

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

<p>Technology & Physiology (ARTP)</p>	<p>recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS</p>	<p>basis for the preparation of guidance to the NHS</p>	
<p>Association for Respiratory Technology & Physiology (ARTP)</p>	<p>Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS</p>	<p>However, we would like to highlight some errors in the draft document:</p> <p>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.</p>	<p>Comment noted. Section 1.3 has been amended accordingly.</p>
<p>Association for Respiratory Technology & Physiology (ARTP)</p>	<p>Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views</p>	<p>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.</p>	<p>Section 2.2 is not a recommendation and does already mention oximetry.</p>

	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.	Section 4.1.11 is not a recommendation, but lists the evidence. It refers to the 6 studies reporting SF36 subscales which compared CPAP with placebo or usual care and quotes the data from the assessment group page 69 and table 5.5.
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 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

<p>British Sleep Society</p>	<p>Whether all the relevant evidence has been taken into account</p>	<p>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.</p>	<p>Section 4.3.11 which discusses the evidence base for the effect of CPAP on road traffic accidents has been amended.</p>
<p>British Sleep Society</p>	<p>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</p>	<p>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.</p> <p>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.</p>	<p>Section 4.3.11 which discusses the evidence base for the effect of CPAP on road traffic accidents has been amended.</p>
<p>British Sleep</p>	<p>Whether the</p>	<p>The impact and implications for the NHS are appropriate</p>	<p>Comment noted.</p>

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	This statement refers to the 6 studies reporting SF36 subscales which compared CPAP with placebo or usual care. See assessment report page 69 and table 5.5.
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

<p>Royal College of Nursing</p>	<p>Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS</p>	<p>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 <u>not</u> 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.</p>	<p>Comment noted. Section 1.3 has been amended.</p>
<p>ResMed</p>	<p>Whether all the relevant evidence has been taken into account</p>	<p>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?</p>	<p>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.</p>
<p>ResMed</p>	<p>Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence</p>	<p>Yes.</p>	<p>Comment noted</p>

	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	<p>We are writing to add our support to the comments of the British Thoracic Society on the above appraisal.</p> <p>We are delighted to see that the ACD recommends CPAP for people with moderate and severe obstructive sleep apnoea (OSA).</p>	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	<p>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.</p> <p>We need to ensure that the definition of sleep specialists is something that is robust and exists in the outline description</p>	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	<p>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.</p> <p>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</p>	Comment noted. Section 2.2 has been amended.

	appropriate	<p>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.</p> <p>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.</p>	
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

<p>of Medicine (Sleep Section</p>	<p>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</p>	<p>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.</p>	<p>2.4 has been amended.</p>
<p>Royal Society of Medicine (Sleep Section</p>		<p>Penultimate paragraph there is a gap between s_urgery.</p>	<p>Comment noted</p>
<p>Royal Society of Medicine (Sleep Section</p>	<p>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</p>	<p>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.</p>	<p>Comment noted</p>

<p>Royal Society of Medicine (Sleep Section</p>	<p>appropriate 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</p>	<p>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.</p>	<p>Comment noted</p>
<p>Royal Society of Medicine (Sleep Section</p>	<p>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</p>	<p>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.</p>	<p>Comment noted. Section 4.1.14 has been amended accordingly.</p>

<p>Royal Society of Medicine (Sleep Section)</p>	<p>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</p>	<p>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.</p> <p>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.</p>	<p>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</p>
<p>Royal Society of Medicine (Sleep Section)</p>	<p>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</p>	<p>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.</p> <p>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.</p>	<p>Comment noted. The NICE methods guide specifies that costs will be considered from an NHS and Personal Social Services perspective.</p>

<p>Royal Society of Medicine (Sleep Section)</p>	<p>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</p>	<p>4.3.11 Issue of driving as above.</p>	<p>Section 4.3.11 which discusses the evidence base for the effect of CPAP on road traffic accidents has been amended.</p>
<p>Royal Society of Medicine (Sleep Section)</p>	<p>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</p>	<p>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.</p>	<p>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.</p>

<p>Royal Society of Medicine (Sleep Section)</p>	<p>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</p>	<p>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.</p>	<p>After issuing guidance NICE provides implementation tools for the NHS.</p>
<p>Respironics</p>	<p>Whether all the relevant evidence has been taken into account</p>	<p>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.</p>	<p>Comment noted.</p>
<p>Respironics</p>	<p>Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis</p>	<p>Our comments are referenced according to the headings in the original Appraisal consultation document (issue date August 2007).</p> <p>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:</p>	<p>Comment noted. Section 1.3 has been amended</p>

	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	<p>2.2</p> <p>The Appraisal Consultation Document states that</p> <p>“OSAHS is usually diagnosed....by overnight oximetryor 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)”</p> <p>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</p> <p>“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”</p>	Comment noted. Section 2.2 is a general introduction to the technology.
Respironics	Whether the summaries of clinical and cost effectiveness are reasonable	<p>3.2</p> <p>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</p>	Comment noted. Section 3.2 has been amended.

	<p>interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate</p>	<p>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:</p> <p>“Masks should be replaced at least annually and long term follow up of patients is critical to ensure compliance”</p>	
Respironics	<p>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</p>	<p>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”.</p>	<p>Comment noted. Section 3.3 has been amended.</p> <p>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.</p>
Respironics	<p>Whether the summaries of clinical and cost</p>	<p>3.5 Concerning the lifespan of the device, we suggest that it would</p>	<p>Comment noted. Section 3.5 has been amended.</p>

	<p>effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate</p>	<p>also be helpful to mention that the patient interface should be replaced more frequently, for example after the mention of the device life:</p> <p>“Mask lifespan is 6-12 months”.</p>	
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