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# IMPRESS

Improving and Integrating Respiratory Services

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# Service Specification for Investigation and treatment of Obstructive Sleep Apnoea Syndrome

Association for Respiratory Technology & Physiology

The Sleep Apnoea Trust

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

**The British Thoracic Society**[+] (BTS) has over 2,800 members who are actively working in a variety of healthcare professions to improve the standards of care for people with lung diseases. Just over half the members are secondary care physicians and doctors in training and the remainder are respiratory nurse specialists, respiratory physiotherapists, respiratory technical and physiological measurement professionals, smoking cessation practitioners and staff working in primary care. The Society publishes treatment Guidelines and related educational materials; runs an annual Scientific Meeting and an annual conference and short course programme catering for the multi-professional team; publishes the journal *Thorax*; provides tools to assist individual and team review and performance improvement (including audit and peer review); and works with strategic partners such as GPIAG and patient organisations to raise the profile of the speciality and advocate for improvements in standards.

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**The General Practice Airways Group*** (GPIAG) is an independent charity representing primary care health professionals interested in delivering the best standards of respiratory care. It is dedicated to achieving optimal respiratory care for all through:

- Representing primary care respiratory health needs at policy level
- Promoting best practice in primary care respiratory health through education, training and other services
- Supporting the development of primary care health professionals in respiratory medicine
- Facilitating and leading primary care respiratory research.

For further information and details of how to join the GPIAG see www.gpiag.org

The **ARTP** is the professional body representing the standards and quality for all staff who work in respiratory physiology measurement in the UK. ARTP has been established for over 33 years and has set standards in quality and training for the measurement of respiratory physiology in patients whether that is during wakefulness or sleep. The ARTP/BTS Certificate of Competence in Spirometry is the “gold standard” in quality spirometry training and is recognised by primary and secondary care staff across the UK. ARTP have just launched ARTP SLEEP as the professional body branch of our organisation aimed at nurses, physiotherapists and scientists who are predominantly working in services for the diagnosis and treatment of sleep disorders including sleep apnoea. We offer training, quality standards for equipment and service and contribute to key consultations on sleep related services in the UK. For more information visit www.artp.org.uk

**Sleep Apnoea Trust** (SATA) is a charitable support group which works to improve the lives of sleep apnoea patients, their partners and their families. The group has been established for 16 years and operates throughout England & Wales. Through our telephone helplines we assist those suffering from sleep apnoea to obtain a timely and accurate diagnosis of their condition, and provide advice and support to those who are undergoing CPAP therapy. Information is provided through our website www.sleep-apnoea-trust.org and by a range of advice leaflets and newsletters, which are supplied to more than 130 sleep units throughout the country. We hold an annual conference, and have encouraged the formation of a number of local patient support groups We produce medical alert cards and we also campaign for fairer allocation of Government funds to sleep services.

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## Executive Summary

1. This document explains the nature of the obstructive sleep apnoea syndrome (OSAS), its epidemiology, how it should be effectively investigated and treated, and advises on the optimal requirements for the service which needs to be commissioned. It has been produced jointly by representatives of the professional organisations most closely involved in the care of patients with OSAS – the British Thoracic Society (BTS) (1), the Association for Respiratory Technology and Physiology (ARTP) (2) and the General Practice Airways Group (GPIAG) (3) – and the patient support organisation, the Sleep Apnoea Trust Association (SATA) (4).

2. Due to the relatively recent appreciation of its importance as a major health problem, OSAS has suffered from poor understanding and recognition by both the community at large and health professionals. Consequently, many patients experience considerable difficulty in having their condition appreciated, investigated and effectively treated, a problem exacerbated by the low priority hitherto given to adequate specialist services.

3. OSAS is very common, affecting individuals in all age groups. The most accurate epidemiological data have been obtained in middle aged populations in whom it affects between 2 and 4% of men and about one third that proportion of women. Its prevalence is strongly correlated with obesity and consequently is rising in the general population. However, it is not confined to the obese with about 30% of affected individuals being nonobese.

4. The most important symptom is excessive daytime sleepiness; this significantly impairs quality of life and, if severe, can affect cognitive function. Adverse effects on work performance are common, with serious consequences for the individual, even including dismissal. Individuals with uncontrolled OSAS have a high rate of road traffic accidents, varying between 3 and 7 times that of the general driving population; accidents result not only from falling asleep at the wheel, but also from impaired concentration due to sleepiness.

5. Assessment of suspected OSAS requires both clinical expertise and appropriate sleep investigation. Diagnosis requires specialist clinical experience and depends on the combination of the clinical history and the result of a sleep study.

6. The most effective treatment for symptomatic OSAS is by continuous positive airway pressure (CPAP). The effectiveness of this treatment has recently been confirmed by a NICE Health Technology Appraisal (5). Effective CPAP treatment requires considerable professional input and expertise in education and encouragement of the patient. Few other medical treatments produce such profound improvements in quality of life and social functioning and relationships.

7. A comprehensive service for patients with suspected OSAS requires a specialist multidisciplinary team and includes initial clinical assessment, investigation, diagnosis, provision of treatment, education and support of patients, clinical and technical follow up, long term supervision of treatment and prompt provision of replacement equipment and parts.

8. To achieve the goal of fair, safe, effective and personalised services, commissioners need to address inequities of provision, and to commission a comprehensive, specialised, responsive, timely and individualised service for investigation and treatment of OSAS in accordance with the recommendations of the NICE HTA.

# 1. General background

## 1.1 Definitions and Prevalence

"Apnoea" means cessation of breathing; this document relates to obstructive sleep apnoea in which breathing during sleep is periodically interrupted by closure of the upper airway (pharynx) for between 10 and about 45 seconds. Partial obstruction of the upper airway results in periods of reduced ventilation (hypopnoea). Most individuals with the obstructive sleep apnoea syndrome (OSAS) have a combination of apnoeas and hypopnoeas.

Many otherwise healthy individuals have brief periods of apnoea and/or hypopnoea during sleep and it is important to distinguish "obstructive sleep apnoea" (the phenomenon observed during a sleep study) from the obstructive sleep apnoea syndrome, which implies the combination of sleep disordered breathing with attributable symptoms. It is the latter which requires a specialist service for diagnosis and treatment.

OSAS entered the mainstream medical literature only about 30 years ago and has only reached general public awareness in the last 10 years. As an apparently "new" condition, it has suffered from poor understanding and recognition by both the community at large and health professionals. Consequently, many patients experience considerable difficulty in having their condition appreciated, investigated and effectively treated, a problem exacerbated by the low priority given hitherto to adequate specialist services.

Estimates of prevalence conducted 10-15 years ago suggest that the condition affects 2–4% of middle aged males and about one third to one half as many adult females. Recent estimates suggest that only 20–30% of affected individuals have currently been diagnosed in the UK. Furthermore, the prevalence is increasing as the frequency and severity of obesity is increasing in this, as in all advanced countries.

As a guideline, and based on current estimates of prevalence and activity, an average PCT responsible for a population of about 0.5 million might expect approximately 500 new referrals to be made per annum, 200 new patients to be provided with CPAP p.a. and a cumulative follow up population of 1500 under supervision and receiving long term CPAP treatment.

## 1.2 Causes and Effects

Sleep, even in healthy individuals, is accompanied by loss of stability of the upper airway (pharynx), a phenomenon manifested most commonly by snoring which represents vibration of this unstable airway. In about 20-30 % of loud snorers, the pharynx is so unstable that it narrows and may occlude periodically during sleep, resulting in recurrent hypopnoeas and/or apnoeas. These brief episodes are accompanied by reduction in blood oxygenation (desaturation) and are terminated by transient semi awakening. The consequent fragmentation of sleep results in the characteristic daytime symptoms which are essentially those of chronic sleep deprivation.

Any normal variation or pathological abnormality which tends to reduce the size of the pharynx during wakefulness will predispose to the development of apnoeas during sleep. The commonest such factor in adults is obesity, particularly of the upper body and neck, as this implies increased deposition of fat around the airway. Other potential contributors include certain types of craniofacial bone structure and enlarged tonsils (particularly in children and some young adults).

## 1.3 Symptoms

Although the breathing problems of patients with OSAS are confined to sleep, the main symptoms are experienced during waking hours with, characteristically, a feeling of unrefreshing sleep on waking, sometimes with headache, and daytime sleepiness which can impair social functioning, domestic harmony, work performance and the ability to drive safely. The sufferer may be aware of waking occasionally at night with a sensation of choking, but most apnoeas and hypopnoeas resolve without conscious awareness. Partners are, however, often alerted by very restless sleep, with apnoeas (or "breathholding") interspersed between periods of loud snoring. Another common symptom is the need to pass more urine at night, which can lead to inappropriate referral to a urologist.

## 1.4 Effects on Quality of Life, morbidity and mortality

The excessive daytime sleepiness significantly impairs quality of life and can be severe enough to affect cognitive function. Adverse effects on work performance are common, with serious consequences for the individual, including accidents and falling asleep at work, which may even lead to dismissal. Individuals with uncontrolled OSAS have an increased rate of road traffic accidents (RTAs), varying between 3 and 7 fold that of the general driving population; accidents result not only from falling asleep at the wheel, but also from impaired concentration due to sleepiness (6).

Over the long term, untreated OSAS makes an important contribution to vascular disease as it is an independent risk factor (over and above any confounding effects of coexistent obesity) for hypertension, and thus is relevant to other cardiovascular disease particularly stroke (7).

### 1.5 Classification of OSAS

Grading of severity of OSAS is based on the frequency of apnoeas and hypopnoeas per hour of sleep or of the study period (Apnoea/Hypopnoea Index – AHI events/hour) and the consequent symptoms. Alternatively, the frequency of accompanying dips in oxygenation during sleep is used (oxygen dip rate – ODI). The most widely used classification is that recommended by the American Academy of Sleep Medicine (8): patients with significant symptoms are graded as having mild (AHI 5-14), moderate (AHI 15-30) or severe (AHI > 30) OSAS. However, the relation of AHI to symptom severity is, at best, very weak and it is the symptoms which relate best to the potential benefits of treatment.

### 1.6 NICE Approved Treatment

The most effective treatment for symptomatic OSAS is by continuous positive airway pressure (CPAP), using a flow of air generated by a small electrically powered compressor and delivered to the pharynx via any of several nasal or oronasal interfaces. The effectiveness of this treatment has recently been confirmed by a NICE Health Technology Assessment (5). For CPAP treatment to be effective requires considerable professional input and expertise in education and encouragement of the patient, choosing the appropriate interface, dealing with causes of discomfort and monitoring compliance etc. Embarking on CPAP treatment is potentially a lifelong commitment both by the patient and the specialist service involved.

### 1.7 Other Treatment Modalities

Alternative forms of treatment include intraoral mandibular advancement devices which fit over the upper and lower teeth and are moulded with the aim of producing some protrusion of the lower jaw during sleep, thereby increasing pharyngeal size and stability. Pharyngeal surgery is sometimes performed, but, with the exception of tonsillectomy in patients with very large tonsils, it is not generally recommended for patients with symptomatic OSAS. General lifestyle advice should also be provided, particularly to those who are overweight or obese, although a Cochrane review in 2001 identified no good evidence of benefit in this population (9). In morbid obesity, successful bariatric surgery has been shown significantly to improve OSAS (10). The drug modafinil is occasionally used as an adjunct to treatment in patients who have residual sleepiness despite regular use of CPAP.

### 1.8 Preventive Strategies

The main preventive strategy for OSAS relates to the prevention and management of obesity. Although closely correlated with obesity, however, it should be noted that other factors, related particularly to the size and shape of the pharynx (throat), interact with obesity in causing obstructive apnoeas during sleep. Furthermore, a significant proportion of individuals (about 20–30% in the UK) with symptomatic OSAS are not overweight; this is particularly so in certain ethnic groups such as those of Far Eastern origin.

### 1.9 Scope of this Service Specification

This document sets out the standards which, in the view of the patient and professional organisations involved, are required of services in order to deliver high quality assessment, diagnosis and treatment for people with suspected or confirmed obstructive sleep apnoea syndrome.

## 2 Definitions and Abbreviations

| | |
|---|---|
| OSA: | *obstructive sleep apnoea*: absence of breathing (> 10 seconds) during sleep despite continuing respiratory effort; usually due to transient closure of the upper airway (pharynx)<br>*obstructive sleep hypopnoea*: reduced airflow due to partial obstruction of the upper airway. |
| OSA(H)S: | *obstructive sleep apnoea (hypopnoea) syndrome*: periodic closure (partial closure) of the upper airway resulting in clinical symptoms (usually daytime sleepiness). |
| Hypoventilation: | more prolonged reduction in ventilation for part or all of the night. |
| OHS: | obesity-hypoventilation syndrome – persistently reduced or ineffective ventilation both day and night due to very severe obesity, resulting in daytime respiratory failure (i.e. raised arterial $PCO_2$); most individuals also have OSAS. |
| $SaO_2$: | arterial oxygen saturation, recorded continuously by an oximeter, usually on the finger (sometimes designated $SpO_2$ to indicate recorded by pulse oximeter). |
| PSG: | polysomnography – detailed sleep study, including various combinations of recordings of chest and abdominal movement, airflow, oxygen saturation, audiovisual signals and ECG, plus neurophysiological signals recording electroencephalography (EEG), electrooculography (EOG), and electromyography (EMG). |

Respiratory PSG (also known as "limited" or "cardiorespiratory" sleep study): usually 4–6 signals as above, but excluding neurophysiological signals (i.e. sleep duration and staging are not available).

AHI: apnoea/hypopnoea index: the average frequency of apnoeas plus hypopnoeas per hour of sleep (or per hour of study if neurophysiological signals are not available).

ODR/ODI: oxygen dip rate/oxygen desaturation index: the average frequency of dips in $SaO_2 \geq 4\%$ per hour of study (ODR is often < AHI).

CPAP: continuous positive airway pressure: treatment comprising a portable, electrically powered pump which delivers air, usually at a previously determined pressure of between 4 and 20cm $H_2O$.

APAP: autoadjusting positive airway pressure – treatment with a device which supplies air at a variable pressure, adjusted automatically in response to continuous monitoring of the patency of the airway. Often used at the introduction of CPAP treatment in order to "titrate" the requisite pressure to the optimal level; sometimes also used for long-term positive pressure treatment.

NIV: non-invasive ventilation, usually by "pressure support" (bilevel pressure) with individually determined inspiratory (IPAP) and expiratory (EPAP) pressures.

Interface: a device connecting the CPAP or other pressure-generating equipment to the patient's airway, usually a close-fitting mask over the nose or nose and mouth; alternatives include nasal "pillows" and buccal devices.

Ramp function: a comfort feature of most CPAP devices whereby the airway pressure is increased to the prescribed level over the first 10–20 minutes of use.

Humidifier: an in-line system which warms and humidifies the air from a CPAP device prior to delivery to the patient; usually a simple reservoir which is refilled with water each night.

(IO)MAD (intraoral) mandibular advancement device: a moulded plastic device fitted over upper and lower front teeth with the aim of producing a degree of mandibular protrusion, therefore improving the stability of the pharynx during sleep.

Bariatric surgery: gastric or gastrointestinal surgery performed to produce weight loss, by either reducing the capacity of the stomach or bypassing part of the small intestine.

## 3. Existing guidance for sleep apnoea service provision

Guidelines for investigation and treatment of OSAS were produced in 2003 by the Scottish Intercollegiate Guideline Network (SIGN) (11), but have not been implemented widely in England and Wales. CPAP was recommended by NICE in a Health Technology Appraisal (HTA) published in March 2008 (5). The recommendations are to be implemented by the end of March 2009. The conclusions of the NICE HTA were:

1. Continuous positive airway pressure (CPAP) is recommended as a treatment option for adults with moderate or severe symptomatic obstructive sleep apnoea/hypopnoea syndrome (OSAHS).
2. CPAP is only recommended as a treatment option for adults with mild OSAS if:
   - they have symptoms that affect their quality of life and ability to go about their daily activities, and
   - lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate.
3. The diagnosis and treatment of OSAHS, and the monitoring of the response, should be carried out by a specialist service with appropriately trained medical and support staff.

Recommendations for provision of sleep diagnostic and treatment services in general have been published by the Department of Health (England) in relation to achieving patient waiting times of less than 18 weeks (12). In addition, clinical algorithms for investigation and treatment of OSAS have been published as part of the "Map of Medicine" initiative, endorsed by the DH (13).

The service specification presented here focuses on OSAS and is intended to aid both commissioners and providers of health care in delivering a high quality and cost effective service for the investigation and treatment of patients with

this condition. It has been produced jointly by the British Thoracic Society (BTS) (1), Association for Respiratory Technology and Physiology (ARTP) (2), General Practice Airways Group (GPIAG) (3), and the patient support group, the Sleep Apnoea Trust Association (SATA) (4).

## 4. Aims and Components of a sleep apnoea service

A full service for patients with suspected OSAS includes initial clinical assessment, investigation, diagnosis, provision of treatment, patient support and education and clinical and technical follow up, long term supervision of treatment and prompt provision of replacement equipment and parts. In order to satisfy the principles of the recent Darzi report on the NHS (14), the provision of care should be fair, safe, effective and personalised. For OSAS these principles can readily be satisfied by removing inequities of provision, improving road safety by ensuring that effective treatment is available for all who need it, in accordance with the recommendations of the NICE HTA and providing a responsive, timely and individualised service for investigation and treatment. In our view this is best achieved by an easily accessible comprehensive service, core components of which include:

- Initial assessment of patients referred from primary or secondary care, including evaluation of the primary problem, differential diagnosis and relevant comorbidity
- Availability of an experienced specialist multidisciplinary team, comprising medical, nursing and scientific or technical specialists
- Ready access to facilities for investigation of possible OSAS on a domiciliary and/or in-patient basis
- Availability of, or reasonable access to, facilities for more detailed sleep investigation as required
- Facilities, equipment and experienced personnel necessary to initiate CPAP treatment
- Personnel and facilities to provide necessary support and training for patients commencing CPAP therapy
- Availability of a wide range of interfaces to allow provision of the most appropriate CPAP machine and interface, plus humidifier if required
- Regular monitoring and follow-up of patients
- Open access for CPAP-related problems or telephone help and support line, 9-5/Mon-Fri
- Provision of replacement machines and parts as required
- Monitoring of patient compliance, symptoms and side-effects of treatment
- Onward referral for more specialised investigation where clinically appropriate
- Reporting to the patient's registered GP and secondary care specialist(s) following each patient contact (other than parts provision)
- Providing advice and reports for other agencies eg occupational health services and DVLA regarding medical fitness for work and driving
- A database of patients receiving CPAP, to include equipment type, interface, settings, service history and compliance
- Providing advice and recommendations on alternative or adjunctive treatment eg weight reduction, mandibular advancement devices
- Close liaison or integration with services which share similar expertise and technology (eg long term domiciliary NIV)
- Ready access to, and cooperation with, clinical services dealing with the common comorbidity of OSAS (obesity, diabetes, cardiovascular disease, ENT conditions, etc)
- Obtaining data on patient related outcome measures (PROMs) in accordance with agreed audit criteria and providing reports for monitoring and informing commissioning decisions.

## 5. Roles of primary care

Most primary care practitioners have limited experience of the condition; it is not widely taught in medical schools and features only very briefly in the General Practice training curriculum. Individuals with OSAS may consult their General Practitioner (GP) with snoring and/or nonspecific complaints, including poor quality sleep, fatigue, mood disturbance and relationship problems. The recognition and diagnosis of OSAS would be improved if GPs were trained or reminded to consider the possibility of OSAS in such situations. GPs should be encouraged to use the Epworth Sleepiness Scale as a simple guide to the severity of daytime sleepiness. The NICE HTA (5) recognised that there are currently insufficient resources and expertise in primary care for general practitioners to take the main responsibility for patients being treated with CPAP for OSAS. However, GPs clearly have a very important role in the initial suspicion or recognition of the condition. Normally, this leads to referral to secondary care, usually to a respiratory medicine department with an experienced team providing a sleep apnoea service. Depending on local arrangements and geography, "outreach" sessions may be provided by specialist teams in a primary care setting. Patients not requiring specific treatment are referred back to the general practitioner, who also shares responsibility for the clinical follow up of those receiving treatment. Good liaison and communication with primary care is an important responsibility of service providers, and should include guidance for primary care practitioners on how to recognise problems and complications in patients on CPAP treatment.

## 6. Role of specialist service

The NICE HTA (5) recommendation no. 3 (para. 3 above) emphasises the need for investigation and treatment by a specialist service because all the randomised controlled data demonstrating the considerable cost/benefit ratio of CPAP in OSAS come from hospital departments with experienced medical and support staff, together with the necessary infrastructure. Other evidence shows that patient support influences compliance with therapy (and therefore, cost/benefit ratio). In cannot be assumed that similar benefit would accrue if the treatment was initiated and monitored in a less expert and supportive environment. Integration with related services (eg domiciliary NIV) and close synergy with services covering the common comorbidities of OSAS offer both clinical and financial economies. Provision of therapeutic equipment by secondary care benefits similarly from economies of scale.

### 6.1 Role of clinician responsible for specialist service

The service requires an appropriately experienced medical lead (usually a consultant respiratory physician) to provide clinical leadership, service development and innovation. In addition to overall supervision of the service, his /her roles include clinical assessment, recognition of relevant comorbidity, interpretation of the sleep study in the context of the overall clinical picture, diagnosis (and differential diagnosis), decisions on treatment and availability for advice to other members of the team and provision of reports to relevant external agencies (eg occupational health, DVLA).

### 6.2 Roles of non medical staff

In most departments, the day to day running of the service is by non medical staff with experience in sleep apnoea. Depending on local circumstances, these include specialist nurses, clinical physiologists, clinical scientists and respiratory physiotherapists. They should have ready access to the physician responsible for the service for clinical advice as required. The roles of individual healthcare professionals vary considerably in different departments, with specialist nurses often having a more clinical and educational role, while technical and scientific staff may be more responsible for diagnostic sleep studies, technical reporting and provision of CPAP, but rigid demarcation of responsibilities is not appropriate. Nurse led clinics for follow up of patients on treatment are the norm in many departments. Adequate secretarial, administrative and IT support is also essential.

## 7. Diagnosis of OSAS

Accurate diagnosis of sleep apnoea and assessment of the likely future benefit from treatment are essential before long term treatment is initiated and should be the responsibility of an experienced physician. Both snoring and sleepiness are very common, with snoring affecting about 40% of the adult population and sleepiness about 10%. Consequently, the two will often occur together by chance and correct attribution of the symptoms and the identification of other reasons for sleepiness require an appropriate clinical history in addition to a sleep study. Other conditions which can cause, or contribute to, daytime sleepiness include narcolepsy and other neurological disorders, depression and periodic limb movement disorder, in addition to the effects of medication, social factors and shift work. Misdiagnosis, and consequent inappropriate provision of CPAP, are both wasteful economically and potentially harmful to patients. As with any other serious condition, confirmation of diagnosis is necessary before embarking on potentially lifelong treatment. Incorrect diagnosis and inappropriate provision of CPAP equipment are not uncommon, leading to waste for the NHS, delaying optimal treatment of the individual and undermining the value of an otherwise highly effective form of treatment. If a patient's care is transferred to a different sleep service (e.g. due to relocation or seeking a further opinion) the evidence for the diagnosis and appropriateness of the treatment should be fully reviewed. Differential diagnosis also includes the distinction from central sleep apnoea (e.g. as seen in some patients with congestive heart failure) and the recognition of patients with chronic respiratory failure, due, for example, to obesity hypoventilation syndrome or coexistent COPD, as they may require alternative treatment such as nocturnal non-invasive ventilation. Furthermore, it is important that other health problems associated with OSAS, such as hypertension, diabetes and the metabolic syndrome are identified and treated appropriately.

## 8. Types of Investigation

The technology used for investigating sleep apnoea is of secondary importance to the experience and training of those interpreting the results. Investigations for suspected OSAS are often performed in the patient's home, using either oximetry or Respiratory polysomnography. Depending on local circumstances, studies may need to be performed in hospital, e.g. if patients have to travel a long distance and/or express a preference for in hospital rather than domiciliary investigation. A minority of patients require full polysomnography in hospital, particularly if there is serious doubt about the diagnosis.

Oximetry alone can confirm severe OSAS but has significant rates of both false negatives and false positives, such that Respiratory PSG is now preferred as the primary investigation in many departments. Irrespective of the type of investigation, accurate reporting, recognition of artefacts and interpretation in the clinical context are essential, and these require considerable experience. Reliance on automated analysis to decide potentially lifelong treatment produces too many errors for clinical acceptability and all sleep studies should be subject to detailed manual review of any automated scoring.

Detailed specifications for diagnostic sleep equipment can be found in *Appendix A.*

## 9. Management of OSAS

The treatment of a patient with OSAS (or any other type of sleep-disordered breathing) should not be determined solely by the result of a sleep study. The decision requires specialist medical input and depends on the combination of symptoms, clinical assessment, the results of the sleep study and the patient's willingness to accept the treatment proposed. A sleep study is used to identify the presence of sleep disordered breathing, clarify its nature and assess the severity of the physiological disturbance, but the decision to treat and the long term benefits of treatment depend more on pretreatment symptoms than on precise indices derived from a sleep study. A decision to treat based solely on measurements such as the apnoea/hypopnoea index (AHI) is not appropriate and is unlikely to result in good compliance with therapy. Weight reduction advice is important for the overweight and obese, but many patients with OSAS are of normal weight or only mildly overweight. In patients with troublesome symptoms it is not appropriate to defer treatment with CPAP pending attempted weight loss. Other forms of treatment which may be relevant to particular individuals include bariatric surgery, tonsillectomy or an intraoral mandibular advancement device.

## 10. Treatment by Continuous Positive Airway Pressure

The treatment of OSAS by CPAP is highly effective. It usually implies an indefinite commitment by both the patient and the sleep service, as treatment, at least of more symptomatic individuals, is potentially lifelong. It is a testament to the efficacy of CPAP that many thousands are willing to use it every night despite the inconvenience and occasional discomfort. Few other medical treatments have such profound effects on quality of life and social functioning and relationships. It is important that CPAP is provided within the context of a face to face education package, so that patients fully understand the nature and aims of treatment, how to recognise when these are not being achieved, how to maintain the equipment and whom to contact for advice and replacement parts. Unlike most forms of medical treatment for chronic conditions, CPAP has the distinct advantage that use of the treatment can be continuously monitored. Such monitoring should be an essential component of periodic surveillance and is an important outcome to document as part of clinical audit.

### 10.1 Specifications for CPAP and related equipment

Details of the essential and desirable technical features of CPAP and related devices are given in *Appendix B.*

### 10.2 Initiation of CPAP treatment

Some patients struggle at first with CPAP treatment and without appropriate support would not persist. Education, encouragement, attention to detail and time spent with the patient are essential at the start and during the early period of treatment and have a major influence on long term compliance. Prescription of the equipment alone, without such support, is likely to be unsuccessful. It is common experience in specialist centres that inadequate initial introduction of the treatment can have a negative effect and can lead to individuals being regarded incorrectly as "CPAP intolerant". Although subsequent re-introduction with more appropriate education, encouragement and support may still succeed, the initial experience can seriously prejudice eventual success. Companies should not supply devices to the general public unless they have contacted the patient's named sleep specialist and received a copy of a recent sleep study report or a clinical letter confirming the diagnosis of obstructive sleep apnoea together with the recommended device settings.

### 10.3 Pressure setting

In many departments the pressure is decided after using an auto-titrating device (APAP) for the first night or few nights, with the optimal fixed pressure inferred from the overall pressure profile recorded (e.g. by setting the pressure at the 95th centile of the auto CPAP recording). Others use an algorithm or a standard pressure with later adjustment as required (e.g. increasing empirically if the patient reports continued snoring while using CPAP).

APAP for long-term treatment may be indicated:

- When fixed pressure CPAP fails due to discomfort, particularly when high pressures are required.
- If a cost benefit analysis shows that the use of APAP, by removing the requirement to establish the fixed pressure a patient requires, is cheaper than CPAP.

Bilevel pressure support (non invasive ventilation) may be indicated when a patient presents with decompensated ventilatory failure (raised $PaCO_2$ and low pH), when symptomatic hypercapnia persists on CPAP alone or when either of these develops during follow up (eg in the face of progressive weight gain). A service which combines the management of OSAS and domiciliary NIV allows such transfer to occur smoothly.

### 10.4 Patient interfaces and humidifiers

The original method for applying CPAP to treat OSAS was via a tight fitting nasal mask. Subsequently a large range of nasal, oronasal, oral and full face "interfaces" have been developed; each may be supplied by several manufacturers and most come in various sizes. Interfaces are more important for comfort and compliance with treatment than the CPAP hardware itself and not infrequently, patients need to try several different devices before identifying the one which suits them best and produces minimal discomfort. It is, therefore, essential that services have a variety of interfaces and a range of such "consumable" items from several manufacturers should be available. Detailed specifications for interfaces are given in *Appendix C*.

The most frequent side effect of CPAP treatment is uncomfortable drying of the pharyngeal and buccal mucosa. In most patients this is alleviated by changing to an oronasal interface or adding a heated humidifier to the circuit. Some CPAP devices are supplied with integral humidifiers. On average about 40–50% of patients receiving long term CPAP treatment benefit from humidification of the air. Technical specifications for humidifiers are summarised in *Appendix B*.

### 10.5 Initial treatment phase

In many centres, the decision about long term treatment with CPAP follows a trial period (often 2–4 weeks). In the early weeks of treatment with CPAP, frequent contact may be required by the patient for troubleshooting, encouragement, re-fitting or changing interfaces, adding a humidifier etc. Such contact can be either face to face or by telephone but, in either case, it is essential that patients have ready access to experienced staff. Even with optimum encouragement, education, trials of various interfaces etc, a proportion of patients eventually do not persist with CPAP treatment. In some, the symptoms may have been due to other causes such as depression or medication, while a few are genuinely intolerant of the treatment due to problems such as claustrophobia. Early review should allow most of these issues to be clarified and with appropriate choice of patients, the "failure rate" is likely to be no more than 20%. Health professionals need to be aware that CPAP can have a significant placebo effect, in which case early symptomatic benefit may not be sustained, emphasising the need for accurate pretreatment diagnosis and effective follow up with routine monitoring of objective compliance.

### 10.6 Persisting symptoms

A minority of patients remain sleepy despite good compliance with CPAP. Causes include inadequately titrated pressure or mask leakage, in addition to other causes of sleepiness, such as comorbidity, medication or social factors eg shift work or inadequate sleep duration. Persistent sleepiness should prompt senior medical review to consider alternative diagnoses, the need for a more detailed sleep study and/or the need for repeat CPAP titration.

### 10.7 Long term supervision of CPAP treatment

Once CPAP treatment has been established satisfactorily, the patient should remain under periodic review, combining clinical contact with a check on the machine (interface, headgear, filters, compliance). Annual review is usually desirable but some with well controlled OSAS may be seen less frequently provided they have ready access to technical support for replacements and breakdowns. Effective liaison with primary care should ensure that such patients are seen promptly for full clinical review should the need arise.

Periodic review is required for several reasons including:

- Patients may not be aware that a part of their system is no longer functioning properly.
- Some patients give up CPAP following an event such as a cold and, as a consequence of recurrent sleepiness, may not be motivated to return to CPAP. Encouragement and re-fitting often correct this. Failure to continue CPAP, with a return of symptoms, essentially means that resources expended originally on diagnosis and treatment were wasted.
- The pressure required may change, e.g. following weight loss or gain, tonsillectomy, or correction of any underlying hormonal abnormality (e.g. hypothyroidism, acromegaly).
- Some patients slowly develop chronic ventilatory failure and may need consideration of transfer to NIV/bilevel pressure support.
- Many patients appreciate the reassurance that the condition remains well-controlled, if only on an annual basis.
- A record of compliance and symptoms needs to be kept for auditing and quality assurance purposes.
- In the case of professional drivers, the DVLA require annual confirmation of symptom resolution and compliance with CPAP.

Irrespective of the need for regular follow up, interim ad hoc contact is frequently necessary, particularly for troubleshooting problems and replacing masks, tubing or headgear and ready availability of experienced personnel is essential. This service may be provided either by open access during normal working hours or by telephone contact. Replacement parts need to be dispatched promptly if patients are unable to collect them. On average, masks and other interfaces require replacement every 9–12 months, while CPAP pumps usually survive for an average of about 7 years.

Further clinical attention may be necessary during long term treatment to deal with problems such as major nasal congestion, nasal bridge ulceration and persisting sleepiness. Failure to address these issues will lead to lower compliance and poor resolution of symptoms, or, indeed, to the patient stopping CPAP. Although most of the follow up is appropriately performed by experienced non-medical staff, specialist medical advice should be readily available if the cause of problems such as persistent or recurrent sleepiness is not immediately evident. Advice is often required for patients who require hospitalisation for surgical procedures or other reasons, as many medical and nursing staff in other specialties are unfamiliar with OSAS and its treatment.

## 11. Other Methods of Treatment

### 11.1 Intraoral mandibular advancement devices

A variety of intraoral devices, aimed at stabilising the pharyngeal wall during sleep, is available. Most are made to fit over the upper and lower teeth, with the lower jaw partly protruded. They range from simple “boil and bite” devices which can be purchased directly to more complex custom made devices supplied by dentists or orthodontists after appropriate impressions have been taken with the lower jaw protruded to the desired extent. Some are “titratable”, in that they allow gradual mandibular protrusion over days or weeks. The exact place of these devices in management of OSAS is unclear, although their efficacy is clearly less than that of CPAP in patients with more severe disease (15). They are used as “next best” treatment in patients with milder disease who find CPAP inconvenient and, occasionally, as an adjunct to CPAP in more severe disease. As primary treatment for OSAS, they should be provided only on specialist recommendation after full assessment.

### 11.2 Weight reduction and bariatric surgery

Weight management advice should be readily accessible where clinically appropriate. Occasionally, dieting is sufficiently effective for the symptoms of OSAS to resolve and for CPAP no longer to be necessary, but in most symptomatic individuals this remains a long term aim which is never realised.

In a few individuals with severe obesity and appropriate indications, bariatric surgery may be considered as a treatment option for OSAS. Depending on the weight loss achieved, this type of treatment has been shown to improve or cure OSAS, along with its other recognised health benefits (10). Referral should follow agreed protocols and will often be initiated by the General Practitioner. Such patients are likely to continue to require CPAP therapy up to and after surgery, though in the longer term it may prove possible to discontinue it, provided that reassessment confirms adequate resolution.

Because of the strong association of OSAS and obesity, all patients being considered for bariatric surgery should be evaluated by screening for potentially relevant symptoms, followed if appropriate by a diagnostic sleep study.

### 11.3 ENT surgery

Before the introduction of CPAP, tracheostomy was sometimes used as the only effective treatment for patients with OSAS, but it is performed very rarely nowadays. Tonsillectomy has an role in the management of some, usually younger, individuals with significant tonsillar hypertrophy and may be curative, especially in children. Other types of pharyngeal surgery are not usually recommended in patients with symptomatic OSAS. Procedures to improve nasal patency are occasionally helpful, for example in individuals in whom compliance with CPAP is limited by nasal obstruction.

## 12. Information for patients

Appropriate adjunctive support for patients should be freely available, with information leaflets available in clinical areas. A range of literature and a helpline are provided by the patient support organisation, the Sleep Apnoea Trust Association (4). Educational and training videos e.g. related to initiation of CPAP are used in some departments and are strongly recommended.

## 13. Implications of OSAS for driving

A diagnosis of the sleep apnoea syndrome has important implications for driving. This does not apply to individuals in whom apnoeas may be demonstrable during sleep, but who are otherwise asymptomatic. In the UK, the DVLA states clearly that a patient with OSAS should inform them of the condition and that driving should cease until symptoms are controlled (6). It is very important in this context to differentiate sleep apnoea (the pathophysiological finding) from the sleep apnoea syndrome (which combines sleep disordered breathing with relevant clinical symptoms). The latter requires accurate diagnosis in both technical and clinical terms. Whether the symptoms are sufficiently severe to impair the ability to drive safely, or, indeed, whether they are actually related to the sleep apnoea, requires specialist medical assessment. Neither blanket bans on driving, based solely on the result of a sleep study, nor deliberate evasion of the issue are appropriate. In addition, a diagnosis of sleep apnoea has important implications for motor insurance as companies generally consider that the condition should be declared and they

might decline to cover someone who subsequently turns out to have sleep apnoea and who has not told either the DVLA or the insurance company. This is a particularly difficult area and patients need guidance if they are not to run foul of the law and risk the legal consequences. A properly documented, evidence based, diagnosis of sleep apnoea (or alternative disorder) is therefore essential. In addition, establishing whether resolution of symptoms has been sufficient to allow resumption of driving once the patient has started treatment is often an important component of the follow up and requires specialist medical opinion.

Clearly, driving issues are of particular importance to professional drivers and to others whose livelihood depends on their ability to drive safely. Individuals falling into these categories need urgent investigation and treatment and a facility for "fast tracking" should be available. After resuming driving, once symptoms are controlled, drivers of heavy goods and public service vehicles may require specialist annual review to confirm their continued fitness to drive.

## 14. Resource requirements for sleep services (personnel and facilities)

It is difficult to be specific when recommending staffing requirements due to the varying ways in which established services have evolved and also to the considerable variation in size of catchment areas. Economies of scale are self evident, not only in terms of equipment provision but also in patient education eg, with group initiation of CPAP as practised in some units. It is also important to recognise the cumulative effect of the inevitably growing number of patients on long term treatment. Consequently, most departments which have been in operation for some years have seen considerable growth in total numbers requiring long-term supervision. This growth is likely to continue for the foreseeable future as best estimates suggest that no more than 1 in 4 patients with symptomatic OSAS in the UK have so far been identified. Furthermore, the increasing prevalence of obesity (especially morbid obesity) in the general population inevitably implies a parallel increase in the prevalence of OSAS. Convenient access to specialist facilities for investigation and treatment are therefore essential for the population of each PCT (or equivalent). Our consensus view is that these facilities should be available in each large general hospital or group of hospitals and usually provided by the Respiratory Medicine department or service.

The following suggestions should be taken as only approximate and the numbers of staff required are likely to increase as accrual of follow up patients continues. As a guideline, an average PCT responsible for a population of about half a million might expect approximately 500 new referrals per annum, 200 new CPAP patients per annum and a cumulative follow up population of 1500 on long term CPAP treatment. For this level of activity a sleep apnoea service is likely to need:

- consultant medical staff (usually respiratory physician) 0.5 – 0.8 wte
- nursing/scientific/technical staff 3 – 4 wte
- secretarial/clerical staff 1 wte

Additional requirements will apply to services which care for patients with OSAS within a comprehensive service covering the broad range of sleep disorders and for those also responsible for domiciliary NIV.

Single rooms need to be provided for in patient sleep investigations. Many diagnostic investigations and initiation of CPAP are performed in a domiciliary setting with the patients attending the department for instruction, education and demonstration. Adequate clinical space and facilities for patient education need to be provided. An accurate database of patients on long term treatment is an essential component of the service.

Access to full PSG is necessary for a minority of patients but this will not be available in every department/service. It should however, be possible for appropriate patients to be referred conveniently to a facility which provides this service without undue delay or the need for lengthy travel.

## 15. Training requirements

### 15.1 Medical personnel

Training and experience in sleep disordered breathing is an essential part of the curriculum for all specialist registrars in Respiratory Medicine (16). Trainees should spend a minimum of 3 months in a service under the supervision of an experienced physician. This period should allow the trainee to assess at least 50 new referrals, to report 50 sleep studies and supervise CPAP initiation in at least 20 patients, together with appropriate follow up experience. All respiratory consultants appointed in the last few years have significant experience. A longer period of subspecialty training (minimum 12 months) is recommended for those responsible for a comprehensive sleep service (11). Sleep apnoea should feature more prominently in the medical undergraduate and general practice curricula.

### 15.2 Nonmedical personnel (physiologists, scientists, specialist nurses, physiotherapists)

Standards for training of clinical physiologists and clinical scientists are covered in detail by the ARTP (17). The skills and knowledge required imply that an experienced practitioner would be graded at AfC Band 6 or above; s/he needs to have supervised experience in a department providing sleep diagnostics, to have analysed and reported

at least 50 respiratory sleep studies and to have initiated CPAP treatment in at least 20 patients under the overall supervision of an experienced consultant physician

No specific training requirements have been laid down for other health professionals involved in the investigation and treatment of sleep apnoea. Many are nurses with several years' clinical experience, usually in associated areas such as general respiratory medicine or a high dependency unit. Others may be experienced respiratory physiotherapists. The training of such individuals is mainly by supervised work experience which should be similar to that outlined above and should also include attendance at a relevant training course such as those provided by the BTS, ARTP and British Sleep Society (18).

## 16 Performance indicators/service audit tools should include:

### 16.1 Availability of facilities and services

The equipment available for diagnosis and monitoring of OSAS should include:
Oximeters capable of recording $SaO_2$ and pulse rate at the appropriate sampling frequency (see *Appendix A*) for at least 8 hours overnight. They need to be small and comfortable so as to disturb sleep as little as possible, using finger probes rather than ear probes. The downloaded data on $SaO_2$ and heart rate should be displayed sufficiently clearly for individual oscillations over a time frame of 30 seconds to be visible. Reporting of results must be by trained and experienced individuals and interpreted in the relevant clinical context as artefacts, misdiagnosis, false positives and false negatives are frequent.

Respiratory polysomnography (RPSG) ie devices that record several physiological signals, giving more information than oximetry alone and improving the diagnostic accuracy. Depending on the particular device, the signals recorded (in addition to $SaO_2$ and pulse rate) include various combinations of :oro-nasal airflow (via pressure signals), sound (for snoring), ribcage and abdominal movements (for recording respiratory effort and paradox), and posture. As with oximeters, the overnight recordings need to be fully visible for analysis and interpretation, a process that requires considerable experience; computer derived indices alone are not adequate. Oximetry and RPSG can be carried out in hospital or at home. The relative costs and convenience of the two approaches will depend on individual and local circumstances, including patient choice, geography and availability of facilities. Patients travelling a long distance often prefer to be studied in hospital rather than make the journey twice, as is necessary for collection and return of the recording device. The ability to perform a synchronous video recording in a sleep laboratory is particularly helpful in difficult cases, and also for education and training. If studies are being done in the patient's home, it is essential that clear (usually written) instructions are given. For in patient studies, overnight facilities need to be quiet and temperature controlled, resembling a normal bedroom as much as possible.

Full polysomnography ie including the recording of neurophysiological signals (electroencephalography (EEG), electro-oculography (EOG), and electromyography (EMG)), in addition to the signals included in RPSG. These neurophysiological signals allow the staging of sleep and the identification of cortical micro-arousals, but they are not necessary for diagnosis of the great majority of patients with OSAS; full PSG but may be indicated particularly if the differential diagnosis includes other sleep disorders. The relevant facilities and expertise may not be available locally but the method of access should be clearly defined.

### 16.2 Availability of experienced personnel

Sleep services involving the care of patients with sleep apnoea need to be led by a consultant (usually, though not exclusively, a respiratory physician) fully trained and experienced in sleep medicine. Sleep disorders are often lifelong and both making the correct diagnosis and providing the best treatment available are clearly essential. Thus, the overall responsibility for the service requires the diagnostic and therapeutic experience of a medically trained specialist. Many of the functions within a department providing a service for patients with OSAS are appropriately carried out by non-medical staff and the recommendations for training outlined in paragraph 15 should be in place.

Depending on the particular requirements of the service, a blend of technical and nursing expertise will be required. The setting up, and downloading of sleep studies and the maintenance of the equipment are more usually the responsibility of scientific and technical staff, while clinical consultation with patients is more usually the role of a specialist nurse. Any such demarcation is, however, in no way proscriptive and there are successful services delivered entirely by each professional group. Experience, enthusiasm and empathy with the patients are more important than professional alignment. All aspects of diagnosis and management require a significant time commitment and it is essential that a sufficient number of experienced individuals is available for the likely workload. Considerable administrative and clerical work is also required to run an efficient and responsive service and the appropriate secretarial/administrative time needs to be made available. Staffing guidelines in relation to the size of population served are indicated in paragraph 14. Many established departments have a responsibility for educating trainees in all the relevant professions and additional time will be required for training and education.

### 16.3 Requirements for CPAP treatment

*Interfaces*

As the requirements of individual patients vary considerably, a range of interfaces from a number of manufacturers must be readily available

*Initiation of treatment*

Patients starting CPAP treatment are often very anxious about the prospect and, to ensure optimal compliance, knowledgeable, enthusiastic and sympathetic personnel are required to deliver an appropriate induction programme. The initial patient training may be given individually or in a group, but masks and other interfaces need to be fitted individually in quiet and confidential surroundings. Educational aids, such as video and PowerPoint presentations, are extremely useful to ensure all relevant points are covered at each training session. For this a comfortable room with computer and video display facilities, in addition to individual fitting rooms, are required.

*Pressure Titration*

The pressure required by individual patients can be determined by various methods (see paragraph 10.3). The method adopted, the supporting evidence and success rate should be cited.

*Regular monitoring*

All patients using CPAP must have rapid access to skilled follow-up and equipment maintenance; this includes ready availability of medical advice where services are run primarily by nonmedical personnel. Facilities for appropriate trouble-shooting, such as home overnight monitoring and auto-titrating machines, are also required.

Following satisfactory control of OSAS with CPAP, patients should be reviewed periodically (eg annually) with monitoring of the following outcome measures:-

- CPAP compliance/adherence (from internal machine data)
- Symptom control (from appropriate scoring systems, e.g. ESS)
- Potential side effects (from appropriate interview questions)
- Potential ventilatory failure (from appropriate measurements, e.g. $SaO_2$ and blood gases)

*Rapid response service*

Support by telephone needs to be provided 9-5/Mon-Fri (with answerphone facility at other times). Patients with problems that are not soluble by telephone, should be offered an out-patient appointment within 3 days, or a 9–5 / Mon–Fri “drop-in” service should be available. The service should include both skilled advice on CPAP issues, as well as immediate replacement of parts.

### 16.4 Availability of database

An up-to-date database of patients receiving CPAP must be maintained and available to all staff caring for these patients at the time of any interaction, either by phone or face to face. In addition this database can be used to keep information for audit purposes (eg compliance and current ESS) and for research. Information should be readily available on annual numbers of referrals, sleep studies and CPAP issues.

### 16.5 Access to other treatments

*Intra-oral mandibular advancement devices*

Although the place of oral devices for the control of sleep apnoea is not fully established, they are a possible alternative for patients with mild OSAS, or as a second line therapy for patients who are truly intolerant of CPAP. Availability via NHS funded services is variable around the country, but advice on accessing an appropriate service should be available for those in whom this type of treatment is recommended.

*Obesity services*

Because obesity plays a large role in causing OSAS, weight reduction services are a useful adjunct to a sleep service. Access to such a service, as well as to departments providing bariatric surgery is recommended.

*Cardiovascular risk reduction*

Comorbid disease is very common in patients with OSAS and screening for hypertension, diabetes and lipid abnormalities is appropriate, unless already undertaken by primary care.

### 16.6 Patient Related Outcome Measures and Audit

The overall clinical success of CPAP induction and support can be monitored and measured as the proportion of patients originally set-up on CPAP who are still using it at one year, with a compliance >3 or 4 hours per night.’ It should, however, be noted that CPAP is often used initially as a ‘trial of therapy’, partly for diagnostic reasons and consequently, a certain ‘failure’ rate is to be expected unless the denominator is adjusted to take account of this

practice. If, however, the evaluation is confined to patients with more severe disease (e.g. an initial AHI/ODI >30 per hour and initial ESS >12), services should aim to achieve >90% of such patients satisfactorily established on treatment and continuing to use CPAP regularly at one year.

Patient satisfaction surveys should be performed to monitor the success of treatment in terms of symptom control, as well to evaluate aspects of the service, such as the environment, accessibility, organisation, information given and performance of the personnel involved and policies for remedying any deficiencies identified should be established.

### 16.7 Research

There are many unanswered questions about OSAS and the possible long term benefits of treatment, particularly in relation to vascular risk (e.g. the likelihood of heart attack and stroke). It is, therefore, very important that services are able and willing to participate in appropriate clinical trials, otherwise progress in this area will stagnate. Similarly, there is a need for research into the health economic benefits of investigation and treatment of OSAS, as, without further information, there is the potential for both inappropriate over- and underprovision of treatment.

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## APPENDIX A Specifications for diagnostic equipment*

### GENERAL

Sleep investigational equipment should comply with international/European Union standards which include IEC 60601-1 General Requirements for Safety of Medical Electrical Equipment and CE Marking.

Operating instructions must be in the English language with appropriate clear diagrams, and illustrations.
Infection Control.

Any reusable physiological sensor which may come into contact with the patient must be capable of withstanding robust disinfection or cleaning by normal infection control methods. Manufacturers should specify the process of decontamination to be used for each sensor supplied. All the cleaning processes and reagents specified must be readily available in the United Kingdom. Patients undergoing sleep studies should be instructed to bathe/shower, to wear clean night attire, and to sleep in a bed with freshly laundered bedding.

**Maintenance and Security of Recorded Data**

Systems which rely on laptop computers to record data in real time are not recommended given the security implications. All recorded data should be archived for future reference, preferably using the hospital server rather than less secure DVD or external hard drive. Equipment should include the facility to compress/decompress data in order to minimise archive storage requirements. An archived recording should not exceed 10Mb.

### TECHNICAL REQUIREMENTS

**General**

Sampling frequencies must be appropriate for the frequency characteristics of the physiological signals being captured. The minimum acceptable digital resolution is 12 bits per sample.

**Oximetry**

Users need to be aware of the limitations of an inadequate sampling frequency when using pulse oximeters in the diagnosis of OSAS as this can seriously underestimate the severity of desaturation events (dips). The minimum acceptable sampling frequency of oximeters for use in sleep studies is 5Hz. Some oximeters record samples only every 5 or 12 seconds which is inadequate. Similarly, data averaging or smoothing by the download software can further compromise the specificity of oximetry for diagnosis. Equipment manufacturers and suppliers should clearly state in their instruction manuals and specifications what data averaging and smoothing algorithms are being applied.

In addition to finger probes, others are available for ear lobe, toe, nose and forehead. In general, finger and ear lobe probes appear to be the more accurate though recent technological advances have improved the accuracy of forehead probes.

The oximeter memory should be capable of storing at least 12 hours' data.

*Alarms*

An adjustable low saturation alarm is advisable but it should be possible to turn it off in order to record the patients' usual values.

*Artefact*

It is important to be aware that the degree of desaturation varies with the baseline $SaO_2$. Younger, otherwise healthy, individuals are less likely to show desaturations, while if the baseline $SaO_2$ is low, desaturations will be more marked.

Motion artefact is common and it is important for an experienced person to check the computer analysis, deleting artefactual dips as appropriate.

The performance of pulse oximeters is affected by poor perfusion and skin pigmentation. Many of the commonly used oximeters are inadequate for obtaining reliable recordings in patients of African, Afro-Caribbean or Asian origin.

**Snoring**

Snoring can be recorded using a variety of microphone types (tracheal, attached to airflow sensor tubing, room, etc) or the associated oscillations of nasal pressure can be derived mathematically from a pressure transducer used to measure airflow.

**Chest and Abdominal Movement**

Chest wall and abdominal movement are usually measured semi quantitatively using inductance bands, strain gauges or magnetometers, with the phase relationship used to identify respiratory events as obstructive or central.

**Airflow**
A pneumotachograph gives accurate, quantitative information but is too cumbersome for routine use. In practice, airflow is usually derived semiquantitatively using thermistors (which detect changes in inspired and expired air temperature) or nasal cannulae (which measure changes in nasal pressure). The former are less accurate for identifying hypopnoeas and nasal pressure is usually the preferred choice. The vibrations associated with snoring can also be identified using this signal.

**Body position**
Body position is measured using either a mercury switch or a piezo-electric device, usually on the chest or abdominal band. The measurement is important to check if respiratory events are position-dependent.

**Video**
Digital video is sometimes incorporated in a polysomnography system or there may be a separate system with digital or analogue video. It should be possible to time-synchronise the data to the events on video.

**Respiratory Polysomnography**
Equipment should be portable, battery powered and no larger than 34 cm when height, width and depth are summed. Devices should not require connection to an external computer during recording. They should have a minimum recording duration of 12 hours without replacement of batteries or recharging. Data must be downloadable and editable using either the manufacturers' software or a generic download software package. Clear verbal and written instructions, complete with simple diagrams, should be provided to patients for any domiciliary diagnostic investigations.

**Polysomnography**
Technical requirements are detailed elsewhere (17). For sleep staging, The recommendations of the American Academy of Sleep Medicine (19) should be followed.

Portable full polysomnography systems are available for use in the patient's own home, but they are not widely used for clinical investigation.

## APPENDIX B Specifications for CPAP and related therapeutic equipment*

Minimum standards for construction and performance of CPAP devices are essential to ensure the safety and effective treatment of patients. However, such standards are of no benefit unless the manner of provision of CPAP to patients and the subsequent monitoring and clinical supervision conforms to similarly robust standards. It is only by adopting this strategy that CPAP service provision will not be subject to the lowest cost without guarantee of quality.

CPAP devices have many optional features but certain essential features are necessary to ensure safe and effective treatment with minimal discomfort and infrequent need for contact with the sleep service. The device should have the facility for supplementary oxygen to be fed into the circuit when indicated (eg in patients with persistent hypoxaemia due to coexistent Chronic Obstuctive Pulmonary Disease or the Obesity Hypoventilation Syndrome).

**General standards**
Relevant minimum standards for CPAP devices ("IKK requirements") have existed in Germany for more than a decade. These also define a testing procedure for verification of compliance of any device, with standards in respect of operational noise level, stability and change of the respiratory tract pressure, gas purity, warming the inhaled air and, where appropriate, proof of humidity performance. No specific standards operate in the UK but CPAP devices should comply with international/European Union standards including those related to safety of medical electrical equipment and warranties; CE marking is essential. Operating instructions must be in the English language with appropriate clear diagrams, figures and pictures.

**Operational Modes**
There must be two modes of operation:
The prescriber/clinician mode enables settings to be made or adjusted and then locked so that the user cannot make adjustments; the user mode enables a limited range of comfort settings to be adjusted by the user.

**Cleansing and Infection Control**
The units must be easy to operate, use, clean and disinfect. Cleansing should be with recommended and widely available household cleaning agents. All parts which come into contact with the skin or mucosa should be confirmed as biocompatible and toxicologically safe. The device must be supplied with robust but flexible tubing of 2 metre (+/- 20 cm) length which fits firmly but easily using a 2 mm connection complying with EN 1281-1. The tubing must be washable using

recommended household cleansing agents and also be able to withstand disinfection/autoclaving to recognised hospital standards (low temperature steam [90˚ C], ethylene oxide). If a humidifier is used it must be possible to dismantle it completely and disinfect all parts thermally (machine washable).

**Portability**
Weight should not exceed 1.5 kg or 2.0 kg with an integral humidifier (without water). The sum of width, depth, and height should not exceed 45 cm for easy transport when travelling on airplanes, etc. With an integrated humidifier attached, the sum of W+D+H must not increase by more than 50%. The device must be supplied complete with a shoulder style carry bag to house all components and mask accessories. The maximum dimensions of the bag must not exceed 23 x 36 x 56 cm to comply with international aviation specifications for carry-on hand luggage.

**Noise**
Noise levels can often influence the tolerability of the patient or partner during long-term use of CPAP. Acceptable levels of noise (in decibels) are taken from manufacturers' data. These may not reflect standard methods of measuring noise, are dependent on the pressure setting, and may relate only to the noise level when the device is new. The acceptable noise range is 30 dB at 10 $cmH_2O$ at a distance of 1 metre (independent, standardised assessment conditions).

**Controls**
Control buttons should be large enough to be located easily in dark conditions. The use of raised patterns (e.g. like Braille) on control buttons is recommended, as also is use of controls which illuminate for a short period when pressed.

**Pressure settings**
The therapeutic pressure for OSAS is usually in the range 5–15 $cmH_2O$, but some patents may require pressures up to 20 $cmH_2O$. Devices should therefore deliver pressures from 4–20 $cmH_2O$ (in not greater than 0.5 $cmH_2O$ increments).

With bi-level devices both IPAP and EPAP are quoted. EPAP should be in the range 4–20 $cmH_2O$ and IPAP 4–30 $cmH_2O$. Bi-level devices should show a clear analogue or digital display of the actual pressure being delivered. Pressure settings must be protected against inadvertent adjustment.

CPAP machines should achieve the set pressure with a tolerance in accordance with international standards (e.g. IKK). Pressure checks should be performed by providers of service using a manometer which is routinely checked against a water manometer across its range every 6 months. The stability of pressures < 10.0 $cmH_2O$ should be ± 1.0 $cmH_2O$ and for ≥ 10.0 to 20.0 $cmH_2O$ should be ± 2.0 $cmH_2O$. Acceptable pressure tolerance (i.e. the pressure between the set CPAP pressure and the respiratory pressure on inspiration and expiration) should not exceed 0.67 $cmH_2O$. The ramp minimum pressure is a prescriber setting and should be adjustable from 4 $cmH_2O$ in no greater than 0.5 /$cmH_2O$ increments. The delay/ramp period should be adjustable from zero to 45 minutes maximum with the facility for the prescriber to set and lock in a shorter maximum period. The actual pressure should be displayed rather than a permanent fixed/set value. No device under fault condition(s) should be capable of delivering a pressure > 30 $cmH_2O$.

**Flow and Leak**
The device must be capable of performing correctly with automatic compensation over a minimum altitude range of sea level to 2500 metres.

**Flow**
Maximum flow is measured as free flow from the outlet of the device.
90 L.min-1 at 6.5 $cmH_2O$ (1/3 max pressure)
135 L. min.-1 at 13 $cmH_2O$ (2/3 max pressure)
165 L. min.-1 at 20 $cmH_2O$ (max pressure)

**Power supply**
All CPAP devices must have an automatic universal power supply which allows 100 to 240 V operation at 40–60 Hz without the need to change settings. Options for 12V and 24V DC operation are encouraged. Maximum power consumption without humidifier on 230 V AC power must be < 30 watts.

**Setup of prescribed parameters**
This must be achievable either directly using the operational keys on the device or remotely using PC/Mac software by means of USB or Data Card application. A default option for the settings applied by the prescriber to be locked and non-adjustable by the user is mandatory.

**Service**
CPAP devices and humidifiers should have minimal requirements for routine maintenance other than filter changes.

**Compliance measurement**
The compliance meter should not just measure motor usage, but should measure hours run at pressure. Some devices can detect when breathing is occurring and that the device is not simply switched on with a fixed resistance. This is important to ensure that patients are complying with treatment and may have medico-legal implications for CPAP patients involved in road traffic accidents.

**Optional features of CPAP devices**
These are often manufacturer specific features which add extra benefit to patients or service providers that may improve compliance, comfort and tolerance of the treatment. For example, there may be an Auto On/Off switching function which is breath actuated (typically by 2–3 breaths with the mask applied) and is a prescriber setting.

**Auto adjusting devices**
Auto adjusting devices (APAP) should provide a download facility to generate graphical reports showing (i) the delivered pressure versus time, (ii) any leak versus time and (iii) detection of any obstructive events (apnoeas, hypopnoeas, flow limitation and snoring). The use of mean, median and 95th centile pressure value (or similar) should be displayed. However, all suggested titration values should be validated in terms of the expected therapeutic response.

**Memory cards**
Some systems support remote compliance uploads via a data card system or similar technology (direct connection via USB to computer) allowing details of usage to be viewed remotely from the patient; such data should be stored for at least 6 months in the CPAP or data card.

**Humidification**
A humidification chamber or device should be capable of being attached or detached without the need to change the patient's CPAP device.

It must be possible to provide humidification of both cold and warm air and relative humidity should be adjustable from at least 70% to at least 90%.

The humidifier, like the CPAP device, must comply with all relevant standards (CE). It must be easily removable by the user, cleansable with common recommended household cleansing agents and dishwasher safe. Maximum power consumption with humidifier on 230 V AC power must be < 80 watts. When used with heated humidification, the device must provide water ingress protection if tilted 90 degrees in any direction.

## APPENDIX C Specifications for CPAP interfaces*

The interface material must be reasonably break-proof and long lasting. Whilst appreciating that certain components may be constructed for rigidity and strength, the interface must be as soft and pliable as possible to provide maximum patient comfort and the mask edges should not harden with age and cleansing. All materials used for the construction of interfaces and headgear must be independently certified as being medical grade, hypoallergenic substances. Interfaces must be available in a range of sizes and be adjustable to suit the requirements of the individual patient. Forehead rests where fitted must be adjustable for height, reach and rake. They should be capable of being dismantled and reassembled by an inexperienced user. All component parts must be able to be cleansed using recommended and widely available household cleaning agents.

Interfaces are required by legislation to be marked as either reusable or for simple patient use. Reusable masks must be able to withstand disinfection/autoclaving to recognised hospital standards (e.g. low temperature steam [90˚ C], ethylene oxide). However, care should be taken with reference to manufacturers to check whether cleaning methods have been tested.
It must be possible to connect a CPAP machine from any manufacturer/vendor to any CPAP mask/interface without adaptors. All interfaces should have a quick-release lock and full face masks must comply to safety standards that avoid risk of asphyxiation if the device fails or there is a power cut.

*These are abbreviated versions of the full specifications published by ARTP as "ARTP Standards of Care for Sleep Apnoea Services" (17)

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