



SLEEP APNOEA TRUST

*Working to improve the lives of sleep apnoea patients
their partners and families*

*National Institute for Health & Clinical
Excellence*

Health Technology Appraisal

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

Submission by Sleep Apnoea Trust

1. Introduction

This submission is made to the National Institute for Health and Clinical Excellence by Sleep Apnoea Trust (Registered Charity no. 1056963) to assist it in the Health Technology Appraisal of CPAP treatment.

Sleep Apnoea Trust is a charitable patient support group, which for the past fourteen years has supported sleep apnoea sufferers, their partners and families, throughout England & Wales. The Trust provides assistance through:

- A patient association (Sleep Apnoea Trust Association) whose members provide mutual support
- *Sleep Matters* a newsletter published at regular intervals
- telephone help lines
- a website www.sleep-apnoea-trust.org.
- the provision of medical alert cards
- an annual conference.

It also seeks to publicise this condition (which is misunderstood and often wrongly diagnosed) through the appropriate media. Sleep Apnoea Trust does not provide medical advice, and we leave it to other contributors to make the technical case for CPAP treatment. We are concerned to ensure that you understand the real suffering which is caused by this disease, the difficulty in receiving a proper diagnosis, and the efficacy of CPAP treatment.

The points made by us in evidence are supported wherever possible by quotations from a large number of sufferers and their families. This evidence comes from our members who have volunteered to make their experiences public. Their comments have been made anonymously, but it would be possible for the Reviewing Committee to meet these witnesses if they wished, and to discuss any points with them. Alternatively the complete file of Case Histories is available for your inspection.

2. Description of the Disease

Obstructive sleep apnoea - referred to simply as sleep apnoea in this document – causes the main airway to collapse wholly or partially as soon as the subject falls asleep. Breathing ceases for several seconds, but defence mechanisms in the body usually detect the situation and rouse the sleeper to a state of semi-consciousness. This causes the airway to open and the subject gulps in a breath, but is often not aware of awakening. He then falls asleep again and the whole cycle repeats itself. This commonly happens several hundred times per night, causing the sufferer to become sleep – deprived. This activity is accompanied by loud snoring and extreme restlessness, as the sufferer struggles for breath. The sleep of bed partners -and often the entire family unit- is disturbed, resulting in the sufferer being forced to sleep separately in another room. The disease is insidious and becomes worse over time. It is quite common for sufferers to have the condition for ten years before they are able to receive a correct diagnosis. Often the condition is misdiagnosed as stress or depression and medication is prescribed which actually makes the condition worse. During this time the patients struggle to carry on with their lives, with severe consequences for their family relationships, their driving skills, and their performance at work.

3. Symptoms

The main symptom is excessive daytime sleepiness, but this fails to describe the severity of the condition. Eventually the sufferer experiences mental and physical exhaustion and mood swings, resulting from long term sleep deprivation, and is unable to concentrate on any subject. It is a constant struggle to stay awake, and the sufferer has no idea of the cause of these symptoms. He or she is often unable even to contemplate taking exercise and may experience a substantial increase in weight. This impacts on general health – the sufferer will often consult his GP, but usually in vain since the most common prescription is tranquillisers, which cause the muscles around the airway to relax even further and so worsen the condition. There is a proven link between sleep apnoea and hypertension and type 2 diabetes is commonly found in those with sleep apnoea.

3.1 Family Life

The effects of the condition on family life are best illustrated by the following quotations from sufferers

- *As far back as 20 years ago (in my mid forties) I was aware that I was having problems staying awake during the day. I was also exhausted most of the time, and disinclined to do anything except sleep. This was particularly hard on my wife, who was at home with the children - she had to put up with violent snoring and restless movements at night, and by the time she had cleared up after a meal, and was ready to chat about the day, I was fast asleep on the settee. She was left feeling bereft, as I was totally useless at home, having no energy to cope with the children or life in general. Socially I was a joke (literally!): we were often out to dinner parties with friends, but it was well known that I would never make the dessert course - I would be left snoring in a corner while they got on with the dinner party. Sadly many of them must have reached the conclusion that I was simply being rude.*
- *It comes to something when you go to bed at 10pm, get up at 8am having slept through (you think), and you're more tired at breakfast than you were the night before. It comes to something when you tell your GP about this (and the abominable snoring, and the three- pee-a-night symptoms) and all he does is prescribe tranquillisers.*
- *In the early 1960's (age early 20's) my snoring was so loud that I used to sleep in the bedroom furthest away from my other family members. In 1965 I spent six months in hospital following a serious motor accident. Out of many patients who spent time on the Ward, the majority complained of my loud snoring. None of the medical staff could have realised that I was suffering from Obstructive Sleep Apnoea. I married in 1977 and my wife also complained of my loud snoring and we were soon using separate bedrooms. By this time I had also started to fall asleep at the theatre/cinema and even when we went out to dinner. My powers of concentration gradually became atrocious and I lost all interest in sex.*

3.2 Performance at Work

Most sufferers are still of working age, and many have reached the stage where they occupy senior positions. They try to carry on with their careers but inevitably they are not able to concentrate, and they lack energy. They become much less effective and often lose their jobs, since they are perceived to be stressed or “burned out”. We have counselled many patients on our help lines who have lost their careers and businesses, whilst suffering from undiagnosed sleep apnoea.

- *I was very fortunate in being a senior member of my firm. Before the condition was discovered I often fell asleep in the office and once or twice actually in meetings. My colleagues were concerned and supportive, but if I had been more junior I suspect my job would have been at risk. I am sure that I was performing at about 60% of my normal capacity and whilst nothing has come to light that I did incorrectly before diagnosis in the nearly two years since I started using CPAP, I am sure that the standard of my work was barely adequate.*
- *If your living is as a broadcaster and you are thus rather dependent upon your voice, it comes to something when you know you're going to get at least two chest infections a year, which always last for ever, and often render you speechless for weeks. OK, my enforced silence provides some well-deserved rest in the daytime for a long-suffering wife, kept awake by my snoring at night, I suppose, but not good in the communication business!*
- *I was conducting a long one-to-one meeting with a new client, who was explaining all the problems that I had been brought in to solve, when I actually fell asleep in the meeting, and had to be wakened by the client. Fortunately he did not report the incident, accepting my explanation that I was feeling ill, but I realised that my career would be on the line if there was any recurrence.*

3.3 Driving Skills

This is perhaps the most serious consequence of untreated sleep apnoea. Most sufferers appreciate that they have some degree of impairment brought about by daytime sleepiness, but since they have no idea what is causing the problem, they try to carry on with their normal driving pattern. Eventually the disease will progress to the stage where they are liable to fall asleep involuntarily at the wheel. Research suggests that drivers with untreated sleep apnoea are more than five times as likely to be involved in road traffic accident – the Department of Transport holds statistics on road accidents, which may of use to you.

- *In August 2003 John Stevens died in a road accident when driving to work. John was 41 years old, had been married to Alison for 17 years and had two young sons. As a motorway roadworks technical manager, John's job regularly involved driving long distances and as such he was an experienced driver. Yet according to witnesses of the accident, his car had veered off-course shortly before hitting another vehicle and spinning onto the verge. For several years before the accident John had grown progressively sleepy during the daytime, despite regularly getting around 7 hours sleep each night. However, John's sleep was marked by periods where he would briefly stop*

breathing altogether, before breathing normally again. He also suffered from heavy snoring, which had worsened as John had put on weight – one result of his sleepiness was that he exercised less.

Although John refused to see it as a serious problem, the snoring had reached the stage where Alison was forced to sleep in another room, while his sleepiness was leading to mood swings that were affecting their relationship. John was also in denial about his daytime drowsiness, despite regularly falling asleep at home and occasionally at work, leading on one occasion to a minor accident. He eventually admitted to Alison that his reluctance to act was partly based on a fear that he would not be able to work. However, his employers were beginning to be concerned about his health and insisted on a medical check.

On hearing of John's excessive sleepiness, breathing pauses at night and heavy snoring, his doctor suspected obstructive sleep apnoea, a sleep condition that is more common in overweight men. With the right treatment almost all patients are able to live a normal life and John was referred to his local sleep clinic to confirm the diagnosis, receive advice and begin treatment. Unfortunately, as is common with many under-funded NHS sleep centres, his initial appointment involved a wait of several months.

Three months before the appointment John suffered his fatal road accident. The other driver involved in the accident commented that John wore a vacant expression and did not react to the impending crash. John was almost certainly asleep at the wheel. If John and his family had received an earlier diagnosis and prompt treatment, then his life could have been saved.

- *In August 1997 we had been out walking in the morning had a light lunch (no alcohol) a further walk in the afternoon and was driving home in a very hot sultry atmosphere I said to my wife I feel awful and I'm going to stop in the lay-by at the bottom of the Downs, as we approach the lay-by you could not see it for dust as combine harvesters were operating nearby. "Oh we'll stop on the "Ridgeway" and carried on it is a long straight rise up the hilltop as we approached the hilltop I apparently dozed off next thing was that we hit a tree at about 60mph, fortunately neither of us was seriously injured although I was taken by ambulance to hospital with an aggravated spinal complaint.*
- *It comes to something more serious, even life-threatening, when at 9am you're fighting to stay awake only five miles into the M40.*
- *I was driving the family back from Scotland, and by the time we reached the M6 in Lancashire they had dropped off to sleep. The road was busy, but despite this I also fell asleep. Previously on a couple of occasions I had nodded off in the car for a few seconds, but this was more serious. I was in the fast lane traveling at 70+, and I woke up just as we crossed on to the hard shoulder. Somehow we had crossed all 3 lanes safely - I assume that other drivers saw the car drifting and made way for me. I do not know why I woke up - I think that a truck driver may have hooted me, but I am not sure.*

4. Difficulties in getting the correct treatment

The first option for someone suffering from untreated sleep apnoea is to consult a general medical practitioner. Often this is totally ineffective, and sometimes makes the position worse. Most GPs are still unaware of the condition, many misdiagnose it and a substantial minority do not believe that the condition exists. The problem is that medical students still receive very little training about the condition, and it can be confused easily with stress and depression. Most patients are given advice about their lifestyle, or are treated with anti-depressants. Often these will relax the muscles in the throat even more, and will worsen the sleep apnoea. The essential referral to a sleep unit is often missed and a large number of patients have told us that they had to wait up to 10 years or more before being correctly diagnosed. Even if the correct primary diagnosis is made, there are long waiting lists for treatment in many areas of the country, and in some places (including substantial cities such as Portsmouth) the local Primary Care Trusts have withdrawn funding for CPAP treatment. It is certain that the position will be improved only by the success of this technology appraisal. A wide ranging publicity campaign will also be required along with improved training for doctors. A few years ago Sleep Apnoea Trust sent information about the disease to every GP in England & Wales. Whilst this had some effect, a much greater effort will be needed if doctors are to be able to make a correct preliminary diagnosis

- *Go away, lose weight, sort out your lifestyle, and leave me to deal with patients who really are ill! (comments made by a GP in Cornwall to a patient subsequently diagnosed with sleep apnoea)*
- *I was seeing my GP for 20 years about sleep problems before I finally got to a sleep clinic, and it was not my GP who referred me to it. Initially my GP was trying home remedies to stop me from snoring, which he seemed to see as the whole problem. Then after about 10 years a programme on television was brought to my attention which discussed OSA and CPAP, I immediately went and saw my doctor to try to get him to refer me to a sleep clinic, his response was that we should eliminate every other possible cause of my problem before that. So he referred me to various doctors including a psychiatrist who advised me to lose weight, which I did, then he referred me several times to an ENT surgeon who carried out several pointless operations, until the surgeon could think of nothing else to do and then it was this ENT surgeon who referred me to the sleep clinic, I think he was just sick of the sight of me.*
- *For many years I visited my doctor, telling him that I felt utterly exhausted during the day; falling asleep at work and whilst driving in my car the 23 miles each day to work. This resulted in many near misses and luckily only two very minor accidents. After the second, I went to see another doctor who suggested O.S.A (Obstructive Sleep Apnoea) and got my doctor to refer me to Queen Alexandra Hospital in Portsmouth. At my appointment I was told there was no funding for my condition. Luckily (again), the doctor could see I was having problems and referred me to Southampton Hospital where I attended a sleep clinic. I was diagnosed with a severe case of sleep apnoea and told to stop driving.*

5. Successful Treatment for Sleep Apnoea

Our experience in advising and counselling sleep apnoea patients over a number of years has convinced us that CPAP is the only available technology which treats the condition successfully. We are aware of some patients with mild symptoms who have used a mandibular device with some success, but the overwhelming body of evidence tells us that a CPAP device fitted by a specialist sleep unit, which provides proper initial instruction and aftercare, gives by far the best results. As far as we can tell the failure rate of CPAP usage is low and often results from failure to fit the nasal mask properly, and to monitor usage in the first few weeks.

The technology is not easy to use – most people find it very difficult at first to sleep in a mask which covers either the nose or in some cases the nose and mouth. Problems can also arise with rhinitis, or nasal stuffiness, due to the effect of cold air passing through the nose. These symptoms can usually be alleviated by the use of nasal sprays or a heated humidifier – a low cost piece of equipment, which increasingly is being produced as an integral part of a CPAP machine. Considering that the treatment has to be used every night for life, and that the machine has to be taken everywhere the patient travels, the failure rate seems remarkably low.

The reason for the low failure rate is clear. Using CPAP provides such a dramatic improvement in the quality of life that patients are prepared to put up with the difficulties of the technology. In many cases this improvement is not only dramatic but also immediate, and in almost all cases they will become used to the therapy within a few months. After a successful introduction to the therapy most patients become so used to the procedure that they rely on it, and find it difficult to sleep without the machine.

We believe that CPAP should be made available to all who suffer from sleep apnoea – whether they are classified as mild or severe. Because the therapy can be difficult to use in the early stages, patients who do not perceive that they are receiving enough benefit will stop using CPAP, and the machines can then be returned to the sleep clinics for use by other patients. Each year more than 300 sleep apnoea sufferers and their partners attend our conference, during which they talk to other patients about their experiences. The view expressed by most new patients and their family members is: *CPAP has given me back my life.*

- *I believe that my husband has suffered from Sleep Apnoea for many years, although his condition was not investigated, let alone diagnosed. He frequently stopped breathing during the night, and was constantly having to get up to go to the toilet. The lack of proper sleep made him very irritable to live with, at times to the detriment of our family and social life. On one occasion he went to sleep at the wheel of the car, seriously injuring a passenger as well as writing off the car. He was also obliged to retire early as he could not stop dropping off to sleep at his desk, and his concentration deteriorated. My husband was fortunate when a new doctor had his condition investigated. Acute Sleep Apnoea was diagnosed, and he has now been*

on CPAP for over a year. Since his first night using a mask his condition has improved dramatically. He now sleeps well at night and can once again lead a normal life. In effect CPAP has given us both back our lives.

- *I am now TOTALLY dependant on my CPAP machine, and cannot sleep or even doze without it. I do travel quite a lot and the first thing I look for in hotels, whether here, abroad or on ships etc. is "where the electric plug point is!!" My CPAP machine is my life-line and I would not be without it now.*
- *After an appointment in the late 2000 I was diagnosed with obstructive sleep apnoea and was prescribed CPAP treatment. Since then my life has been 100 percent better. I no longer suffer from the daily drowsiness and feel much fitter in myself. One month after using the CPAP machine I found myself driving from my home town of Aylesbury, to the top of North Yorkshire without feeling any effects of tiredness or fatigue.*
- *Thank the Lord for the Sunday Times, as old rugby pal and past room-share snore sufferer reads about Sleep Apnoea and CPAP treatment. Off I go to the Churchill Hospital Oxford as quickly as my tired little legs will carry me for a 'sleep test'. Half way through the night I am woken by a doctor, who says 'Please, Mr K***, put this mask on before we resort to murder here', I did, I breathed, I slept like a baby as the flow of air kept my throat from collapsing. The next morning, the M40 was plain sailing. My day seemed to be being lived by a Trevor 20 years younger, with energy for everything. That night, with my CPAP machine duly installed at home - I slept, my lady wife slept, so did the children, even the cat. My life had been revolutionised in a trice, and I have used my 'blower' every night since - and that's TEN YEARS of being totally awake, snoreless, pee-less and chest infectionless. A miracle of very basic and cheap technology but, believe me, a life saver.*
- *I clearly remember the day I was finally confirmed as having sleep apnoea and the morning after using the CPAP machine for the first time. I felt so good that I was virtually dancing around the house - I rang everyone that I could think of to tell them how well I felt. My wife said that one day I was forty going on sixty and the next day forty going on six! Since then life has gone on and on improving. I've lost two stone in weight as I now have energy again and the dog now gives me looks such as "oh no, do I have to go for another walk again!". All this for the small price of wearing a mask each night with a light whooshing noise - I know which I choose.*
- *I still cannot believe how the use of a CPAP machine has turned my life around. That terrible exhaustion and not knowing why has disappeared. My husband can now relax, especially at night. Any inconvenience that the machine brings is far outweighed by the new life that I now enjoy*
- *I found it very difficult for the first night because the feeling of suffocation still existed to a small degree, but by the end of the first week I was beginning to feel the benefits from deep refreshing sleep.*

Without my best friend (my CPAP machine) life for the past 11-12 years would have been without doubt downhill all the way. Life would have been very dangerous without it

• ***Before CPAP treatment:-***

Over a period of 25+ years -progressively worsening

- * *Loud snoring*
- * *Continually falling asleep while watching TV, listening to radio, reading the paper or even having breakfast. Particularly likely at meetings, in discussions and at the theatre, cinema or pub*
- * *Had to ask my wife to drive on many occasions*
- * *Moody*
- * *Miserable*
- * *Separate bedrooms*
- * *Partner unable to sleep because of noise of snoring, amount of movement in bed and fear of me passing out whilst holding breath*
- * *No energy*
- * *Sleepless/disturbed nights*

As an example of the level of snoring- two workmen were using pneumatic drills to dig up the road outside my house. I was in bed following a nightshift. The workmen stopped drilling and put down their jackhammers to try and find out where the noise of my snoring was coming from.

I have had during the last 25 years

1. *operation to surgically remove some of soft palate- which had very short term affect/improvement (12 months)*
2. *Second operation (Laser treatment) to limit vibration in the uvular, snoring and apnoea- but which had no affect, and*
3. *Countless weight reducing regimes, which had mixed success and at best only resulted in temporary improvements.*

Immediately after first night of CPAP treatment:-

- *No snoring*
- *Back in bedroom*
- *Wide awake during daytime and evening*
- *Alert*
- *Energetic*
- *Less time in bed but more rest*
- *Focused*
- *Enthusiastic*
- *Happier*
- *No mood swings*
- *Confident*
- *Living life to the full again*

The CPAP apparatus has completely improved the quality of our lives!

6. Conclusions

CPAP is a brilliantly simple concept which uses air at a slight pressure to act as an “air splint”, holding the airway open, and removing entirely the symptoms of sleep apnoea. The treatment offers a permanent solution and is effective almost immediately. The technology relies on simple low cost equipment, and avoids the use of expensive drugs or surgical treatment. In most cases the improvement in the sufferers’ quality of life is dramatic – they are able to resume their lives, and become, once again, valuable members of society who make a full contribution to their family life and their careers, and who can drive without endangering themselves and other road users.

Their general health will also improve – at a considerable cost savings to the NHS. It is clear that there would be substantial net saving in health costs if CPAP became widely available, and the many undiagnosed sufferers could be treated. In addition the benefits to industry and to the economy generally, from improved performance at work and the decrease in road traffic accidents would bring vast financial benefits. Above all NICE has an opportunity to enable thousands of people to *get their lives back* by approving CPAP as a technology for general use.

We urge NICE not to miss this opportunity.

Sleep Apnoea Trust

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