

Position Paper

Best Practice Guidelines for Provision of CPAP Therapy

EXECUTIVE SUMMARY	2
INTRODUCTION	3
CPAP - Treatment for Obstructive Sleep Apnoea	3
CPAP Treatment Guidelines – Supporting Evidence	3
RECOMMENDATIONS.....	5
Financial and Business Arrangements:	6
Conflicts of Interest:	6
Organisational Considerations:	7
Facilities:.....	8
Training of CPAP Providers/Practitioners:	8
Provision of equipment:	9
Initiation of treatment:	10
Ongoing Management of CPAP Usage:	11
Quality Assurance.....	13
ATTACHMENT 1 – CONTENT OF REPORTS	15
GLOSSARY	16
CONFLICT OF INTEREST	19
REVISION DETAILS	19
REFERENCES	20

EXECUTIVE SUMMARY

Continuous Positive Airway Pressure (CPAP) is a first line treatment for moderate to severe obstructive sleep apnoea (OSA). CPAP is almost 100% effective when used regularly but adherence with treatment poses problems for many patients. The provision of CPAP involves more than simply selling a CPAP device and mask: it involves education, support and ongoing care including the monitoring of treatment adherence. This is often a shared responsibility between the patient, the sleep physician, the sleep clinic and a third party such as a business or organisation which provides CPAP equipment. This document sets out the minimum expected standards for a business or organisation which intends to provide a CPAP service.

The basic requirements are:

- An organisational framework that demonstrates a commitment to CPAP provision as a significant activity
- Premises that are appropriate for the services provided.
- Staff who are appropriately trained
- A choice of CPAP equipment sufficient to meet individual patient needs
- A CPAP initiation service which provides patients with adequate information and education to instil confidence in their treatment.
- A CPAP follow-up service which comprises an appropriate number of follow-up contacts and the opportunity for patients to access the service on an as-needed basis.
- An infrastructure that enables timely and efficient communication with sleep clinics and referring doctors about their patients.

Because the management of a patient on CPAP is a shared responsibility, good communication and clear delineation of duties is critical to overall success. Different sleep clinics have established different models of CPAP provision where the levels of responsibility delegated to an external supplier of services may vary. Some sleep clinics may perform some or many of the services detailed in the document in-house, others may delegate most services to the CPAP provider. The patient's general practitioner may also be involved in aspects of care. The split of duties is not critical to the overall success of treatment provided that all aspects are effectively managed by one party or another and there are effective lines of communication. The level of delegation will depend on individual circumstances and is to be decided between sleep clinic, general practitioner and provider. Irrespective of the agreed model, delegation of aspects of care does not absolve the referring doctor or sleep clinic from taking primary responsibility for overall coordination of the patient's management of their sleep disorder.

INTRODUCTION

CPAP - Treatment for Obstructive Sleep Apnoea

Obstructive sleep apnoea syndrome is a condition that occurs in an estimated 5% of the adult population. There is ongoing debate about methods of diagnosis, definitions of OSA severity and the effectiveness of various treatment options. These considerations are beyond the scope of this document which assumes that the referring doctor has made an informed decision about the supply of Continuous Positive Airway Pressure (CPAP) to the patient.

By maintaining upper airway patency, CPAP is almost always effective in controlling the apnoeic events and through randomised controlled trials has been shown to improve the symptoms of OSA¹.

“In patients with OSA of varying severity, there is level I evidence that nCPAP (compared with no nCPAP) reduces objective daytime sleepiness (in patients with moderate to severe disease), improves some measures of cognitive performance, reduces symptoms, reduces depression, and improves perceptions of quality of life, energy and vitality.”²

There is also evidence that CPAP treatment reduces cardiovascular mortality and morbidity in patients with OSA^{3,4}, reduces daytime sleepiness⁵ and reduces the risk of motor vehicle crashes⁶. A number of studies and reviews have concluded that CPAP is a cost effective intervention in symptomatic patients with moderate to severe sleep apnoea.⁷

Bi-level positive airway pressure (BPAP) is commonly used in patients requiring ventilatory support for medical conditions which result in neuromuscular or mechanical limitations to breathing. Although some of the principles contained in this document are appropriate to provision of BPAP, in general the specialised nature of the medical condition requires ongoing management of treatment by a specialist sleep physician and appropriately resourced sleep clinic. In selected instances BPAP may be used as an alternative to CPAP in the treatment of OSA and in this case considerations applying to CPAP should be taken to apply equally to BPAP devices.

CPAP and BPAP treatments are also effective in the management of obstructive sleep apnoea in childhood but given the specialised nature of the issues in this group, it is considered to be best managed directly by a specialist paediatric sleep physician and appropriately resourced sleep clinic.⁸

CPAP Treatment Guidelines – Supporting Evidence

Adherence to CPAP treatment is the largest factor impacting on the effectiveness of treatment. It is recognised that a multitude of factors impact upon CPAP adherence^{9,10,11,12} and two Cochrane reviews have addressed these issues^{13,14}. A number of professional societies have issued guidelines for the diagnosis and

treatment of OSA with CPAP^{15,16,17}. These evidence-based guidelines consistently promote the following best practice principles.

- The diagnosis and treatment of obstructive sleep apnoea syndrome (OSAS), and the monitoring of the response, should be carried out by a specialist service with appropriately trained medical and support staff.
- Treatment with CPAP must be based on a prior diagnosis of OSA established using an acceptable method.
- Close follow-up for CPAP usage and problems in patients with OSAS by appropriately trained health care providers is indicated to establish effective utilization patterns and remediate problems, if needed. This is especially important during the first few weeks of CPAP use.
- CPAP usage should be objectively monitored

Despite the relative paucity of evidence available on the effectiveness of various interventions aimed at improving adherence, quoted studies showed:

- Patient education about the nature, complications and treatment of OSA with CPAP is an important component of all treatment strategies. This education should be given by a health professional with training in the area of CPAP treatment and sleep disorders¹⁷.
- Psychological factors, particularly positive beliefs about treatment, are significant in predicting CPAP adherence¹⁸. A formal cognitive behavioural therapy intervention of two hours duration has also been shown to improve attitudes to CPAP and uptake of treatment.¹⁹
- Behaviour of patients in the first two weeks of CPAP treatment predicts whether they will use it in the long term. Late intervention may not be as effective as efforts made to maximise usage at the initiation of therapy.^{20,21}
- Weekly phone calls during the first month and written information have been shown to be effective in improving adherence when compared to no intervention.²²
- Long-term follow-up for CPAP-treated patients by appropriately trained health care providers is indicated yearly and as needed to troubleshoot mask, machine, or usage problems.
- The patient's partner should be involved in the CPAP treatment process as their acceptance and support of treatment is important in encouraging uptake and continued adherence with treatment¹⁸.

In terms of the appliances used for CPAP treatment of OSA, the available evidence suggests that:

- The addition of heated humidification is indicated to improve CPAP utilization particularly where there is evidence to suggest that side effects associated with mask or mouth leak are present.^{9,23} Heated humidification may also be indicated in geographical areas where there is significant seasonal variation in ambient conditions.
- There is a paucity of evidence that auto-CPAP is more effective in improving adherence than conventional CPAP^{24,25} and there is evidence that in conditions other than uncomplicated OSA auto-CPAP may be contra-indicated. Conditions in which auto-CPAP may be contraindicated include congestive

- heart failure, chronic obstructive lung disease, obesity hypoventilation syndrome or where there is evidence of co-existing central sleep apnoea²⁶.
- A number of manufacturers offer pressure-relief CPAP devices which lower pressure during expiration with the aim of increased comfort for the patient. Studies have demonstrated that this modality is as effective as conventional fixed pressure CPAP and may be preferred by the patient but have not shown improved adherence to treatment as a result of improved comfort.^{27,28}
 - BPAP is an optional therapy in some cases where high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure and may be indicated where respiratory co-morbidities exist, however it is not indicated as a treatment modality for uncomplicated OSA and may be contraindicated for certain conditions including central sleep apnoea.
 - While some features may vary between them, there is little objective evidence to support the superiority of one manufacturer's fixed pressure CPAP device over another. In general, any commercially available CPAP device which has been through the appropriate regulatory system is safe and will adequately treat OSA but the provider and prescriber should be aware that warranty, reliability and access to service facilities will be important to the patient.
 - Manufacturers have implemented a number of different algorithms to determine pressure requirements in auto-CPAP devices. CPAP providers and clinicians involved in the prescription process should require the manufacturer to provide evidence that their device is effective in treating the breathing and arousal associated with OSA.²⁹
 - There is no evidence to support the use of one type of nasal, full face mask or other interface over another.⁸ Patient preference and individual fit and seal are the best guides to interface selection.

In addition to education about CPAP therapy, initiation of CPAP treatment should also include general advice on lifestyle and medical issues which may impact on the success of CPAP treatment.³⁰

- Patients who smoke should be advised to stop.
- Excess alcohol should be avoided.
- Nocturnal sedatives or sleeping tablets should be avoided.
- Advice regarding body weight and its interaction with OSA should be provided if appropriate.
- Patients should be informed about the impact of sleeping position on sleep apnoea severity.
- Relief of nasal obstruction should be viewed as an adjunct to CPAP therapy, potentially improving uptake or adherence.³¹

RECOMMENDATIONS

The success of CPAP therapy is critically dependent on the role of sleep clinic and CPAP provider. Models of care vary between those where the sleep clinic initiates and monitors therapy with the CPAP provider simply providing equipment, to those where the sleep clinic delegates most aspects of therapy to the CPAP provider. The recommendations that follow are for a comprehensive CPAP therapy initiation and follow-up service. Responsibility for the various service components should be

decided upon by consultation between the requesting doctor, the sleep clinic and the CPAP provider, bearing in mind that the ultimate responsibility for the management of the patient rests with the doctor responsible.

Financial and Business Arrangements:

Whilst CPAP provision may not constitute the entire business of the organisation it should be sufficiently important that the organisation makes an ongoing commitment to maintain expertise and to stock appropriate quantities of consumable and equipment items.

Patient education and support is essential to successful initiation and maintenance of CPAP therapy and provision of CPAP without appropriate face-to-face education and ongoing support is inappropriate. Sales of pumps or interfaces over the internet must be supported by an agency which provides this education and support service.

Provision of CPAP does not end with the sale of a CPAP device. The organisation providing CPAP must undertake to provide ongoing service of the equipment, and ongoing advice and support to the patient. Considerable expertise and organisation is required to do this effectively and staff should receive adequate training to ensure that they are able to deal with patients in an effective and appropriate manner. A minimum throughput of patients is essential to maintain expertise. An appropriate facility to undertake CPAP fitting is also required. This should be a private area and have a bed where patients can trial masks in all sleep positions.

Ensuring the quality of the service provided is part of a good business model. The provision of CPAP lends itself to the measurement of quality because some of the outcome measures, for example CPAP adherence, are clear indicators of the quality of the service. The CPAP provider should develop a system which supports simple quality assurance measurement.

Conflicts of Interest:

Whilst provision of CPAP devices requires the application of skills and knowledge, the sale of the device to a patient is a commercial transaction from which the provider expects to earn income. Similarly the provider of diagnostic services has special training and knowledge which entitles them to earn income from the services provided. Where an individual has financial interests in both activities this is a clear duality of interest and must be recognised as such. The Royal Australasian College of Physicians Code of Professional Behaviour requires that this be managed:³²

“The principle guiding the responses to dualities of interests relating to the clinical setting is that the relationship between clinician and patient should not be compromised by commercial or other interests that could subvert the principle that the interests of the patient should be primary.”

The interest of the patient in the process is to receive impartial advice about their diagnosis and the preferred treatment option, including the option to explore treatment other than CPAP devices.

There is compelling evidence to suggest that despite the best ethical standards held by clinicians, pecuniary interests do influence behaviour and it is likely that the only way in which this potential conflict of interest can be managed is by a clear separation of roles and responsibilities.

For these reasons it is not desirable for an individual clinician engaged in diagnosis of OSA to derive income from the business of CPAP provision. Nor is it desirable for an organisation engaged in CPAP provision to provide diagnostic services with a view to profit from subsequently selling CPAP to a patient.

If compelling reasons exist to prevent this separation of roles, for example geographic isolation, sleep physicians or sleep clinics involved in diagnosis and selling or hiring CPAP equipment should declare this conflict of interest by informing patients of this in advance of any such sale or offer for sale or hire.

Organisational Considerations:

CPAP provision requires an ongoing commitment to provide care to patients commenced on treatment. This requires a considerable investment in facilities and in equipment or consumables that may be required by patients. Providers should be fully cognisant of the level of commitment and range of services required to successfully manage CPAP and their responsibility as an integral part of the ongoing provision of health care to the patient.

- The CPAP provider shall demonstrate a commitment to CPAP provision as a significant activity in its business.
- The CPAP provider shall have established links with referring doctors and sleep clinics to ensure continuity of care for the patient.
- The CPAP provider shall not derive profit from both diagnostic services for OSA and the sale of CPAP equipment or masks.
- The CPAP provider shall not offer free, not-for-profit or discounted diagnostic services with a view to subsequent sale of CPAP to a patient.
- The CPAP provider may, on written request of a referring Sleep Physician or sleep clinic, offer additional services such as trials of auto-titration to determine pressure requirement.
- A schedule of technical services to patients such as CPAP pressure checks or machine downloads shall be agreed between the referring doctor or sleep clinic and CPAP provider. Reports of these services shall be communicated to the treating clinician or sleep clinic.
- The CPAP provider shall maintain a range of CPAP machine types (eg, auto and fixed pressure) although these may be exclusively from one manufacturer.
- The CPAP provider shall maintain a broad range of CPAP interface types and sizes (eg, nasal masks, full face masks); it is important that these be from more than one manufacturer.

- The CPAP provider shall maintain sufficient supplies of consumable and commonly used spare parts to ensure that they can remedy common patient problems with a same day service.
- The CPAP provider shall be adequately resourced to undertake the required follow-up consultations and accommodate patient-initiated visits.
- The CPAP provider shall have machines available for loan or rental to patients in the event of breakdown of the patient's equipment. This ensures that CPAP treatment and symptom control can continue despite breakdown.

Facilities:

The facility for CPAP provision is a health care facility. It must reflect the professional responsibilities of health care providers by ensuring confidentiality in an environment which is conducive to undertaking professional consultation.

- Provision of CPAP or CPAP supplies without access to a facility which provides for face-to-face set-up is inappropriate.
- The CPAP provider may offer services in the patient's home but shall also maintain a facility for treatment of patients who prefer to visit the CPAP provider's premises.
- The CPAP provider shall provide services in an environment which is used exclusively for CPAP service or similar activity during periods of patient attendance.
- The facility shall be private, allowing the patient and the treating professional to maintain confidentiality. The environment shall be quiet and conducive to relaxation.
- The facility shall include a bed or a chair that reclines to the horizontal. It is important for the CPAP provider have the ability to test aspects of mask fit in all sleeping positions.
- The facility shall include an appropriate clean-up area where CPAP equipment can be cleaned and disinfected to manufacturer's recommendations.

Training of CPAP Providers/Practitioners:

The initiation and ongoing care of patients on CPAP requires the exercise of both technical and patient management skills. While the requesting doctor has primary responsibility for the care of their patient, the CPAP provider will inevitably be involved in discussions about medical issues relating to the patient's ongoing treatment. It is critical that the CPAP provider understands their role in the process and understands when referral for medical issues is required. For this reason adequate training and access to professional advice is required for all persons involved in the provision of CPAP. This training is best provided by an organisation which is external to the agency or device manufacturer and should involve experienced sleep physicians and CPAP specialists associated with a sleep service which has been accredited by the Australasian Sleep Association. Agents of device manufacturers also have a responsibility to ensure that the practitioners in their retail outlets are appropriately trained in the use of their specific devices, but this should not be the only training available to a CPAP practitioner.

- An organisation providing CPAP treatment shall employ at least one health professional with training in medicine, nursing or an allied health profession.
- All employees of the organisation (CPAP practitioners) who undertake patient contact, either by phone or in person, shall be educated in OSA and CPAP.
- CPAP practitioners shall undertake a training course in CPAP fitting and troubleshooting and be fully conversant with equipment offered before undertaking patient contact. At least one person within the organisation should have undertaken training through an external training course.
- Where the necessary expertise already exists subsequent training may be provided in-house, but use of an external training organisation or suitably qualified and experienced sleep specialist is preferred.
- CPAP practitioners shall undertake ongoing in-service training with a session dedicated to training provided at least once per year. Where the necessary expertise exists this training may be provided in-house, but use of an external training organisation or suitably qualified and experienced sleep specialist is preferred.
- CPAP practitioners shall be closely supervised in CPAP fitting and troubleshooting for a minimum of ten (10) patient fittings before operating as a sole practitioner. Ongoing moderate supervision shall occur until a senior health professional judges them to be competent. Records shall be kept of this training process.
- CPAP practitioners shall be subject to ongoing assessment by the organisation; this may involve observation, supervision or tests of knowledge. This assessment shall be an on-going process with records kept of annual proficiency.
- To maintain adequate skill levels CPAP practitioners shall have primary responsibility, on average, for a minimum of two (2) patient encounters per day.
- The organisation shall commit to the ongoing training and assessment of CPAP practitioners.
- The manufacturer supplying equipment to CPAP providers shall ensure that all practitioners responsible for patient care are trained in use of the manufacturer's product and that the skill levels of the practitioners continue to be adequate.

Provision of equipment:

The supply of CPAP equipment must be undertaken with a full understanding of the patient's medical condition including co-morbidities. Prescription of CPAP requires the requesting doctor to exercise clinical judgement as to the appropriate type of treatment and substitution or variation of treatment without full knowledge of the patient's medical condition is inappropriate. The patient prescription is the document used to communicate this information. A sleep physician is the most appropriate person to provide this prescription and some private health insurance agencies may restrict reimbursement to patients who are diagnosed with a full overnight sleep study and managed by a sleep physician.

- CPAP shall be issued to new patients only on receipt of a valid prescription from a medical practitioner, preferably from a sleep physician.

- The prescription shall indicate the nature of PAP treatment (fixed pressure, auto or bi-level) and the required pressure or pressure range.
- The type of device supplied (fixed pressure, auto or bi-level) shall be as prescribed. Bi-level or auto devices are contra-indicated in some patients and substitution for fixed pressure devices shall be undertaken only on the advice of the referring doctor or clinic.
- The CPAP device shall provide a measure of patient usage.
- The CPAP provider shall have available a range of interfaces including as a minimum nasal masks, full-face masks and nasal pillow devices of various sizes.
- A simple nasal mask is generally the interface of choice however, where a prescription indicates a preferred interface type or preferred manufacturer this type of interface shall be supplied.
- In the event that the CPAP provider feels that a change of interface from the prescribed type (eg, nasal to full face) should be effected, approval from the referring doctor or clinic shall be obtained.
- If the CPAP provider has an ongoing agreement with the referring doctor to allow interface substitution or where no interface preference is indicated, substitution may be undertaken at the discretion of the CPAP provider.
- A heated humidifier shall be provided only upon receipt of a valid prescription or where the CPAP provider has an ongoing agreement with the referring doctor to supply this to patients.
- The CPAP provider shall have available a range of accessories such as chin straps to improve mouth leak.
- The CPAP provider shall check the pressure delivered to the interface, by use of a manometer or similar device.
- Replacement CPAP pumps may be issued without prescription provided that the CPAP provider is able to sight the original prescription. If the time between prescription is long, eg more the two years, the patient should be advised to consult their sleep physician. Replacement CPAP masks may be issued without prescription.
- If during any patient visit the CPAP provider becomes aware of factors likely to impact on the patient's treatment (eg weight gain or loss) the patient should be advised to consult their sleep physician.
- Provision of CPAP pumps or interfaces without a face-to-face contact with a CPAP provider, Sleep Clinic or other appropriately trained healthcare professional is inappropriate.

Initiation of treatment:

Initiation of CPAP treatment and the patient's initial experience with treatment is the most critical factor in determining the success of subsequent treatment. Whilst this may be largely delegated to a CPAP provider, the referring doctor and sleep clinic, as with any prescribed treatment, have a duty of care in this process to ensure that the patient is aware of the nature and complications of CPAP treatment and the implications of failed treatment.

Education and reassurance are critical components of the initiation of therapy. This process must be interactive with the patient having opportunity to have their questions

answered and concerns addressed. The involvement of the patient's partner in this process is important to encourage acceptance and subsequent adherence. The education process must involve an opportunity to experience CPAP and appropriate interfaces. For some patients an extended trial in the home may be necessary before committing to CPAP therapy or to a type of interface. The CPAP provider shall have capacity to provide the patient with a trial of CPAP for sufficient time to allow an informed choice.

- An appointment for the initial supply of CPAP shall be available within 7 days of the receipt of a prescription.
- The initial set-up of a patient on CPAP shall provide sufficient time for the patient to feel informed about their treatment and to experience CPAP. A minimum of one (1) hour is suggested.
- The patient's partner should be encouraged to attend and become involved in the CPAP treatment process.
- The patient shall be provided with education about the nature, potential complications and benefits of treatment of OSA with CPAP and factors which may impact on tolerance and effectiveness
- The patient shall be provided with specific information about the CPAP device, interface and any accessories supplied. This shall include information about cleaning and safety.
- The CPAP provider shall make all reasonable attempts to minimise mask and mouth leak by the selection of appropriate interfaces and the use of appropriate accessories.
- The interface fit shall be assessed while the patient lying down in supine and lateral postures.
- The patient shall be given the opportunity to try a variety of CPAP interfaces to ensure optimal fit and comfort and minimal leak. This trial may be conducted within the facility but is best conducted at home where the patient has adequate time to assess comfort and fit.
- The CPAP provider shall have equipment for trial of CPAP therapy at home. The loan of equipment shall be for a minimum of one week up to a maximum of 3 months. Before reissue equipment shall be cleaned and disinfected to manufacturer's recommendations. The CPAP provider may charge an appropriate rate for this service.
- The CPAP provider must comply with expected confidentiality requirements. This includes requiring signed permission from the patient to supply details of equipment, CPAP usage and any other relevant information regarding the patient to any third party other than the referring doctor or clinic.
- Following initiation or trial of treatment, the CPAP provider shall provide to the referring doctor or clinic a report which details the equipment supplied and the outcome of the trial. The nature and content of this report should, as a minimum, include the parameters detailed in Attachment 1.

Ongoing Management of CPAP Usage:

The success of CPAP treatment depends on its continued use. As with any chronic disease the treating doctor, whether it be a general practitioner or specialist physician, has a responsibility to manage their patient's ongoing care. Although certain duties

may be appropriately delegated to a CPAP provider this does not absolve the treating doctor from taking primary responsibility for overall coordination of the patient's management of their sleep disorder.

In the event of equipment or interface failure, it is important that CPAP usage be reinstated promptly as symptoms including excessive daytime sleepiness will recur quickly. Provision of replacement equipment should occur in the context of a face-to-face consultation. Even in patients who are well established on CPAP treatment, periodic review of CPAP usage, side effects and reinforcement of treatment principles is appropriate. In the interests of expediency it may be necessary to supply replacement equipment without this face-to-face consultation but this must be followed at the earliest opportunity by a patient review.

- The CPAP provider shall contact the patient in the early phase of CPAP treatment to assess adherence to treatment and occurrence of complications or side-effects. It is suggested that this should occur within 7 days of treatment initiation. This contact may be face-to-face or by telephone.
- Where the patient is experiencing problems with CPAP use or side-effects, the CPAP provider shall provide appropriate advice on remedial action. This may require the scheduling of a face-to-face consultation or referral to the referring doctor or sleep clinic.
- Where poor CPAP use, side effects or other issues likely to impact on treatment efficacy (eg weight gain or loss) are judged to be significant issues the CPAP provider shall notify the referring doctor or sleep clinic.
- Remedial action involving change to the prescribed treatment shall be undertaken in consultation with the referring doctor or sleep clinic, except where the CPAP provider has an existing agreement with the referring doctor or clinic to implement agreed actions without further consultation, eg the provision of a chin strap or alternative interface.
- Where there is evidence to suggest that side effects associated with mask or mouth leak are present a heated humidifier may be appropriate. This should be implemented in consultation with the referring doctor or sleep clinic, except where the CPAP provider has an existing agreement with the referring doctor or clinic to supply a humidifier in appropriate circumstances.
- The CPAP provider shall contact the patient at agreed intervals throughout the first year of treatment. A minimum of four such contacts (including that specified above) shall occur. It is suggested that approximately 7, 30, 60 days and approximately 12 months after treatment initiation are appropriate times. It is preferred that all contact be face-to-face, but where this is not possible due to constraints of distance, for example, telephone consultations should be conducted. Where problems are being experienced, face-to-face contact should be arranged. It is expected that these visits will take 30 minutes to complete. At this time the provider shall
 - Determine the patient's usage from the meter of the CPAP device and calculate the average daily hours of CPAP usage.
 - Check the device and humidifier (if supplied) for satisfactory operation.
 - Check filters and associated equipment and advise the patient of any faults and suggested remedial actions.
 - Check the mask and head-gear for satisfactory condition and advise the patient of any faults and suggested remedial actions.

- Provide further information and education to the patient as required.
- Contact the referring Sleep Physician or sleep clinic if major problems are encountered and especially if the CPAP provider cannot remedy the said problem(s) or if the patient has either discontinued CPAP treatment or proposes to do so.
- Subject to confidentiality considerations, the CPAP provider shall provide a report to the referring physician or sleep clinic with details of the consultation and the patient's CPAP usage.
- The CPAP provider shall provide both a face-to-face consultation service and a telephone support service to address any issues that the patient may experience with the use of CPAP treatment. This service shall be available promptly. It is suggested that this be available within two (2) days of the patient request.
- The CPAP provider shall provide a "CPAP download" service for the patient, at which time the patient's usage shall be determined and reported to the referring doctor or sleep clinic.
- The CPAP provider shall have available loan equipment so that if it is necessary for a patient to return their equipment to the manufacturer for repair, a loan machine can be provided.
- Provision of replacement equipment including CPAP pumps or interfaces should occur in the context of a face-to-face consultation with the CPAP provider.
- Where, in the interests of expediency, replacement equipment is provided without a face-to-face consultation a patient review visit must occur at the earliest opportunity.
- At each occasion when the patient visits the CPAP provider for treatment related issues, the CPAP provider shall provide to the referring doctor or clinic a report which indicates the action taken.

Quality Assurance

Businesses should monitor the effectiveness of the services that they provide. For a CPAP provider to maintain credibility with their customers, both requesting doctors and patients, it is critical that they be able to demonstrate effectiveness. There are a number of simple subjective and objective measures that can be used to achieve this including the monitoring of treatment success.

- The CPAP provider shall maintain a patient register or data base to facilitate patient follow-up. This data base shall be secure and protected, so as to respect patient confidentiality.
- The data base shall allow simple measures of CPAP success to be collected and recorded for each patient. This may include patient visits, CPAP equipment type, CPAP treatment usage and symptom scores.
- The CPAP provider shall have a system for dealing with patient complaints and have an established relationship with sleep clinics to provide ongoing advice on patient management when needed.
- The CPAP provider shall review the quality of their service and the outcome of their treatment on a regular basis.

- CPAP providers shall comply with all existing requirements in the maintenance of confidentiality and security and release of the information they hold on patients. These requirements are defined by each State or Territory.³³

ATTACHMENT 1 – CONTENT OF REPORTS

Communication between the CPAP Provider and referring clinician is critical to effective ongoing management of the patient's medical condition. A written report on the patient's CPAP treatment is an essential component of this process and shall be provided at each occasion that the CPAP provider assesses treatment efficacy or adjustments treatment parameters.

The content of the report may be agreed between the referring doctor or sleep clinic and the CPAP provider but as a minimum it should include:

- Patient identification – three discrete identifiers (e.g. name, sex, date of birth, hospital or clinic record number).
- Treating medical officer.
- Make and type of CPAP pump.
- Make, type and size of CPAP mask.
- Details of any optional accessories, e.g. humidifiers.
- Prescribed pressure.
- Measured pressure on presentation.
- Total hours of use of CPAP machine.
- Average hours of use per night.*
- Patient reported side effects.
- Comments on patient acceptance of machine and adherence to treatment
- Any other factors likely to affect treatment efficacy.

* A report which details night-by-night usage of CPAP provides additional information about factors which may impact upon adherence to treatment and is preferred to simply average hours of usage.

GLOSSARY

Accessories – devices which may assist in CPAP treatment such as chin straps or humidifiers.

Adherence – also called compliance, is the ongoing effective use of CPAP treatment, usually measured as the average number of hours of usage per night.

Allied health professional – someone with training in a medically related area, such as physiotherapy, or pharmacy, or a scientist involved in sleep medicine.

Assessment – CPAP practitioners should be subject to ongoing assessment by the organisation; this may involve observation, supervision or tests of knowledge; this assessment should be an on-going process with records kept of annual proficiency.

Auto-CPAP – a type of CPAP machine which is able to sense disordered breathing or OSA and adjust the pressure supplied to overcome this.

Auto-titration – a study in which an Auto-CPAP device is used to determine the minimum pressure needed to control OSA in a particular patient.

Best practice – a commonly accepted set of recommendations or guidelines which define the best way to treat a patient with a certain medical condition.

BPAP – bi-level pressure delivered by PAP machines which adjust the pressure delivered to the patient in phase with the breathing cycle. They will generally deliver lower pressures during expiration and higher pressures during inspiration and may assist patients who cannot tolerate the increased work of breathing associated with CPAP usage.

Cardiovascular morbidity and mortality – concomitant illness or death resulting from effects on the heart or circulatory system (commonly hypertension, arterial disease, heart attack, stroke or cardiac dysrhythmias).

Chin-strap – a device worn around the chin and over the head which assists in keeping the mouth closed and controlling pressure-leaks through the mouth.

Cleaning and disinfection – the process of making a CPAP interface or PAP pump safe for continued use. Manufacturers of these devices specify the minimum cleaning that is required.

Cochrane Review – an authoritative summary of the evidence-based medical literature relating to a certain topic.

Comorbidities – concurrent illness (commonly cardiovascular morbidity, obesity, dyslipidaemia, diabetes, ENT problems).

Consumables – items such as filters, seals, tubing and humidifier chambers that may require replacement during the life of the PAP device.

CPAP – Continuous Positive Airway Pressure: a device that creates a positive pressure in the upper airway to prevent airway-collapse during sleep. It comprises a simple air pump, a wide-bore delivery tube and a well-sealed mask on the patient's face.

CPAP Practitioner – an employee of a CPAP provider who undertakes patient contact either by phone or in person.

CPAP Provider – an organisation or business, either for profit or not for profit, established to provide CPAP services to patients.

Diagnostic service – a service whose responsibility is the diagnosis of patients with OSA. Commonly this is a Sleep Laboratory which may have links with a public or private healthcare facility but increasingly, diagnostic services in the home are being offered as an alternative.

Download – the process of obtaining a read-out from a CPAP device of the patient's usage. Some machines will provide night-by-night usage profiles, which are preferred,

but simple measurement of the hours of usage is adequate for a patient who is well established on CPAP.

External Training Course – A formalised educational program addressing the issues of OSA and CPAP treatment which is conducted by an organisation which is external to the agency or device manufacturer. This organisation should involve experienced sleep physicians and CPAP specialists associated with a sleep service which has been accredited by the Australasian Sleep Association

Evidence-based guidelines – recommendations for patient treatment based on the scientific and medical literature, commonly issued by professional societies.

Fixed-pressure CPAP – the simplest form of CPAP device, which is designed to maintain a constant pressure throughout all phases of respiration throughout the night. The pressure requirement is generally specified in cmH₂O on the basis of a titration sleep study.

Follow-up visit or consultation – a consultation initiated by the CPAP Provider to undertake a scheduled check of the patient's CPAP treatment and to address any technical issues.

Full-face mask – a mask that seals around the nose and mouth, which may be preferable for patients where leakage of pressure through the mouth is a significant problem.

Head gear – the collection of straps or other devices used to hold the mask securely in place on the patient's face.

Health care professional – medical practitioner, nurse or allied health professional.

Humidifier – a device to add water vapour to, and commonly to warm, the inspired air from a CPAP device to improve patient comfort. Heated humidified air is more comfortable for most patients than cold dry air and may improve their CPAP experience.

Interface – the generic term for the mask or other device which connects via a tube to the CPAP pump and provides a seal to the patient's airway, in order to deliver the pressurised air without leak. This is commonly a well-fitting mask over the nose but may also be a mask over the nose and mouth or a device that seals inside the nostrils or the mouth.

Internet sales – sales of CPAP equipment, either pumps or masks, where the equipment is purchased through an internet based vendor with the expectation that the patient will commence treatment without face-to-face consultation with a CPAP provider or sleep clinic.

Leak – unintended loss of air through the mask or patient's mouth or nose. Leak may reduce the pressure supplied, in which case the CPAP pump will compensate to some extent by increasing its flow rate. This may make the patient's CPAP experience less comfortable than is desired

Nasal mask – a mask that seals around the nose. This is the most common type of mask and is the easiest with which to obtain a leak-free seal. It is satisfactory for most patients, as the nasal route is the major route for breathing during sleep.

Nasal obstruction – the nose is the major route of breathing during sleep and obstruction of the nasal passages is a common factor in poor CPAP adherence.

Nasal pillows – an interface which has grommets that seal inside the nares in order to achieve a leak-free seal when CPAP pressure is applied to the nose.

OSA – Obstructive Sleep Apnoea: a condition of repetitive occlusions, usually of the upper airway, during sleep.

OSAS – Obstructive Sleep Apnoea Syndrome: the combination of OSA and sleepiness during the daytime.

Outlet – the premises of an organisation or business established to provide CPAP services to patients.

Patient-initiated visit – a consultation initiated by the patient to address some aspect of their CPAP treatment.

Prescription – A request from a medical practitioner for CPAP which defines the CPAP modality (fixed-pressure or auto PAP device) and the pressure to be used or, in the case of an auto device, the range of pressures within which the machine should be set to operate. A prescription may also specify a requirement for a particular interface type and humidifier.

Pressure check – the process of checking the pressure being supplied to the patient, using an external pressure measuring device or manometer. This should form part of the set-up protocol for a patient and should be checked at all patient visits because external factors such as blocked filter systems can impact on the pressure delivered.

Pressure relief CPAP – a mode of operation where the machine adjusts the pressure delivered to the patient in phase with the breathing cycle. The machine will deliver slightly lower pressures during expiration and may assist patients who experience difficulty breathing against a fixed pressure.

Randomised controlled trial – a scientific comparison of two or more different forms of treatment, commonly an active treatment compared to an inactive or placebo treatment.

Regulatory authority – In Australia, the Therapeutic Goods Association (TGA), which must approve medical devices before they may be used in patient care.

Shall – within the context of a recommendation, indicates a mandatory condition to be met.

Should – within the context of a recommendation, indicates a desirable but not mandatory condition to be met.

Sleep clinic – a health care facility which provides diagnosis and medical care for patients with sleep disorders, including sleep apnoea.

Sleep disorders - a range of medical and psychological problems occurring during sleep, the most common of which are sleep apnoea, snoring, insomnia and restless legs syndrome.

Sleep Study – a combination of measurements, usually conducted overnight, with the purpose of diagnosing a patient with a sleep disorder such as OSA.

Spare parts – spare parts for CPAP devices or masks that may fail or be broken.

This includes such things as mask cushions, head gear that hold the mask in place and tubes between the pump and the mask.

Titration study – a sleep study where CPAP at varying pressures is delivered to the patient in order to determine the minimum pressure needed to control their OSA.

Training course – formalised training courses for CPAP treatment and OSA are provided by some organisations (see External Training Course). In addition, training courses are usually provided by the manufacturers of CPAP equipment and may also be available through a local sleep clinic.

Trial – loan of equipment allowing a patient to try CPAP in their own home. Trial equipment should be equivalent to that provided for purchase and when reissued must be cleaned and disinfected according to manufacturer's instructions and checked for safety.

CONFLICT OF INTEREST

The Author derives no income from either diagnosis or treatment of sleep disorders and has no financial interest in any business concerned with the manufacture or sale of equipment for the treatment of sleep disorders.

REVISION DETAILS

First Written	19 July 2007	A. Thornton
Version 2.0	5 July 2008	A. Thornton
Version 2.1	26 July 2008	A. Thornton
Version 2.2	14 January 2009	A. Thornton

REFERENCES

- 1 Sanders MH, Montserrat JM, Farré R, Givelber RJ. Positive Pressure Therapy A Perspective on Evidence-based Outcomes and Methods of Application. *Proc Am Thorac Soc* 2008; 5,161–172.
- 2 National Health and Medical Research Council, Australia. Effectiveness of nasal continuous positive airway pressure (nCPAP) in obstructive sleep apnoea in adults. NHMRC Report, Feb 2000.
- 3 Buchner NJ, Sanner BM, Borgel J, Rum LC. Continuous Positive Airway Pressure treatment of mild to moderate obstructive sleep apnea reduces cardiovascular risk. *Am J Respir Crit Care Med* 2007; 176, 1274–80.
- 4 Marin, S. Carrizo, E. Vicente, A. Agusti . Long-term cardiovascular outcomes in men with obstructive sleep apnoea-hypopnoea with or without treatment with continuous positive airway pressure: an observational study. *Lancet* 2005; 365 (9464), 1046-1053.
- 5 Patel SR, White DP, Malhotra A, Stanchina ML, Ayas NT. Continuous Positive Airway Pressure Therapy for Treating Sleepiness in a Diverse Population With Obstructive Sleep Apnea. Results of a Meta-analysis *Arch Intern Med* 2003;163:565–71
- 6 George CFP. Reduction in motor vehicle collisions following treatment of sleep apnoea with nasal CPAP *Thorax* 2001; 56:508-512.
- 7 NICE technology appraisal guidance 139. Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome. 2008. At www.nice.org.uk/TA139.
- 8 AAP Section on Pediatric Pulmonology. Clinical Practice Guideline: Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome. *Pediatrics*. 2002;109(4):704-712.
- 9 Engleman HM, Wild MR. Improving CPAP use by patients with the sleep apnoea/hypopnoea syndrome (SAHS). *Sleep Med Rev* 2003;7:81–99.
- 10 Weaver TE, Grunstein RR. Adherence to Continuous Positive Airway Pressure therapy: The challenge to effective treatment. *Proc Am Thorac Soc* 2008; 5, 173–178.
- 11 Weaver T, Chasens E. Continuous positive airway pressure treatment for sleep apnea in older adults. *Sleep Med Rev*. 2007; 11(2): 99–111.
- 12 Olsen S, Smith S, Oei T, Douglas J. Health Beliefs Model Predicts Adherence to CPAP before Experience with CPAP. *Eur Respir J*. 2008 Apr 16. [Epub ahead of print]
- 13 Haniffa M, Lasserson TJ, Smith I. Interventions to improve compliance with continuous positive airway pressure for obstructive sleep apnoea. Art. No.: CD003531. DOI: 10.1002/14651858.CD003531.pub2.
- 14 Chai CL, Pathinathan A, Smith B. Continuous positive airway pressure delivery interfaces for obstructive sleep apnoea. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Art. No.: CD005308. DOI: 10.1002/14651858. CD005308.pub2.
- 15 Kushida CA, Littner MR, Hirshkowitz M et al. Practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep-related breathing disorders. *Sleep* 2006;29(3):375-380.
- 16 Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of obstructive sleep apnea in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007

-
- 17 McKay T, et al. Management of obstructive sleep apnoea/hypopnoea in adults. A national clinical guideline. Scottish Intercollegiate Guidelines Network. Guideline 73, June 2004. At www.sign.ac.uk.
 - 18 Olsen S, Smith S, Oei T. Adherence to Continuous Positive Airway Pressure Therapy in Obstructive Sleep Apnoea sufferers: A theoretical approach to treatment adherence and intervention *Clinical Psychology Review* 2008; 28(8): 1355-1371.
 - 19 Richards D, Bartlett DJ, Wong K, Malouff J, Grunstein RR. Increased adherence to CPAP with a group cognitive behavioral treatment intervention: a randomized trial. *Sleep*. 2007 30(5):635-40
 - 20 Popescu G, Latham M, Allgar V, Elliot MW. Continuous positive airway pressure for sleep apnoea/hypopnoea syndrome: usefulness of a 2 week trial to identify factors associated with long term use. *Thorax* 2001;56:727-33.
 - 21 Budhiraja R, Parthasarathy S, Drake CL, Roth T, Sharief I, Budhiraja P, Saunders V, Hudgel DW. Early CPAP use identifies subsequent adherence to CPAP therapy. *Sleep*. 2007; 30(3):320-4.
 - 22 Chervin RD, Theut S, Bassetti C, Aldrich MS. Compliance with nasal CPAP can be improved by simple interventions. *Sleep* 1997;20: 284–89.
 - 23 Nilius G, Domanski N, Franke K-J, Ruhle K-H. Impact of a controlled heated breathing tube humidifier on sleep quality during CPAP therapy in a cool sleeping environment. *Eur Respir J* 2008; 31:830-836
 - 24 Ayas NT, Patel SR, Malhotra A, Schulzer M, Malhotra M, Jung D, Fleetham J, White DP. Auto-titrating versus standard continuous positive airway pressure for the treatment of obstructive sleep apnea: results of a meta-analysis. *Sleep* 2004;27:249–253.
 - 25 To KW, Chan WC, Choo KL, Lam WK, Wong KK, Hui DS. A randomized cross-over study of auto-continuous positive airway pressure versus fixed-continuous positive airway pressure in patients with obstructive sleep apnoea. *Respirology*.2008;13(1):79-86.
 - 26 Morgenthaler TI, Aurora N, Brown T, Zak R, Alessi C, Boehlecke B, Chesson AL Jr, Friedman L, Kapur V, Maganti R, Owens J, Pancer J, Swick TJ, Standards of Practice Committee of the AASM. Practice Parameters for the Use of Autotitrating Continuous Positive Airway Pressure Devices for Titrating Pressures and Treating Adult Patients with Obstructive Sleep Apnea Syndrome: An Update for 2007. *An American Academy of Sleep Medicine Report*. *Sleep* 2008; 31(1)141-147
 - 27 Nilius G, Happel A, Domanski U, Ruhle KH. Pressure-relief continuous positive airway pressure vs constant continuous positive airway pressure: a comparison of efficacy and compliance. *Chest* 2006;130:1018–024.
 - 28 Mulgrew AT, Cheema R, Fleetham J, Ryan CF, Ayas NT. Efficacy and patient satisfaction with autoadjusting CPAP with variable expiratory pressure vs standard CPAP: a two-night randomized crossover trial. *Sleep Breath* 2007;11:31–37.
 - 29 Brown LK. Autotitrating CPAP: how shall we judge safety and efficacy of a “black box”? *Chest* 2006;130:312–314.
 - 30 Fleetham J, et al. Canadian Thoracic Society Guidelines: Diagnosis and treatment of sleep disordered breathing in adults. *Canad Respir J*. 2006;13(7), 387-392
 - 31 Sugiuraa T, Nodab A, Nakatac A, Yasudaa Y, Sogaa T, Miyatab S, Nakaia S, Koikeb Y. Influence of Nasal Resistance on Initial Acceptance of Continuous Positive Airway Pressure in Treatment for Obstructive Sleep Apnea Syndrome. *Respiration* 2007;74:56-60
 - 32 Royal Australasian College of Physicians. RACP Code of Professional Behaviour. At <http://www.racp.edu.au>.

33 The Office of the Privacy Commissioner, State & Territory Privacy Laws. At http://www.privacy.gov.au/privacy_rights/laws/