National Institute for Health and Clinical Excellence

Continuous positive airways pressure (CPAP) for the treatment of obstructive sleep apnoea/hypopnoea syndrome (OSAHS)

Response to comments received on the draft scope

Comment 1: the draft remit

Section	Consultees	Comments	Response
Remit size	British Sleep Society	Nasal continuous positive airway pressure (CPAP) is the mainstay of treatment used in patients with symptomatic Obstructive Sleep Apnoea (OSA). There is not uniform or adequate provision for this treatment across the United Kingdom. Other treatments are used less often and a specific evaluation of the cost effectiveness of CPAP as intervention for treatment of symptomatic OSA is appropriate.	Comment noted
	Association for Respiratory Technology & Physiology	Nasal Continuous Positive Airway Pressure is the most common treatment used for symptomatic OSA. This is the treatment that needs assessing to ensure uniform provision across the country. Therefore a focused evaluation of the cost effectiveness of CPAP for symptomatic OSA is entirely appropriate.	Comment noted
	British Thoracic Society	Nasal continuous positive airway pressure is by far the most common treatment used for symptomatic OSA. This is the treatment that needs assessing to ensure uniform provision across the country. Other treatments are much less used, due to higher expense and lack of efficacy, compared to CPAP. Therefore a focused evaluation of the cost effectiveness of CPAP for symptomatic OSA is entirely appropriate.	Comment noted
	Fisher & Paykel Healthcare Ltd	Evaluation of CPAP cost effectiveness for the treatment of OSAHS provides a suitably focussed area for investigation.	Comment noted
	Royal College of Physicians	Nasal Continuous Positive Airway Pressure (CPAP) is the treatment of choice for moderate and severe obstructive sleep apnoeas (OSA). It is increasingly widely used but its cost effectiveness is still disputed. A NICE evaluation is timely.	Comment noted

Section	Consultees	Comments	Response
	ResMed (UK) Ltd	Continuous Positive Airway Pressure (CPAP) is recognised as the appropriate treatment for OSAHS. The level of provision of therapy is generally much lower than in other Western countries; and provision across the UK varies considerable. Therefore a Health Technology Appraisal is appropriate. Untreated OSAHS is linked to other conditions such as hypertention, heart failure, stroke and diabetes thus underlining the huge importance of treatment. The review needs to also cover paediatric patients requiring CPAP/APAP - a rapidly growing group	The relevant trials did not include children, resulting in lack of evidence in this patient group. Therefore it was decided to restrict the population to adults.
	Sleep Apnoea Trust	We should explain that Sleep Apnoea Trust (SAT) does not provide expert medical opinion - it is a charitable patient support group for OSA sufferers, run mainly by those who have been successfully treated for the condition by nasal CPAP. Our knowledge of the subject is gained from those who have used our services (telephone helplines,and conferences etc.) over the past 14 years. We believe that the remit covers the correct area. Nasal CPAP is the only effective treatment for OSA, although dental devices may be helpful for short period use. Surgery is to be avoided - we know of many patients who have been damaged by surgery on the soft palate, and we are not aware of any effective drug treatments. CPAP is extremely cost-effective, but surprisingly many local health authorities fail to provide a service for diagnosis and treatment of sleep apnoea. "Postcode prescribing" is widespread.	The scope does not include surgery as a comparator.
	Section of Sleep Medicine, Royal Society of Medicine.	It is correct to focus on the clinical efficacy and cost effectiveness of nasal continuous positive airway pressure with a view to ensuring equality of provision across the country. The value of alternative treatments is not well established.	Comment noted

Section	Consultees	Comments	Response
	Respironics UK Ltd	Nasal Continuous Positive Airway Pressure is the most common treatment used for OSA. Other treatments are far less commonly used and are accepted to be less efficacious with an associated higher cost than CPAP. A technology appraisal of the clinical and cost-effectiveness is appropriate.	Comment noted
Licensing Issues (only for manufacturers to complete)	Vital-Signs/Breas	No Licences pending	Comment noted
	Fisher & Paykel Healthcare Ltd	There are no specific timescales for licensing and no pending licences in other indications. All of the products and technologies in question are CE marked and may be legally sold in the Europe (United Kingdom inclusive). All declaration of conformities are available.	Comment noted
	Respironics UK Ltd	Respironics CPAP's are licenced for the treatment of adult OSA. Within Respironics there are no other pending licences for other indications.	Comment noted
Wording	Royal College of Physicians of Edinburgh	As the major issue is postcode prescribing rather than proof of efficacy - which has been established in other reviews by SIGN, Cochrane and others - this should perhaps be mentioned in the remit. The word hypopnoea should be spelt correctly!	Comment noted
Timing Issues	British Sleep Society	There is a lack of guidance for PCT s who are not funding this treatment and it urgent to provide clear guidance as the majority of patients remain undiagnosed and untreated. In some areas patients are being told to buy their own CPAP	Comment noted
	Vital-Signs/Breas	The appraisal is urgent for the safety of the potential patient population	Comment noted

Section	Consultees	Comments	Response
	Association for Respiratory Technology & Physiology	Because of historical funding issues many areas have long waiting lists for this treatment (national average 17.5 weeks - maximum reported 300 weeks). NHS Target of 18 weeks referral to treatment will not be achievable without funding for CPAP (being the only practical treatment for the majority of sufferers).	Comment noted
	British Thoracic Society	Many PCTs are not funding this treatment under cover of 'lack of central guidance'. It is therefore urgent to provide clear guidance as the vast majority of patients remain undiagnosed and untreated for lack of a NICE technology appraisal.	Comment noted
	Fisher & Paykel Healthcare Ltd	Very urgent - diagnosis and effective treatment of OSAHS is currently under-resourced in many areas of the country. Many PCT's do not fund a sleep service at all. Furthermore, new & emerging clinical evidence has reported the strong association between untreated OSA and cardiovascular disease, and the cost burden these untreated patients are imposing on National Healthcare.	Comment noted
	Royal College of Physicians	There are wide local variations in funding and prioritisation of CPAP in the NHS. An urgent review is required to harmonise these differences.	Comment noted
	ResMed (UK) Ltd	In many parts of the country, patients are being denied appropriate treatment for their OSAHS due to inadequate funding provision; PCTs "justify" non-funding due to the lack of central guidance. Therefore, an urgent appraisal is required.	Comment noted
	Royal College of Physicians of Edinburgh	Urgent to ensure this treatment is equitably available in all postcodes. It is not at present to the detriment of many patients.	Comment noted
	Section of Sleep Medicine, Royal Society of Medicine.	Many patients are not being treated. Most are in the working age group and may not be as productive as they might otherwise be. Some of these sleepy patients are driving buses or heavy goods vehicles and present a road safety risk. Early clear guidance from NICE would help address these serious issues and save the lives of affected patients and others.	Comment noted

Section	Consultees	Comments	Response
	Sleep Apnoea Trust	The proposed appraisal is urgent. It is clear that only a small proportion of OSA sufferers have been identified and treated. The remainder are trying to carry on with their lives, in ignorance of the danger which they pose to themselves and others. As the disease progresses they are liable to fall asleep uncontrollably whilst driving or operating machinery.They are unable to work effectively, due to sleep deprivation, and their personal relationships are under pressure since their bed partners often become sleep deprived due to snoring and disturbance from the patient There is also a substantial economic cost arising from loss of productivity and the cost of major traffic accidents.	Comment noted
Additional comments on the draft remit	British Sleep Society	CPAP is under-provided or not provided at all in some areas of United Kingdom and a technology appraisal is the most relevant way to address this problem. A wider remit involving guidelines is not necessary at present and guidelines from the Scottish Intercollegiate Guidelines Network (SIGN) are available.	Comment noted
	Section of Sleep Medicine, Royal Society of Medicine	There are currently adequate guidelines from the Scottish Intercollegiate Network so an appraisal of the technology seems appropriate. Currently, the major issue is the effect of OSA on symptoms which can include others you have not mentioned. What do you mean when you refer to 'severity of OSAHS' as an outcome measure? It's unequivocal that CPAP improves the AHI but is this really what matters? It might matter but what we are most interested in is making the patient feel better and perform better.	Comment noted
	Association for Respiratory Technology & Physiology	The 18 week target project is focussing on the diagnosis and provision of CPAP therapy. A wider remit involving guidelines is not necessary at present. There is a reasonable set of guidelines from the Scottish Intercollegiate Guidelines Network, although these are less well read in England.	Comment noted
	British Thoracic Society	The major issue is CPAP under-provision, and therefore a technology appraisal is the most relevant way to address this problem. A wider remit involving guidelines is not necessary at present. There is a reasonable set of guidelines from the Scottish Intercollegiate Guidelines Network, although these are less well read in England.	Comment noted

Section	Consultees	Comments	Response
	Fisher & Paykel Healthcare Ltd	Underprovison of CPAP dependent on geography is the current issue so a technology appraisal will help address this inequality of treatment provision.	Comment noted
	Respironics UK Ltd	A significant number of PCT's are currently not funding this treatment due to a lack of clear direction. Based on this fact and the prevelance of undiagnosed OSA , clear direction is urgent.	Comment noted

Comment 2: the draft scope

Section	Consultees	Comments	Action
Background information	British Sleep Society	Causes and consequences of OSA not covered. Lifestyle modification is not a treatment as shown by Cochrane review. There is robust evidence linking OSA and road traffic accidents	The scope for an appraisal does not contain this level of detail.
	Association for Respiratory Technology & Physiology	para 1 - 'effort' not 'effect' para 4 - most of this text is lifted from the SIGN guidelines however this paragraph has been cut short and ended with '. . .day to day activities' whereas it should end ' . . . activities where reduced alertness is dangerous, such as driving, leading to an increased risk of road traffic accidents.' This is a very relevant aspect that needs to be included into considerations due to the secondary impact on the health economy. A further effect not reflected in the draft scope is the problems some sufferers have with maintaining employment.	Text in scope amended accordingly.
	British Thoracic Society	This is a simple description of the medical problem, although it leaves out some important considerations about cause and consequences of OSA. Obesity is only one of many causes of OSA, for example there are genetic influences, aspects or cranio-facial shape, and pharyngeal pathology (such as enlarged tonsils), that contriibute. Lifestyle modification is alluded to as a treatment, but a recent Cochrane review found no evidence to support this assertion. Smoking is also unlikely to be a significant risk factor. Regardung consequences, there is now considerable evidence linking OSA and road traffic accidents, as well as calculations as to the considerable cost to society that these accidents bring.	Text in scope amended accordingly.

Section	Consultees	Comments	Action
	Fisher & Paykel Healthcare Ltd	"Hypopnoea" is spelt incorrectly. Line 6, 1st paragraph should read "inspiratory effort" (not 'effect'). 4th Paragraph 1st line, missing grammar after 'daily…' It should also state that AHI does not consider periods of Repeated Flow limitation, (Upper Airway Resistance) that does not meet the criteria for Hypopnea i.e no 3% or more desaturation and no 50% or more reduction in baseline flow. This phenomenon can result in repeated awakenings, fragmented sleep and contribute to the adverse cardiovascular consequences associated with OSA. The background info in general covers the basics of the condition, although gives too much emphasis to the lifestyle effects while ignoring the dangers associated with sufferers operating machinery , driving vehicles etc while untreated. It also needs to emphasize more of the very severe health conditions which have been associated with untreated OSA such as diabetes, hypertension, cardiovascular disease, heart attack and stroke. Alternative therapies such as MADs and surgery have only been shown to be successful in limited populations such as very mild OSA. This limitation should be outlined.	Text in scope amended accordingly. The scope does not contain this level of detail.
	Royal College of Physicians	This is a concise view of sleep apnoeas but it should emphasise the lack of evidence of effectiveness of interventions other than CPAP. Lifestyle changes including weight loss have not been shown to be effective in controlled trials. No drugs are effective and mandibular advancement devices are poorly tolerated. The medical consequences such as probable increased risk of stroke, myocardial infarction and hypertension and social effects including road traffic accidents should be emphasised.	Text in the scope has been amended accordingly.
	ResMed (UK) Ltd	The only sort of national guidelines for OSAHS are the Scottish Intercollegiate Guidelines Network (SIGN) - there are no national guidelines for England or Wales.	

Section	Consultees	Comments	Action
	Royal College of Physicians of Edinburgh	The evidence OSAHS causes, and CPAP reverses, hypertension and driving accidents is now robust; the former from animal models, epidemiology and treatment studies and the latter from simulator and case-control studies. The cost benefits of CPAP therapy in terms of road accidents have been estimated(see Douglas & George Thorax 2002;57:93. Obesity is overplayed - only 50% are obese. Facial structure is important too - studies include Mathur et al 1995 and Riha et al 2005. There is also now evidence that CPAP can improve diabetic control in patients with both OSAHS and diabetes - a fairly common association in this obese group [Harsch. AmJRespCCMed 2004;169:156-62; Babu. Arch Int Med 2005;165:447-52].	Comment noted Text in scope amended accordingly.
	Section of Sleep Medicine, Royal Society of Medicine	OSAHS is a highly heritable condition. Many patients with OSAHS are not obese and have no major lifestyle issues. In established sleep centres only about 50% of patients are obese (it seems that, initially, only obese patients are referred). Smoking cessation, while generally laudable, is probably not something to focus on in the context of sleep apnoea. And the evidence for lifestyle modification as an efficacious treatment is not strong. The devastating and costly consequences of untreated OSAHS on car crashes deserve some emphasis.	Text in scope amended accordingly.
	Sleep Apnoea Trust	In the main the information is accurate. Many patients in the first instance are prescribed only lifestyle management by their general medical practitioners, but this seems to be totally ineffective for the treatment of sleep apnoea. Many patients are prescribed sedative drugs initially through a misdiagnosis of their condition, and this makes matters worse.	Noted and scope amended.
	Respironics UK Ltd	The information describes the basic pathophysiology. However, other information regarding other non-obesity related causes is lacking. With regard to consequences, there is a data-gap pertaining to increased healthcare untilisation costs, workforce productivity and road traffic accidents related to untreated OSA.	Text in scope amended accordingly.

Section	Consultees	Comments	Action
The technology/ intervention			
	Association for Respiratory Technology & Physiology	There needs to be some emphasis on the monitoring required to get someone successfully on treatment.	Text in scope ameneded accordingly.
	Fisher & Paykel Healthcare Ltd	It is suggested that there be mention in the technology of Heated Humidification. Humidification has become an integral component to CPAP therapy with extensive clinical support to show significant diminuition of upper airway discomfort when issued in combination. It would be wise to consider positive pressure therapy holistically to include flow generator, humidifier, tubing and mask.	It was agreed that the term CPAP should include any CPAP (fixed) or autotitrating (APAP) regardless of make or whether additional features (such as humidifiers) are used. The scope has been amended accordingly.
	ResMed (UK) Ltd	Continuous Positive Airway Pressure (CPAP) covers two forms of treatment: (1) Constant pressure therapy - the level of pressure being set by the physician according to patient need and (2) automated pressure therapy (APAP) where the flow generator automatically adjusts the pressure on a breath-by-breath and night-by-night basis. This automated technology, while marginally more expensive, is more comfortable for the patient and more cost-effective because it requires less intervention from clinical staff - it enables the patient to be more effectively managed in the home environment. The review therefore must include APAP technology.	It was agreed that the term CPAP should include any CPAP (fixed) or autotitrating (APAP) regardless of make or whether additional features (such as humidifiers) are used. The scope has been amended accordingly..

Section	Consultees	Comments	Action
	Sleep Apnoea Trust	The description is accurate but is perhaps a liitle out of date. Rhinitis can be alleviated by the addition of a heated humidifier, at small additional cost. Considerable progress has been made in the design of CPAP machines and masks in recent years - machines are now very quiet, and masks are designed so that they do not need to be held in place by tight headgear. Many designs of mask ensure that any pressure is taken on the forehead rather than the nasal bridge.	Comment noted

Section	Consultees	Comments	Action
	Respironics UK Ltd	The description is simple and gives a basic desription of the minimal equipment required to provide CPAP. CPAP is the primary intervention for OSA patients with lifestyle modification following as an adjunct. We are unaware at this stage of any scientific evidence regarding lifestyle modification as an effective treatment for OSA.	It was agreed that lifestyle advice should not be a standard comparator because there is strong evidence (from a Cochrane review) that lifestyle advice is not effective. The most appropriate standard comparators were believed to be "No treatment/placebo". It was pointed out that most of the available RCT evidence used "No treatment/placebo" as a comparator when evaluating the effectiveness of CPAP. However it was agreed that studies which compared CPAP to lifestyle advice should still be included in the appraisal, as it can be included under the term "No treatment/placebo". The scope has been amended accordingly.
Population	British Sleep Society	No. The group most affected is the middle-aged population in employment and there are economic and safety consequences from not performing properly at work. There is no particular population subset. Overweight is an increasing risk factor but in most clinics about one third to half the patients are not obese.	Comment noted

Section	Consultees	Comments	Action
	Vital-Signs/Breas	Possibly – Long Distance Vehicle Drivers for Reasons of safety	Subgroups are included under 'other considerations'
	Association for Respiratory Technology & Physiology	The scope seems to be limited to Adults although the text does acknowledge a significant paediatric incidence.	The relevant trials did not include children, resulting in lack of evidence in this patient group. Therefore it was decided to restrict the population to adults.
	British Thoracic Society	The population at risk of OSA is not adequately highlighted. The group most affected is a middle-aged population who are still working, with economic consequences from not performing properly at work, or losing their jobs entirely. There is no particular population subset. Although overweight is an increasing risk factor, in most clinics about half the patients are not obese.	The scope specifies that Evidence on clinical and cost-effectiveness should be presented for different subgroups of patients Text of scope has been amended.

Section	Consultees	Comments	Action
	Fisher & Paykel Healthcare Ltd	Population definition is very general. Maybe an AHI needs to be stipulated such as patients suffering OSAHS	A discussion of subgroups (mild, moderate and severe OSAHS) revealed that it is inappropriate to restrict the population to severity grades at this stage of the appraisal. It was also agreed that a case of OSAHS should be confirmed by a clinical expert in the field (i.e. the patient's diagnosis has been validated via use of accepted instruments such as the AHI index and/or Epsworth sleepiness score.

Section	Consultees	Comments	Action
	Royal College of Nursing, Respiratory Nurses Forum	How do we define OSA, eg some patients may have significant symptoms but score low on the AHI so we should use the Epworth score in defining the patient population as well as the AHI.	A discussion of subgroups (mild, moderate and severe OSAHS) revealed that it is inappropriate to restrict the population to severity grades at this stage of the appraisal. It was also agreed that a case of OSAHS should be confirmed by a clinical expert in the field (i.e. the patient's diagnosis has been validated via use of accepted instruments such as the AHI index and/or Epsworth sleepiness score.
	Royal College of Physicians	OSA becomes more common in middle age. It is probably most cost effective in this age group.	The scope specifies that Evidence on clinical and cost-effectiveness should be presented for different subgroups of patients
	ResMed (UK) Ltd	If anything, the prevalence stated in the brief is under-stated. Prevalence is conservately estimated at 4% of adult males and 2% of adult females (some more recent studies quote higher prevalence rates) giving a population group affected of approx 1.2MM in the UK.	Text in scope amended accordingly

Section	Consultees	Comments	Action
	Section of Sleep Medicine, Royal Society of Medicine	It is not clear that the major burden of this treatable disease falls on the economically active which is important for a proper appraisal of the cost effectiveness of treatment. The importance of obesity is over emphasised.	Text in scope amended accordingly
	Sleep Apnoea Trust	It should be borne in mind that - by the time of diagnosis- often they have been suffering from untreated OSA for more than 10 years. It is a condition which attacks people when they are at the top of their careers - with disastrous consequences. We are aware of many executives who lost their positions when their symptoms were misdiagnosed as "executive stress" or "burnout". Perhaps the most potentially dangerous group of untreated sufferers are drivers of heavy goods vehicles or public service vehicles - as outlined in a recent television documentary ("Killer in the Cab" Real Story BBC1 21 November 2005).	Comment noted

Section	Consultees	Comments	Action
Comparators	British Sleep Society	CPAP is the standard treatment in other countries. Surgery, dental devices, drugs, and lifestyle modification have all been tried. Cochrane reviews highlight the limited effect of all but dental devices, which themselves are only partially effective. lifestyle changes are important for health improvement and are an adjunct to CPAP therapy.	It was agreed that lifestyle advice should not be a standard comparator because there is strong evidence (from a Cochrane review) that lifestyle advice is not effective. The most appropriate standard comparators were believed to be "No treatment/placebo". It was pointed out that most of the available RCT evidence used "No treatment/placebo" as a comparator when evaluating the effectiveness of CPAP. However it was agreed that studies which compared CPAP to lifestyle advice should still be included in the appraisal, as it can be included under the term "No treatment/placebo". Text in scope amended accordingly.
	Sleep Apnoea Trust	We are not qualified to answer this question in detail, but CPAP is the only treatment which has been used successfully by our members.	Comment noted

Section	Consultees	Comments	Action
	Association for Respiratory Technology & Physiology/ British Thoracic Society	Where available, CPAP is the standard treatment across the world. Other treatments, such as surgery, dental devices, drugs, and lifestyle modification have all been tried. Recent Cochrane reviews have highlighted the very limited effect of all but dental devices, which themselves are only partially effective. Where overweight is a contributing factor, then lifestyle changes may be an adjunct to CPAP therapy, and important, of course, for many other health reasons.	It was agreed that lifestyle advice should not be a standard comparator because there is strong evidence (from a Cochrane review) that lifestyle advice is not effective. The most appropriate standard comparators were believed to be "No treatment/placebo". It was pointed out that most of the available RCT evidence used "No treatment/placebo" as a comparator when evaluating the effectiveness of CPAP. However it was agreed that studies which compared CPAP to lifestyle advice should still be included in the appraisal, as it can be included under the term "No treatment/placebo". Text in scope amended accordingly.
	Fisher & Paykel Healthcare Ltd	Yes, CPAP is the recognised treatment for OSA where available.	Comment noted

Section	Consultees	Comments	Action
	Royal College of Nursing, Respiratory Nurses Forum	Outcomes should include return to work particularly in those who drive a lot for jobs or HGV and have had to stop till established on treatment as this has large social economic issues.	The methods for technology appraisals stipulate that costs will be considered from a NHS and Personal Social Services Perspective but not a societal perspective.
	Royal College of Physicians	CPAP is the standard treatment for moderate and severe OSA. Comparison with mandibular advancement devices which are also widely recommended, may be of value.	Comment noted

Section	Consultees	Comments	Action
	ResMed (UK) Ltd	CPAP/APAP is the common therapy used for OSAHS across the world. It is also the accepted therapy amongst professionals in the UK however, because of lack of funding and lack of awareness, most patients with the condition are either being inappropriately treated or not treated at all. "Lifestyle advice" may be a factor in treatment but it is not comparable with effective CPAP/APAP treatment.	It was agreed that lifestyle advice should not be a standard comparator because there is strong evidence (from a Cochrane review) that lifestyle advice is not effective. The most appropriate standard comparators were believed to be “No treatment/placebo”. It was pointed out that most of the available RCT evidence used “No treatment/placebo” as a comparator when evaluating the effectiveness of CPAP. However it was agreed that studies which compared CPAP to lifestyle advice should still be included in the appraisal, as it can be included under the term “No treatment/placebo”. Text in scope amended accordingly.

Section	Consultees	Comments	Action
	Section of Sleep Medicine, Royal Society of Medicine	Treatments other than CPAP are not, in general, very efficacious. Mandibular advancement splints can work but long term use by patients is the exception. Surgical treatment, in general, should be avoided. Lifestyle advice is only appropriate for those that have a lifestyle problem. Not all do.	It was agreed that lifestyle advice should not be a standard comparator because there is strong evidence (from a Cochrane review) that lifestyle advice is not effective. The most appropriate standard comparators were believed to be “No treatment/placebo”. It was pointed out that most of the available RCT evidence used “No treatment/placebo” as a comparator when evaluating the effectiveness of CPAP. However it was agreed that studies which compared CPAP to lifestyle advice should still be included in the appraisal, as it can be included under the term “No treatment/placebo”. Scope amended accodirngly.

Section	Consultees	Comments	Action
	Sleep Apnoea Trust	We comment here on the question put by you that CPAP should be restricted to those with moderate ior severe OSA since this is what tends to happen in practice.We know that often the provision of CPAP is restricted by Sleep Units due to lack of funding. Often the treatment of OSA is regarded as a low priority by local health authorities & PCTs We believe that it would be wrong to restrict CPAP to those whose AHI exceeds an arbritary figure. Even those with mild sleep apnoea can benefit from CPAP. This therapy has to be used every night for life and it can be arduous (particularly in the early months). If an OSA patient is prepared to use CPAP regularly because of the improvements to his qualty of life, it should be available to him.	A discussion of subgroups (mild, moderate and severe OSAHS) revealed that it is inappropriate to restrict the population to severity grades at this stage of the appraisal. It was also agreed that a case of OSAHS should be confirmed by a clinical expert in the field (i.e. the patient's diagnosis has been validated via use of accepted instruments such as the AHI index and/or Epsworth sleepiness score.
	Respironics UK Ltd	This is a basic description of the population. Although the signs and symptoms may be common across population groups, there are groups whose employment and social consequences of untreated OSA may have a significant impact on the patient or society, e.g. untreated OSA in subjects involved in the vigilance-critical industries.	Comment noted
Outcomes	British Sleep Society	Driving is not considered. There are both simulator and real road studies. Other outcomes including diabetes, heart and strokes are less well researched.	Comment noted
	Section of Sleep Medicine, Royal Society of Medicine	The effect on driving, vigilance as well as falling asleep at the wheel, should be included. What is meant by 'severity of OSAHS'? Is this AHI? Or is sleepiness the measure of severity?	Comment noted

Section	Consultees	Comments	Action
	Association for Respiratory Technology & Physiology	As described above - consider secondary implications to health economy - RTA's, employment, misdiagnosed depression, etc	All health outcomes are included in the appraisal. Wider societal outcomes are outside the remit of this appraisal.
	British Thoracic Society	These are partly described, although there is no reference to driving. There are both simulator and real road studies to consider, as well a those describe in the 'other considerations' box below. Other outcomes are much less well researched, such as insulin resistance, cerebro- and cardio-vascular disease. However there are a few RCTs on cardiac function following CPAP showing improvements.	Comment noted
	Fisher & Paykel Healthcare Ltd	All well covered, however in addition to incidence of associated disease, the additional costs to the government which might be incurred from untreated OSA such as road accidents, working accidents should also be considered.	Scope amended accordinly.
	Royal College of Physicians	The proposed outcome measures are all appropriate but indices of relief of cardiovascular complications could be included.	All health effects are included.
	Royal College of Physicians of Edinburgh	Need to include driving, blood pressure benefits. Not clear what severity of OSAHS means as an outcome - rather ill defined.	Comment noted
	Respironics UK Ltd	These are partly described. Other outcomes relate to improvments in cardiac and cerebral function. Other benefits are the socio-economic factors related to reduced road traffic accidents, work absenteism.	The evaluation of wider societal outcomes are outside the remit of this appraisal.

Section	Consultees	Comments	Action
Economic analysis	British Sleep Society	Treatment of OSA is likely to be lifelong. Most costs occur in the first months of diagnosis and treatment but overall cost needs consideration in the longer term. The reduction in road traffic accidents must be an important part of the economic analysis.	The economic analysis will include the costs of set up, subsequent assessment of appropriate airflow calibration and patient treatment compliance.
	Association for Respiratory Technology & Physiology	What is an appropriate time span?? Age of machine (5-7 yrs not including consumables)? Lifetime of patient?	The time horizon of the economic evaluation should be an appropriate time period over which the costs and benefits of the technology can be expected to be differ from the comparator.
	British Thoracic Society	Treatment of OSA is likely to be very long-term if not lifelong. Therefore, although the majority of costs occur in the first few months of diagnosis and treatment, they should be considered over a much longer time period. The reduction in road traffic accidents due to improved vigilance is an important part of the economic assessment.	The economic analysis will include the costs of set up, subsequent assessment of appropriate airflow calibration and patient treatment compliance.

Section	Consultees	Comments	Action
	Fisher & Paykel Healthcare Ltd	CPAP as a treatment for OSA is a long term therapy, it would be appropriate to evaluate economic evaluation over more than a year.	The time horizon of the economic evaluation should be an appropriate time period over which the costs and benefits of the technology can be expected to be differ from the comparator.
	Royal College of Physicians	CPAP is usually a life long treatment with continuing effectiveness but most of the cost incurred is in the first year of treatment. Economic analysis should include the benefits of reduction in road traffic accidents.	The evaluation of wider societal costs are outside the remit of this appraisal, but all health effects are included as outcomes.
	ResMed (UK) Ltd	This definition seem reasonable and should include the cost of NOT appropriately treating with CPAP/APAP - ie drugs, etc.	Comment noted
	Royal College of Physicians of Edinburgh	As CPAP units often last 10+ years this needs to be factored in to the cost/benefit analysis. Unlike evaluation of drugs the costs are front loaded. Driving and cardiovascular benefits must be included.	The time horizon of the economic evaluation should be an appropriate time period over which the costs and benefits of the technology can be expected to be differ from the comparator.
	Section of Sleep Medicine, Royal Society of Medicine	The benefits of treatment occur over a long period after an initial expenditure, the ongoing costs being less. Road crashes, especially fatal ones, as well as causing appalling human misery are extremely expensive and the economic analysis should include this.	The evaluation of wider societal costs are outside the remit of this appraisal, but all health effects are included as outcomes.

Section	Consultees	Comments	Action
	Sleep Apnoea Trust	Others will provide you with the exact cost of providing CPAP therapy for OSA patients. It must be self evident that the cost is tiny when compared with the economic costs to the NHS and others of dealing with major traffic accidents and non-performance at work. This economic cost is in additon to the personal cost of failed marriages and relationships, and the breakup of families arising from untreated OSA.	The evaluation of wider societal costs are outside the remit of this appraisal, but all health effects are included as outcomes..
	Respironics UK Ltd	CPAP is a cost effective treatment for OSA and is usully a life-long treatment. The majority of the cost is in the initial diagnosis and set-up. Therefore, this needs to be absorbed over the term of the treatment.	The economic analysis will include the costs of set up, subsequent assessment of appropriate airflow calibration and patient treatment compliance.
Other considerations	Cephalon UK Ltd	Those patients who, despite optimal CPAP compliance, experience residual symptoms of excessive sleepiness.	Comment noted.
	British Sleep Society	OSA and impaired driving performance must be considered. The cost of accident and impact of drivers losing driving jobs as a result of DVLA legislation. Professional drivers lose income and jobs. Deaths have resulted from drivers waiting for investigation and treatment and continued to drive as seen on BBC documentary.	The evaluation of wider societal costs are outside the remit of this appraisal, but all health effects are included as outcomes.
	Association for Respiratory Technology & Physiology	The issue of daytime sleepiness from uncontrolled OSA and vehicle driving is a vital consideration.	All health effects are included as outcomes.

Section	Consultees	Comments	Action
	British Thoracic Society	The omission of OSA and impaired driving is the most significant one. Not only is there the accident hazard to be considered, but also the economic impact of drivers being stopped from driving due to their sleepiness, a DVLA requirement. This is a particular economic hardship for professional drivers who either lose income and/or their jobs. Long waiting lists for investigation and treatment encourage drivers to ignore their physician's advice to stop driving, with catastrophic consequences: as demonstrated by the case of Mr Paul Couldridge who, while waiting for investigation and treatment, killed two other car occupants due to falling asleep at the wheel, and received an 8 year jail sentence as a consequence (http://news.bbc.co.uk/2/hi/uk_news/england/1768241.stm and http://news.bbc.co.uk/1/hi/programmes/real_story/4446970.stm). There are many other examples that BTS members know of.	The evaluation of wider societal costs are outside the remit of this appraisal but all health effects are included as outcomes
	Royal College of Physicians	CPAP has been shown to reduce the risk of road traffic accidents and improve driving ability on driving simulators. It is common in HGV drivers and an assessment of the reduction of road traffic accidents should be included.	The evaluation of wider societal costs are outside the remit of this appraisal but all health effects are included as outcomes
	ResMed (UK) Ltd	The review should also include a review the economic consequences on both individuals and society of untreated OSAHS - for example, motor vehicle and other occupational accidents due to OSAHS/sleep. Truck drivers and train drivers probably have a significantly higher prevalence than the national average. Screening for this condition is a relatively simple process and could be done easily by PCGs.	The evaluation of wider societal costs are outside the remit of this appraisal but all health effects are included as outcomes
	Section of Sleep Medicine, Royal Society of Medicine	The relevance of OSA to surgery and anaesthesia should be considered.	Surgery is not considered a comparator in this appraisal

Section	Consultees	Comments	Action
	Sleep Apnoea Trust	The provision of treatment for OSA in England & Wales is insufficient and very patchy in its operation. Many PCTs fail to understand OSA and give it a very low priority - with the result that in some cities and substantial towns there is no service whatever. Rural areas tend to be served even more poorly. We are approached by many people in the affected areas seeking help, and often there is no solution to their problems, since PCTs will neither fund a service in their own area, nor pay for patients to be treated elsewhere. When we make representations to the local health authorities we are frequently told that in the absence of a technology appraisal from NICE there is no hope of establishing or maintaining a service. Treatment services for OSA need to be expanded considerably, and it is essential that a favourable outcome should emerge from the current consultation.	Comment noted.
	Respironics UK Ltd	The issue of the socio-economic impact of untreated OSA in the transport industry would be desirable. The are delays in the referral, diagnosis and provision of equipment to treat OSA. In some cases, this has led to fatalities on the road.	The evaluation of wider societal costs are outside the remit of this appraisal but all health effects are included as outcomes.
Additional comments on the draft scope.	British Sleep Society	Surveys by BSS have demonstrated enormous variation in the provision of diagnostic facilities and CPAP for patients with OSA. It is because of this postcode prescribing that a clear analysis of the benefits of CPAP for OSA and clear directive on its use, are extremely important to bring about rational and uniform services across the UK.	Comment noted

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	Association for Respiratory Technology & Physiology	Correct provision of the technology requires proper diagnostics, monitoring and follow up support. The provsion of CPAP nationally is technologically very advanced worldwide, but the practical delivery in the UK is currently a "postcode lottery" which is unjust and illogical in a modern health economy. The independent sector is poised to revolutionise the CPAP market in the UK providing that funding is made available nationally.	Comment noted.
	British Thoracic Society	Recent surveys by the BTS and BSS have demonstrated enormous variation in the provision of diagnostic facilities and CPAP for patients with OSA. PCTs usually have little understanding of OSA and its treatment and therefore they are unable to prioritise appropriately. It is because of this postcode prescribing that a clear analysis of the benefits or otherwise of CPAP for OSA, and then a clear directive on its use, are extremely important to bring about rational and uniform services across the UK.	Comment noted.
	Royal College of Physicians	Treatments for OSA are fragmented and very variable within the NHS. An authoritative NICE survey would bring cohesion to OSA treatment and define the role of CPAP in this.	Comment noted.
	Royal College of Physicians of Edinburgh	Concerns about delays in obtaining CPAP and non-availabilty of CPAP in some places need to be factored in. PCTs have little awareness of this condition. The Scottish SIGN guideline on this area will be helpful.	Comment noted.

Section	Consultees	Comments	Action
	Section of Sleep Medicine, Royal Society of Medicine	The definition of severity is easy to do in an arbitrary way using the AHI but what matters are the symptoms. The correlation between AHI and symptoms is not high. And measuring the severity of symptoms is difficult, the Epworth Sleepiness Score having its limitations. It is patients with moderate to severe symptoms rather than a particular AHI that appear to benefit and some of these do not necessarily have a clearly abnormal Epworth Score. CPAP is not an alternative to lifestyle advice. Patients with exemplary lifestyles may get OSAHS. Surgery may cure OSAHS in a very small number of patients - for example some with enormous tonsils but, in general, has little to offer. Oral devices are of various types. Some work but patients tend not to persevere with treatment long term.	The outcomes in the final scope were clarified to be: OSAHS severity (measured via objective methods); symptom severity; any other health effects (for example accidental injury or hypertension). It was agreed that lifestyle advice should not be a standard comparator because there is strong evidence (from a Cochrane review) that lifestyle advice is not effective. The most appropriate standard comparators were believed to be “No treatment/placebo advice should still be included in the appraisal, as it can be included under the term “No treatment/placebo”. Dental devices were seen as an appropriate comparator in studies in people with mild OSAHS.

Section	Consultees	Comments	Action
Questions for consultation	British Sleep Society	Sleep studies confirm the presence of OSA and symptoms are used to decide on the severity of the condition and the appropriate treatment. Patients sometimes find it hard to describe symptoms and most robust data is on modeate to severe OSA in Randomised Control Studies. However some flexibility should be maintained in when to treat as some supposedly milder cases demonstrate a good response to CPAP.	A discussion of subgroups (mild, moderate and severe OSAHS) revealed that it is inappropriate to restrict the population to severity grades at this stage of the appraisal. It was also agreed that a case of OSAHS should be confirmed by a clinical expert in the field (i.e. the patient's diagnosis has been validated via use of accepted instruments such as the AHI index and/or Epsworth sleepiness score.

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	British Thoracic Society	Defining disease severity can be either by symptoms or sleep study. This duel definition of severity has led to unecessary confusion. Sleep apnoea is treated when symptoms are deemed serious enough by the patient and his/her physician, across a range of sleep study defined severity. The latter is less important then the former in the decision making process, sleep studies are used more to confirm the diagnosis, than define its severity. It might be reasonable to restrict the review to disease with 'moderate to severe' symptoms. However, sometimes patients under-estimate their symptoms and only appreciate their previous degree of disability once treated. Hence many experts in the field regard a thereapeutic response as part of the disease definition, similar to the situation with asthma. Any future guideline restricting treatment on the basis of symptom severity score would reduce the flexibility that probably needs to exist. However in the first instance it may only be possible to draw robust conclusions on moderate to severely symptomatic disease, as this is the group on whom there are most RCT data. Conventionally, moderate symptoms would be defined by the Epworth Sleepiness Score being >9 and <=14, with severe disease being >14. These divisions are fairly arbitrary however. As described above, there are Cochrane reviews of alternative therapies. The only real comparator for mild/moderate OSA are dental devices. However they usually work out more expensive and they are proven to be of lesser efficacy.	A discussion of subgroups (mild, moderate and severe OSAHS) revealed that it is inappropriate to restrict the population to severity grades at this stage of the appraisal. It was also agreed that a case of OSAHS should be confirmed by a clinical expert in the field (i.e. the patient's diagnosis has been validated via use of accepted instruments such as the AHI index and/or Epsworth sleepiness score

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	Royal College of Physicians of Edinburgh	Can or should this proposed appraisal be restricted to people with moderate or severe OSAHS as the current evidence suggests CPAP is not used in patients with milder forms of the condition? If so, how should moderate and severe OSAHS be defined? 1. Current evidence does not indicate that patients with milder forms of OSAHS do not use CPAP. The best available evidence (McArdle. Am J Respir Crit Care Med. 1999;159:1108-14) does indicate that use is not as good in milder groups but it remains the best evidence based treatment available for these patients (Engleman. Am J Respir Crit Care Med. 2002;166:855-9. Barnes. Am J Respir Crit Care Med. 2004;170:656-64). 2. Dividing the condition into severity criteria is difficult and contentious. Splitting solely by severity of breathing abnormality is wrong - as many at all levels of such abnormaility are asymptomatic - and splitting solely by symptoms is also wrong as many are unaware of their sleepiness until after they have benefited from treatment. The Edinburgh group tends to divide sleepy patients (Epworth >11 or sleepy drivers) with AHI>5 into mild (AHI 5-15) or more severe (AHI>15) and on this basis have shown evidence of benefit from CPAP in mild OSAHS in RCTs (Engleman. Am J Respir Crit Care Med. 1999;159:461-7. Engleman. Thorax. 1997;52:114-9). Is CPAP an alternative to life-style advice or is it an adjunctive therapy? It is a vastly more effective adjunct. Lifestyle advice on its own is relatively ineffective but should always be given. Are there any other comparators, e.g. oral devices and/or surgery? Oral devices work (Ferguson. Thorax 1997;52:362-8.Mehta. AJRCCM 2001;163:1457-61. Gotsopoulos. AJRCCM 2002;166:743-8. Gotsopoulos. Sleep 2004;27:934-41), but are less effective according to the 2 well conducted RCTs (Am J Respir Crit Care Med. 2002;166:855-9. Am J Respir Crit Care Med. 2004;170:656-64). There is considerable doubt about the longterm use of MRS devices (McGown. ERJ 2001;17:462-6. Marklund. Chest 2004;125:1270-8. Izci. Resp Med 2005;99:337-46) with no objective measures of use (in contrast to CPAP) , only self reports. Surgery to the upper airway is not of proven value. Mandibulo- maxillary advancement surgery can work but at present is considered is niche treatment for a few highly selected	A discussion of subgroups (mild, moderate and severe OSAHS) revealed that it is inappropriate to restrict the population to severity grades at this stage of the appraisal. It was also agreed that a case of OSAHS should be confirmed by a clinical expert in the field (i.e. the patient's diagnosis has been validated via use of accepted instruments such as the AHI index and/or Epsworth sleepiness score

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope