume reduction surgery |

1. Jones et al 2003

Cost effectiveness of salmeterol in patients with COPD: an economic evaluation

Another short term study, using data from a clinical trial. (16 week)
Salmeterol vs placebo (both of these in addition to standard therapy)

Outcome measures: FEV1 and St George's Respiratory Questionnaire.

Results: £5.67 per symptom free night
Daily cost per health status improved patient (score decreased by 4 or more) £4.44

Difference in cost between treatment and placebo arms is £90.10 for the 16 weeks.

This is a short term study. The authors note the limitations of the study- short time horizon and presence of a clinical protocol and caution against the broad generalisability of the results.

2. Hogan et al 2002

US study.

Long acting B2 agonist vs anticholinergic

Inhaled formoterol dry powder 12 and 24 vs ipratropium bromide 40 pressurized MDI

Based on a previously published 12 week multicentre, double masked randomised parallel group, placebo controlled trial.

N=780

Outcomes: FEV1 and St Georges RQ.

Costs limited to costs of study drugs and rescue medications, because consumption of other health care resources was not assessed in the 12 week trial.

Short term study. Limited cost data – other resource use which is unknown could impact the results.

Results:

IPB gave a 0.137 improvement in FEV1 over placebo, but no difference in QoL as measured by St Georges Questionnaire. Difference in cost was \$37.41

Formoterol 12 gave 0.086 improvement in FEV1 and 5.5 points greater improvement in QOL than IPB. Cost difference was \$138.57

A change of 4 points on SGRQ is considered clinically important.

This is very limited and weak evidence, as this is a short term study, with limitations in its methods.

3. Gallesfoss et al 2002

Patient education and self management on patients with COPD, effect on medication utilization, GP visits, patient satisfaction.

N=62 with mild –moderate COPD at outpatient clinic were randomised.

Control group NOK 19,900

Intervention group NOK 10,600

However, paper talks about the cost of asthma education and hospital care for asthma and includes it in the cost. This is a COPD population.

Exclude study on these grounds

4. Carlucci et al 2003

This is an observational study on 1 unit, looking at 208 episodes of acute respiratory failure due to COPD treated by NIV between 1992-1996.

Looked at rate of NIV success, severity of disease and costs. This is not an economic evaluation

5. Gildea et al 2003

Markov decision model to assess the CE of augmentation therapy for severe alpha 1 antitrypsin deficiency.

Compared:

- ☐ No Aug
- ☐ Aug for life
- ☐ Aug until FEV1 below 35% predicted

Hypothetical cohort of 30,000 46 year old patients, 50% male with FEV1 49% predicted was followed over time using Monte Carlo simulation across 5 health states:

- ☐ FEV1 50-79% predicted
- ☐ FEV1 35-49% predicted
- ☐ FEV1 below 35% predicted
- ☐ Post lung transplantation status
- ☐ Dead

Results: Treatment for life yielded 7.19 QALYs
Cost \$895,243

Treating until FEV1 is below 35% predicted yielded 6.64 QALYs Cost \$511,930

No aug yielded 4.62
Cost \$92,091

ICER \$207,841 per QALY until FEV1 is below 35% predicted

ICER \$312,511 per QALY for Aug for life strategy

All sensitivity analyses produced cost per QALY estimates of over \$100,000

The cost of Aug needs to be reduced from \$54,765 to \$4,900 for the Aug for life strategy to be considered cost effective.

6. Ramsey et al 2003

Cost effectiveness of lung volume reduction surgery for patients with severe emphysema.

Following pulmonary rehab, 1218 patients at 17 medical centres randomly assigned to LVRS or continued medical treatment.

This economic evaluation was run alongside the NETT trial.

Outcome: Cost per QALY gained of LVRS+medical therapy vs medical therapy alone.

Societal perspective, used quality of well being to generate utilities.

Medicare and Medicaid records were used for details of resource use.

At 3 years – Cost per QALY gained = \$190,000

At 10 years – Cost per QALY gained = \$53,000

There is substantial uncertainty in the cost effectiveness estimates, especially the longer term cost effectiveness. In addition, many assumptions had to be made to model the cost effectiveness beyond 3 years.

Abbreviations

QoL	quality of life
CEA	cost effectiveness analysis
CMA	cost minimisation analysis
CUA	cost utility analysis
CDRQ	chronic disease respiratory questionnaire
SGRQ	St George's Respiratory Questionnaire
SF-36	Short Form 36
CE	cost effective
ICER	incremental cost effective ratio
EEACT	economic evaluation alongside a clinical trial
TC	total cost
COI	cost of illness
QALY	quality adjusted life year
HRQL	health related quality of life
AECB	acute exacerbation of chronic bronchitis
COAD	chronic obstructive airways disease
LVRS	lung volume reduction surgery
ICU	intensive care unit
QWB	quality of well being questionnaire
F/U	follow up
LOS	length of stay
RCT	randomised controlled trial
DGH	district general hospital
PR	pulmonary rehabilitation
BA	Beta agonist
CS	corticosteroid