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Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome

Table of Comments from Consultees and Commentators on the ACD

Organisation	Section	Comment	Institute Response
Association for Respiratory Technology & Physiology (ARTP)	Whether all the relevant evidence has been taken into account	We are generally happy that all of the relevant evidence has been taken into consideration. This is a very thorough and robust piece of work and reaches general conclusions that are consistent with the impression that practitioners in the field have of CPAP in OSAHS.	Comment noted
Association for Respiratory Technology & Physiology (ARTP)	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate.	Most of the clinical and cost-effectiveness are reasonable interpretations but we were surprised to find the cost of road traffic accidents was not used in the QALYS analysis. This is a serious oversight and paints an artificial picture of how CPAP impacts on national healthcare economics	The Committee considered the impact of including road traffic accidents on the ICERs in the base case modelling (See 4.2.5). Only subgroup analyses were carried out without inclusion of road traffic accidents.
Association for Respiratory	Whether the provisional	We generally consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable	Comment noted

Technology & Physiology (ARTP)	recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	basis for the preparation of guidance to the NHS	
Association for Respiratory Technology & Physiology (ARTP)	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	However, we would like to highlight some errors in the draft document: Recommendation 1.3 should have the word “initial” removed, so that specialists in sleep medicine (and specifically, obstructive sleep apnoea hypopnoea syndrome) should be involved with the patient pathway throughout their treatment and not just at diagnosis.	Comment noted. Section 1.3 has been amended accordingly.
Association for Respiratory Technology & Physiology (ARTP)	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views	Recommendation 2.2 suggests that OSAHS should only be studied using polysomnography in a sleep medicine centre and refers to AHI values to determine severity. The largest method of screening for OSAHS in the UK is predominantly home oximetry using oxygen saturation “dip rate” as the outcome measure along with arousal rate. This needs amending.	Section 2.2 is not a recommendation and does already mention oximetry.

	on the resource impact and implications for the NHS are appropriate.		
Association for Respiratory Technology & Physiology (ARTP)	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate.	Recommendation 2.4 discusses symptoms but fails to point out that the common symptoms described require referral to a sleep medicine specialist.	Section 2.4 is not a recommendation; it is a general description of symptoms.
Association for Respiratory Technology & Physiology (ARTP)	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the	Recommendation 4.1.10 demonstrates the importance of CPAP in contributing to road traffic accidents, but fails to link this to the cost analysis later. This is illogical and needs amending.	The Committee considered the impact of including road traffic accidents on the ICERs in the base case modelling (See 4.2.5). Only subgroup analyses were carried out without

	preliminary views on the resource impact and implications for the NHS are appropriate.		inclusion of road traffic accidents
Association for Respiratory Technology & Physiology (ARTP)	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate.	Recommendation 4.1.11 states than none of the 6 studies showed a statistically significant difference, yet in the table of evidence, 2 studies clearly did demonstrate a significant difference. This needs amending.	Comment noted. Section 4.1.11 has been amended.
Association for Respiratory Technology & Physiology (ARTP)	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and	Recommendation 4.1.14 needs re-wording to emphasize that greater numbers of ALL healthcare staff will be needed in order to treat OSAHS, but particularly healthcare scientists who have significant expertise and experience in running sleep study services should be considered. Workforce and training issues are crucial for development of services and there needs to be more emphasis on encouraging providers to recruit and develop	Section 4.1.14 not a recommendation, but evidence section.

	that the preliminary views on the resource impact and implications for the NHS are appropriate.	more staff in this area.	
Association for Respiratory Technology & Physiology (ARTP	Are there any equality related issues that may need special consideration	Recommendation 4.3.13 concludes that CPAP should only apply to adults. Clearly with increasing obesity in our population there will be an increasing need for CPAP treatment if not in young children (<5 years) certainly in adolescents (14-18years). This statement will have major repercussions on our population's health if commissioners ignore treating children in the future, which will lead to a net effect of increasing the number of adults treated in the longer term.	Section 4.3.13 is not a recommendation, but explains the deliberations of the Appraisal Committee. Clinical experts present at the appraisal Committee meeting explained that sleep apnoea in children has a different underlying pathology.
Association for Respiratory Technology & Physiology (ARTP		Finally, as a general observation and for future NICE technical reviews, it is disappointing to see no representation of clinical physiologists or clinical scientists on the Appraisal Committee. It is this group of workers who have most experience of diagnostic and therapeutic services for OSAHS. There are several healthcare scientists throughout the UK who could contribute to this role in the future. I suspect they either need to be approached or at least encouraged to approach a position on	The Appraisal Committee is drawn from broad range of professionals from the healthcare sector; it does not consist of topic specialists. Instead topic experts are invited to the

		such an important and influential committee.	Appraisal Committee meeting to answer questions and inform the Committee.
NHS Quality Improvement Scotland (Reviewer 1)	Whether all the relevant evidence has been taken into account	As far as I can see all the relevant evidence that is currently available regarding the effectiveness of CPAP treatment in sleep apnoea has been carefully considered and taken into account	Comment noted
NHS Quality Improvement Scotland (Reviewer 1)	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	The summaries of both the clinical and cost effectiveness of CPAP are reasonable interpretations of the evidence	Comment noted
NHS Quality Improvement Scotland (Reviewer 1)	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a	The provisional recommendations are fair and are justified by the available evidence base	Comment noted

	suitable basis for the preparation of guidance to the NHS		
NHS Quality Improvement Scotland (Reviewer 1)	Whether you consider that there are any potential policy implications for SEHD	There are potential policy implications in that there will be a need for easier access to sleep services throughout the UK as sleep apnoea is a common condition (affecting up to 4% of middle aged men and 2% of middle aged women) and is readily treatable with CPAP and as such more trained sleep nurses /technicians will be required to assess and monitor sleep apnoea patients. There will also be a need to identify sufficient funds to supply CPAP machines / humidifiers to those patients who are identified as having sufficiently severe enough sleep apnoea	Comment noted
NHS Quality Improvement Scotland (Reviewer2)	Whether all the relevant evidence has been taken into account	As far as I know, the relevant information, including the Cochrane review, has been taken into account	Comment noted
NHS Quality Improvement Scotland (Reviewer 2)	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for	Yes from the evidence	Comment noted

	the NHS are appropriate		
NHS Quality Improvement Scotland (Reviewer 2)	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	The recommendations on moderate/severe disease and on diagnosis seem suitable and in accordance with SIGN 73 (2003). The recommendation for people with mild disease may be less easy to interpret.	Comment noted
NHS Quality Improvement Scotland (Reviewer 1)	Whether you consider that there are any potential policy implications for SEHD	The implementation of these recommendations may require policy support	Comment noted
British Sleep Society	Whether all the relevant evidence has been taken into account	Appraisal Consultation Document has incorporated relevant evidence available for clinical effectiveness and cost effectiveness of Continuous Positive Airway Pressure (CPAP) therapy in the treatment of patients suffering with Obstructive Sleep Apnoea Hypopnoea Syndrome (OSAS). The clinical need and practice section contains some areas requiring clarification and these are stated in attached document Points for Review. The technology section provides an accurate summary of CPAP devices.	Comment noted

British Sleep Society	Whether all the relevant evidence has been taken into account	The main omission to this document in the consideration of evidence is the failure to appreciate the importance of CPAP in improving driving performance and acknowledgement of the robust data that it reduces the risk of a motor vehicle accident to that of a "normal" healthy driver on the roads. In this field the relevant evidence has been marginalized. The document states that the data on road traffic accidents "needs to be treated with caution" and this is inappropriate and suggests a lack of understanding by the authors. The reason that RCT trials on roads are not conducted is because robust evidence already exists that CPAP works and therefore trials on roads would be ethically unacceptable.	Section 4.3.11 which discusses the evidence base for the effect of CPAP on road traffic accidents has been amended.
British Sleep Society	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	The clinical effectiveness section is reasonably interpreted with the exception of driving performance and road traffic accidents. The effect of CPAP is to significantly improve driving performance and to significantly reduce road traffic accidents. Important to recognize that HGV and other professional drivers and pilots with OSAS are required by their licensing and regulating bodies such as DVLA and CAA to be established on CPAP therapy before they can return to work.	Section 4.3.11 which discusses the evidence base for the effect of CPAP on road traffic accidents has been amended.
British Sleep	Whether the	T The impact and implications for the NHS are appropriate	Comment noted.

Society	summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	although some clarification should be made on the need for specialist input. All of the evidence from RCT data is supported by early specialist intervention and there would be no guarantee of results if CPAP therapy was set up and monitored in other settings. Further comments are attached in Points for Review	
British Sleep Society	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	2.3 Use craniofacial characteristics not abnormalities	Comment noted. Section 2.3 has been amended.
British Sleep Society	Whether the summaries of	Add partner witnessed apnoeas, add nocturia to list of symptoms. Should add patients with these symptoms should be referred.	Comment noted. Section 2.4 has been amended

	clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate		to include these symptoms.
British Sleep Society	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	4.3.13 Very rare should be taken out and consider OSAHS is less common in the absence of craniofacial characteristics.	Comment noted. Section 4.3.13 has been amended.
British Sleep Society	Whether the summaries of clinical and cost	Studies with robust methodology have shown the positive beneficial effect by improving performance and reducing accidents. This needs to be recognised throughout the document	Section 4.3.11 which discusses the evidence base for the effect of

	effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate		CPAP on road traffic accidents has been amended.
British Sleep Society	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	4.1.11 Two studies show a significant effect of CPAP compared to placebo	Comment noted. Section 4.1.11 has been amended.
British Sleep Society	Whether the summaries of clinical and cost effectiveness are	In the main document there are errors with references- FOR EXAMPLE on several pages the driving data reference refers back to Jenkinsen et al paper which did not investigate driving. C orrect reference should be to Hack et al for driving RCT	Comment noted

	reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate		
British Sleep Society	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	Points regarding specialist services 1.3 The word "initial" is not needed and incorrect. There must be a way for patients to be referred back to specialist services if difficulties arise. The definition of specialist should be clarified and should be worded specialist services with appropriately trained medical support staff	Comment noted. Section 1.3 has been amended accordingly.
British Sleep Society	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for	4.1.14 Healthcare professionals NOT healthcare scientists	Comment noted. Section 4.1.14 has been amended

	the preparation of guidance to the NHS		
British Sleep Society	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	1,2 suggest occasionally recommended for people with severe symptoms and mild OSAHS.	Comment noted. Section 1.2 has been amended
British Sleep Society	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	2.2 Instead of limited study sentence suggest- limited studies of breathing and oxygenation can be enough to confirm the diagnosis or occasionally overnight Polysomnography in a sleep medicine centre The severity of OSAHS is defined by severity of symptoms and number of episodes of AHI. The severity of symptoms needs to be added here.	Comment noted. Section 2.2 has been amended
British Sleep Society	Whether the provisional recommendations of the Appraisal	This document provides a well researched working basis for recommendations on CPAP therapy in OSAS. The provisional recommendations of Appraisal Committee are	Comment noted

	Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	sound and with attention to the above points will constitute a suitable basis for preparation of guidance to the NHS	
British Sleep Society	Are there any equality related issues that may need special consideration?	This document does not raise any equality issues that may need special consideration although at present access to CPAP services is patchy in some areas of UK.	Comment noted
Royal College of Nursing		The Royal College of Nursing welcomes the opportunity to review the Appraisal Consultation Document of the health technology appraisal of Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome	Comment noted
Royal College of Nursing	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	Generally this document is a good review of practice and in our view would not have an adverse affect on patient treatments if the recommendations were accepted.	Comment noted

Royal College of Nursing	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	The recommendation in section 1.3 of the report regarding the diagnosis of obstructive sleep apnoea/hypopnoea, the prescription of CPAP treatment and monitoring of the initial response of sleep medicine - seems vague. For example in some centres, they have anaesthetists and respiratory physicians who review patients with OSA and we would not want this practice to change. Is the term 'Specialist in sleep medicine' meant to be all encompassing? It would be helpful to clarify this point.	Comment noted. Section 1.3 has been amended.
ResMed	Whether all the relevant evidence has been taken into account	We would like you to consider the following as it relates to the point indicated. 4.1.7 The US. JNC-7 report by The US Department of Health and Human Studies, National Heart, Lung and Blood Institute, National High Blood Pressure Education Program include Sleep Apnoea as an identifiable cause of Hypertension. I include a copy of this reference card with this email. Should this be looked at again?	Comment noted. Section 4.3.8 which describes the Appraisal Committee's deliberations of the evidence base for the effect of CPAP on blood pressure has been amended.
ResMed	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence	Yes.	Comment noted

	and that the preliminary views on the resource impact and implications for the NHS are appropriate		
ResMed	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	We would like you to consider the following as it relates to the point indicated. 4.1.14 What about other appropriately trained clinical or technical specialists?	Comment noted. Section 4.1.14 has been amended.
ResMed		Other comments: We would like you to consider the following as it relates to the point indicated. 1.1 CPAP is continuous positive airway pressure, not airways	Comment noted. Section 1.1 has been amended accordingly.
ResMed		2.2 OSA can also be diagnosed using polygraphy (e.g. embletta) or other two channel (Flow and Oximeter) devices.	Comment noted. Section 2.2 contains general detail about the technology.
ResMed		2.4. The most important symptom after snoring is partner-witnessed apnoeas. Other important symptoms are nocturia,	Comment noted. Section 2.4 has been amended.

		morning headaches, and sexual dysfunction (e.g. impotence).	
ResMed		3.4 Please remove "the S6 and S7 range (ResMed UK)" as they are obsolete, and replace with "S8 range (ResMed UK).	Comment noted. Section 3.4 has been amended accordingly.
General Practice Airways Group (GPAIG)	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	We are writing to add our support to the comments of the British Thoracic Society on the above appraisal. We are delighted to see that the ACD recommends CPAP for people with moderate and severe obstructive sleep apnoea (OSA).	Comment noted
General Practice Airways Group (GPAIG)	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	We would like to reinforce the recommendation that diagnosis of OSA and prescription of CPAP should only be carried out by clinicians with expertise in sleep medicine. We strongly support the management of these patients by nurses, technicians and clinicians who have experience and training in the management of sleep disorders. In order that patients are identified and referred to specialist services appropriately, we suggest that an education and training programme for primary care is established to improve understanding and awareness of the condition in primary care.	Comment noted.
General Practice		We trust that the implementation group at NICE has seen our comments relating to implementation from our letter in February	The comments in this letter were reviewed by

Airways Group			Committee members prior to the ACD meeting.
Royal Society of Medicine (Sleep Section)	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	1.3 I do not think it should only be the monitoring of the "initial" response and it should be the whole response both initially and subsequently: "initial" should be removed. We need to ensure that the definition of sleep specialists is something that is robust and exists in the outline description	Comment noted. Section 1.3 has been amended
Royal Society of Medicine (Sleep Section)	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are	2.2 I am pleased that we are using the sleep apnoea/hypopnoea syndrome which associates clinical symptoms together with abnormal physiology. Sometimes the diagnosis is made by using a more "limited" sleep study that involves respiratory monitoring but not full EEG. While I appreciate the severity of OSAHS is determined by the apnoea/hypopnoea index this is only one factor. Frequent arousals as noted by other physiological methods of assessment or EEG changes may be as important. For example a person may snore loudly because of upper airway collapse but may not have a "significant" number of episodes of apnoea/hypopnoea. However if you record	Comment noted. Section 2.2 has been amended.

	appropriate	brainwave activity you will see that they are waking up frequently. I therefore think we need some "opt out" to ensure that patients who are very symptomatic from their upper airway collapse and have disturbed sleep patterns and an element of daytime sleepiness associated with it but do not fulfil the magic AHI index can still receive treatment. I appreciate that I am trying to get over a somewhat of a complex concept and in essence I didn't want to through the baby out with the bathwater i.e. if an individual is very symptomatic and just has a few episodes of sleep apnoea they are still worthy of a trial of therapy.	
Royal Society of Medicine (Sleep Section)	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	I think I would remove the word abnormalities and perhaps use the word features or better characteristics.	Comment noted. Section 2.3 has been amended.
Royal Society	Whether the	There is quite a lot of research to say witnessed apnoeas	Comment noted. Section

of Medicine (Sleep Section	summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	are an important feature of OSAHS, as is nocturnal choking. A common reason for referral is passing urine at night and I think nocturia should be included.	2.4 has been amended.
Royal Society of Medicine (Sleep Section		Penultimate paragraph there is a gap between s_urgery.	Comment noted
Royal Society of Medicine (Sleep Section	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are	I accept we need some timing for how long a CPAP machine works and this does dramatically affect the costings that you have put forward. Whilst some machines do last for 7 years few go on beyond that, some break down earlier. I am not certain how much evidence that really exists for using 7 years and whether 6 is a better figure but realise this too is arbitrary.	Comment noted

	appropriate		
Royal Society of Medicine (Sleep Section	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	The evidence of interpretation on the whole was satisfactory and I understand in 4.1.11 that we have used quality of life. It is the patient's clinical response that is so obviously "overwhelming" to clinicians.	Comment noted
Royal Society of Medicine (Sleep Section	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	4.1.14 This should be a greater number of "healthcare workers" or perhaps better "workforce resources" as it is not purely scientists, although scientists are important in delivering sleep services.	Comment noted. Section 4.1.14 has been amended accordingly.

Royal Society of Medicine (Sleep Section	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate		4.2.5 I am disappointed about the issue that road traffic accidents have not really been factored in. Whilst I appreciate that we are looking in part at the "direct" costs of provision of CPAP there is literature to say that healthcare utilisation is greater before CPAP is utilised and, perhaps more importantly, is the large impact on indirect costs of road traffic accidents. I think there is good evidence to say that people with sleep apnoea are excessively sleepy and do have an access of road traffic accidents. It is therefore valid, though I appreciate perhaps not scientifically as rigorous as you would like, to infer that if you are preventing road traffic accidents and CPAP is also going to reduce general costs of healthcare by reducing accidents.	The Committee considered the impact of including road traffic accidents on the ICERs in the base case modelling (See 4.2.5). Only subgroup analyses were carried out without inclusion of road traffic accidents
Royal Society of Medicine (Sleep Section	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate		Furthermore I think we are not only looking at the impact on healthcare of preventing a road traffic accident but there is no "financial model" that can take into account the loss of a life and the impact on loved ones as a consequence of a road traffic accident which, via CPAP, we can probably prevent. In summary I understand why driving has not featured however I think this is a say omission from both a financial cost base and from a sociological impact.	Comment noted. The NICE methods guide specifies that costs will be considered from an NHS and Personal Social Services perspective.

Royal Society of Medicine (Sleep Section	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	4.3.11 Issue of driving as above.	Section 4.3.11 which discusses the evidence base for the effect of CPAP on road traffic accidents has been amended.
Royal Society of Medicine (Sleep Section	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	4.3.13 I take note that sleep apnoea is thought to be rare in children and adolescents, this is not so. However there is not much epidemiological data to support this conclusion. There are many children with very large tonsils who have sleep apnoea and tonsillectomy can clearly improve these individuals. In addition however there are a large number of children with cranio-facial changes which may or may not alter as the face/body alters with age. However such individuals may have sleep apnoea and do benefit hugely from CPAP. The phrasing of this implies as if we are saying CPAP in children and adolescents is rare and therefore the recommendation of NICE should only apply to adults. This is wrong as many children will be denied what is an effective therapy.	The Committee discussed the use of CPAP therapy for children and adolescents. It concluded that the clinical issues affecting this population are different from the issues encountered in adults. Therefore the available clinical and cost effectiveness evidence was not applicable to children and adolescents.

Royal Society of Medicine (Sleep Section	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	Implementation. This is my major concern and the one I have left until last. For reasons, clearly that I understand, the technological appraisal is only that of CPAP. However it is essential that in the pre-amble that goes with the document there is a clear statement that PCT's/hospitals need to provide adequate facilities for the investigation of patients with suspected sleep apnoea. What may be a very good appraisal and of benefit for patients/carers may not be utilised if PCT's do not allow/fund investigations for sleep problems.	After issuing guidance NICE provides implementation tools for the NHS.
Respironics	Whether all the relevant evidence has been taken into account	My colleagues and I were impressed with the thoroughness of the review and recognise the effort involved in collating such an extensive document and thank you once again for the opportunity to comment.	Comment noted.
Respironics	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis	Our comments are referenced according to the headings in the original Appraisal consultation document (issue date August 2007). 1.3 We believe that the definition "specialists in sleep medicine" is open to interpretation and suggest the following modification, which also conveys the need for long term follow up:	Comment noted. Section 1.3 has been amended

	for the preparation of guidance to the NHS	“The diagnosis of obstructive sleep apnoea/hypopnoea and the prescription of CPAP treatment should be carried out by a qualified physician experienced in sleep medicine. Monitoring of the initial response and long term follow up should be carried out by trained staff with an appropriate professional qualification”.	
Respironics	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	2.2 The Appraisal Consultation Document states that “OSAHS is usually diagnosed….by overnight oximetry ……or occasionally by an overnight polysomnography in a sleep medicine centre. The severity of OSAHS is usually defined by the number of episodes of apnoea/hypopnoea per hour of sleep, expressed by the apnoea/hypopnoea index (AHI)” This is indeed the case, however it is not possible to get an AHI from oximetry alone. We suggest a modification for the second sentence of the paragraph such as “An overnight study allows the severity of OSAHS, defined by the number of episodes of apnoea/hypopnoea per hour of sleep (the apnoea/hypopnoea index – AHI), to be calculated”	Comment noted. Section 2.2 is a general introduction to the technology.
Respironics	Whether the summaries of clinical and cost effectiveness are reasonable	3.2 This section covers treatment compliance with reasons for non use. Compliance is much improved with regular patient follow up and we suggest the importance of acute and long term follow up should be mentioned. While the working life of CPAP machines	Comment noted. Section 3.2 has been amended.

	interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	is adequately covered elsewhere in the report we feel it would be useful for there to be a comment regarding the importance of mask replacement at 6 monthly or maximum yearly intervals. A suggested final sentence for the paragraph could cover both points: "Masks should be replaced at least annually and long term follow up of patients is critical to ensure compliance"	
Respironics	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	3.3 This section recognises the role of Auto-titrating CPAP devices. We suggest the mention of the importance of compliance monitoring with possible cost savings "Compliance monitoring is important however the use of auto-CPAP may also improve the efficiency and cost effectiveness of the service because patients may avoid the need to return to the unit for pressure adjustment".	Comment noted. Section 3.3 has been amended. The probability of home and in-patient titration was included in the assessment group's cost-effectiveness analysis. Section 4.2.7 of the ACD explains that there was an improvement in cost effectiveness with auto-titrating CPAP.
Respironics	Whether the summaries of clinical and cost effectiveness are reasonable	3.5 Concerning the lifespan of the device, we suggest that it would also be helpful to mention that the patient interface should be replaced more frequently, for example after the mention of the	Comment noted. Section 3.5 has been amended.

	interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate	device life: "Mask lifespan is 6-12 months".	
British Thoracic Society and Royal College of Physicians	Do you consider that all of the relevant evidence has been taken into account?	Yes, mainly.	Comment noted
British Thoracic Society and Royal College of Physicians	Do you consider that all of the relevant evidence has been taken into account?	However, it is unfortunate that there is so little data on quality of life in patients with severe OSA which led to a meta analysis of this outcome not being possible in a severe subgroup. It also meant overall that many of the subscales just missed 'significance'. The mapping done by Mark Sculpher's group of ESS across to SF36 shows that the two are strongly correlated; thus one of the studies (86) that found a big difference in ESS, and no change in the vitality subscale of the SF36, is a clear outlier. The appraisal group is therefore right not to have made much of this apparent failure of CPAP to improve quality of life, it makes no sense.	Comment noted
British Thoracic Society and	Do you consider that all of the	We think that the cost efficacy data feel correct, although the inability to include the wider costs of vehicle accidents is	Comment noted. The NICE methods guide

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Royal College of Physicians	relevant evidence has been taken into account?	disappointing. We would suggest that the inability/failure to do this is highlighted as a deficiency that, if taken into account, would further reduce the cost per QALY. There is only one brief reference to this in 4.3.2.	specifies that costs will be considered from an NHS and Personal Social Services perspective
Thoracic Society and Royal College of Physicians	Do you consider that all of the relevant evidence has been taken into account?	The section 4.3.11 specifically concludes that accident costs should be excluded because patients are stopped from driving when diagnosed, therefore treatment would make no further difference. However, this is a severely erroneous approach (as pointed out at the appraisals meeting). If there is no treatment available then there is no point in running a diagnostic service – thus the diagnosis is not made and patients remain on the roads, having accidents: diagnosis and treatment go hand in hand. There is no point in diagnosing just to take patients off the road and then not treating them.	Comment noted. Section 4.3.11 which discusses the evidence base for the effect of CPAP on road traffic accidents has been amended.
Thoracic Society and Royal College of Physicians	Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for	Yes. Although some of the points above are pertinent.	Comment noted

	the NHS are appropriate?		
Thoracic Society and Royal College of Physicians	Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate?	Section 4.3.14 lumps different machine issues along with added humidification. Whereas it is correct to make no differentiation between fixed pressure and auto-CPAP machines (there is no evidence suggesting a significant difference in efficacy), there is data on humidification, as reviewed by the Cochrane group.	Comment noted. It was agreed at the scoping workshop that the term CPAP should include any fixed or auto-titrating devise regardless of make or whether additional features (such as humidifiers) are used.
Thoracic Society and Royal College of Physicians	Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of	As regards the sections 1.1, yes.	Comment noted

	guidance to the NHS?		
Thoracic Society and Royal College of Physicians	Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?	In section 1.2 it might be wiser to say that treatment is indicated in mild obstructive sleep apnoea with troublesome symptoms. As it reads at present, it implies that CPAP is appropriate for mild symptoms, which most would not feel was the correct conclusion from the data.	Comment noted. Section 1.2 has been amended
Thoracic Society and Royal College of Physicians	Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?	As regards section 1.3, this is a potential problem. What is a specialist in sleep medicine? The SIGN OSA guidelines tried to define this and suggested that training as a respiratory registrar with a period on a sleep unit would be the minimum for a clinician. In fact on page 156 (8.4) there is already a definition of a specialist centre which we are surprised has not been used. The non-medical staff would have to have demonstrated an appropriate training on a suitable course or through an apprenticeship on an existing unit. It is important to point out that all the RCT data have come from such experienced units. There is no guarantee that similar results will accrue from inadequately trained staff/units.	Comment noted. Section 1.3 has been amended

Thoracic Society and Royal College of Physicians	Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?	A further problem is that 1.3 only refers to monitoring the initial response. Of course, if the patient is not supported thereafter with advice and replacement parts for the head gear and mask etc then he will stop using it and the whole process will have been a waste of time and money. Thus we think that a statement suggesting that continuing specialist support thereafter is required would be appropriate. Certainly these costs are in the economic model. Therefore we would modify 1.3 to …. and monitoring of the response should be carried out by a specialist service with appropriately trained medical and support staff.	Comment noted. Section 1.3 has been amended
Thoracic Society and Royal College of Physicians	Are there any equality related issues that may need special consideration?	Not that we can see.	Comment noted
Thoracic Society and Royal College of Physicians	Other Specific points	2.2 in the preliminary appraisal consultation document says that OSAHS is usually diagnosed by a sleep medicine specialist by overnight oximetry in the persons home, or occasionally by an overnight polysomnography in the sleep medicine centre. It then defines the condition on the basis of AHI – only derivable from a respiratory polysomnography type study, not oximetry! The evidence for any of this has not really been reviewed but is important. OSAHS includes the word syndrome at the end and is not just a sleep study but includes clinical assessment, mainly the	Comment noted. Section 2.2 has been amended

		history. We would say that:- OSAHS is usually diagnosed from a suggestive history and a positive sleep study. In most cases limited studies of oxygenation and/or respiration ('respiratory polysomnography' or 'limited studies') are enough to provide a diagnosis and assess severity (this is the case in moderate to severe disease and when no other diagnosis such as heart failure is likely). In a minority, further studies using more extensive multi-channel equipment (full polysomnography) may be required, especially when alternative diagnoses are being considered. (Indeed this is what page 156 (8.4) of the main document actually says too.) The severity of OSAHS is usually assessed on both symptoms (often the degree of sleepiness) and the sleep study, either by using the apnoea hypopnoea index (AHI) or oxygen desaturation index, which are roughly equivalent. Mild OSAH (no S),when using sleep study alone, is often defined as AHI 5-14, moderate 15-30, and severe >30: the cut off between mild and moderate when using desaturation index is sometimes set at 10 rather than 15.	
Thoracic Society and Royal College of Physicians	Other Specific points	In 2.3, abnormalities should read characteristics, as the retrognathia (and other subtle differences) that can contribute to OSA can be within the normal range rather than abnormal	Comment noted. Section 2.3 has been amended
Thoracic Society and Royal College of Physicians	Other Specific points	In 2.4, we would add witnessed apnoeas and otherwise unexplained nocturia to the list of OSA symptoms.	Comment noted. Section 2.4 has been amended
Thoracic Society and	Other Specific points	We would also stress the value of recognizing and treating OSA by adding Thus referral to a specialist sleep service is	Section 2.4 is not a recommendation; it is a

Royal College of Physicians		recommended when OSAS is suspected	general description of symptoms.
Thoracic Society and Royal College of Physicians	Other specific points	In 4.1.11 the text says that no study found a statistically significant difference in any of the sub scales etc. This is not correct, the Lancet 1999 study from our group (Jenkinson, 77) did find a significant difference as shown on your pages 208 (Emotional role, Mental health), 209 (Physical role), 210 (Vitality). For some reason (previously pointed out), the summary component scores (Mental and Physical) from the Jenkinson study (table 3, paper page 2102) have been accidentally left out of the tables on page 210. This should be corrected as the mental component summary score was significantly different between real and placebo (P = 0.002). In addition the study from Engleman (78) also showed a significant difference in the vitality subscore (your page 210). Thus the statement in 4.3.5 is unduly pessimistic in my view.	Comment noted. Section 4.1.11 has been amended. .
Thoracic Society and Royal College of Physicians	Other specific points	In the blood pressure assessment, it is unclear why the Faccenda data (94) are not included, other than in the table of studies considered.	Section 4.1.7 provides details of the RCTs which measured daytime mean arterial blood pressure. The Faccenda study did not report daytime and night-time blood pressure separately
Thoracic Society and	Other specific points	In 4.1.13. There is an error in reporting the minimal likely compliance (23-82%), i.e. the 23%. This probably comes from the	Comment noted. Section 4.1.13 has been

Royal College of Physicians		same error on page 10 of the overview, there is an entry in table 3 under Stradling et al 1997 suggesting a compliance of 0.64 and 0.23 at 6 weeks. We assume this is the Thorax 1997:51;72 paper and these data have been quoted incorrectly. The minimal compliance figures were 0.64 and 0.73 with a further 0.23 and 0.25 undecided at 6 weeks whether to continue or not. These numbers should be corrected in the table and in section 4.1.13.	amended.
Thoracic Society and Royal College of Physicians	Other specific points	Section 4.1.14 is in our view not quite correct and would suggest ……..that there are enough trained medical staff in secondary care to investigate the necessary numbers of patients with likely OSA, but further training of support staff for CPAP provision will be necessary over the coming years. There are currently insufficient resources and training in primary care for the continued supervision of patients with OSAHS on CPAP.	Comment noted. Section 4.1.14 has been amended.
Thoracic Society and Royal College of Physicians	Other specific points	Section 4.3.11 We did not understand this section. Some of the so called driving simulators do not really simulate driving at all (e.g. 'Steer Clear'). When the more sophisticated simulators were used, then the RCTs were positive. Therefore we think that this section is too 'pessimistic' on this issue and should imply that the data are mixed but the more sophisticated simulations suggest a significant improvement on CPAP. This is also the section containing the rather odd decision to exclude the costs of road traffic accidents as discussed above.	Comment noted. Section 4.3.11 which discusses the evidence base for the effect of CPAP on road traffic accidents has been amended.
Thoracic Society and Royal College	Other specific points	Section 4.3.13 suggests that OSAHS is very rare among young people. In children of the age where enlarged tonsils are often found (usually 2 to 8yrs or so), OSAHS is relatively common, in	Comment noted. Section 4.3.13 has been amended.

of Physicians		adolescents the prevalence is probably lower but, in the USA, studies have suggested that the increasing levels of obesity are generating significant numbers of cases. We would suggest simply changing very rare even to less common.	
Thoracic Society and Royal College of Physicians	Other specific points	There is a statement on page 4 of the overview that compliance is a problem with CPAP. This implies that it is a particular problem, whereas in fact (as pointed out at the appraisal meeting) the compliance is better than with anti-hypertensives and anti-asthma therapy. We think the statement should simply read that compliance can be improved with the methods detailed, rather than starting with the statement that there is a problem.	Comment not about FAD