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ARTP Standards of Care - Mandibular Repositioning Devices

1.0 INTRODUCTION

The N.I.C.E. Health Technology Appraisal of continuous positive airway pressure (CPAP) for the treatment of Obstructive Apnoea Hypopnoea Syndrome (OSAHS) (2008)⁽¹⁾, the S.I.G.N Management of OSAHS in Adults – a national clinical guideline (2003)⁽²⁾, as well as numerous clinical trials⁽³⁾ recognise the value of Mandibular Repositioning Device (MRD) therapy in ‘simple’ non-apnoeic snoring as well as in the treatment of mild/moderate obstructive sleep apnoea (OSA). MRD therapy may also have a role in the treatment of patients with more severe forms of the disease even when associated with excessive daytime somnolence (EDS) where either CPAP or surgical treatments have failed or where the patient exhibits non-compliance with therapy. MRD therapy may also be used in conjunction with CPAP or as an adjunct to surgical therapy.

As a consequence of these publications, there is likely to be an increase in the provision of MRDs. The risk to patients of an uncontrolled expansion without quality of service is that MRDs may be prescribed inappropriately and that a suboptimal service could be delivered with a variety of standards of care and ultimately, ineffective and inappropriate treatment being delivered.

This document aims to outline some basic standards together with a code of conduct that will protect patients and maintain high standards of quality care for MRD services. The Association of Respiratory Technology and Physiology (ARTP) has consulted with the British Society of Dental Sleep Medicine (BSDSM) in the development of these guidelines.

The MRDs referred to in this document are devices which are custom made for each patient after accurate upper and lower dental impressions; with a relevant jaw registration have been recorded. The device is then made in a specialist laboratory where the technicians have been adequately trained in the manufacture of such appliances. There are a variety of approved designs.

Any patient to be fitted with a custom MRD (unless referred by a specialist Respiratory Physician or Consultant ENT surgeon who has already examined the patient and made a diagnosis) should be screened for signs and symptoms that may predict the presence of OSA and OSAHS prior to appliance manufacture. If OSA or OSAHS is suspected, the patient should be referred for specialist diagnosis prior to constructing a MRD.

All patients seeking treatment with an MRD should receive a thorough evaluation of their dental, periodontal, occlusal and temporomandibular joint status prior to the provision of a device. It therefore follows that any MRD should only be prescribed by a qualified dentist who has received documented training in dental sleep medicine and the provision of MRDs.

1.1 Methodology

A group of experts in the field of MRD therapy have drawn up these guidelines and used evidence from accepted standards, published material and expert opinion.

1.2 Evidence base

The main source of the evidence base comes from the following documents:

- N.I.C.E. Health Technology Appraisal of continuous positive airway pressure (CPAP) for the treatment of Obstructive Apnoea Hypopnoea Syndrome (OSAHS) (2008)⁽¹⁾
- S.I.G.N. Management of OSAHS in Adults – a national clinical guideline (2003)⁽²⁾
- Oral Appliance therapy in Obstructive Sleep Apnea-Hypopnea Syndrome - a clinical study of therapeutic outcomes⁽³⁾
- Comparison of a Custom made and Thermoplastic Oral Appliance for the treatment of Mild Sleep Apnea⁽⁴⁾
- Snoring and the role of the GDP: British Society of Dental Sleep Medicine pre – treatment screening protocol⁽⁵⁾
- Position statement on the treatment of snoring and sleep apnoea in Dental Practice (Dental Protection (UK) Ltd)⁽⁶⁾

1.3 Standards of Sleep Apnoea Diagnostic and Treatment Services

These standards have been compiled to recommend a minimum standard for service delivery and it is advised that they are adopted by any UK provider of sleep apnoea diagnostics or non-invasive MRD therapy used for the treatment of simple non-apnoeic snoring or mild/moderate OSA/OSAHS.

1.4 What do the standards apply to?

The standards apply not only to the appliance itself but also to the general services, including screening for OSA/OSAHS, patient assessment, appliance provision, patient support, valid consent, laboratory manufacture and patient documentation.

1.5 Equipment

There are a variety of custom manufactured MRD designs available. Some designs may be deemed more appropriate for the individual patient after assessment.

1.6 Workforce Issues

1.6.1 Who should deliver these services?

Experienced dental practitioners who have undergone documented training are capable of delivering OSA/OSAHS screening, prescribing and providing MRDs. Some dental practitioners with further training may consider screening including the use of limited channel overnight monitoring equipment. Clinical dental technicians (CDTs) may also provide MRDs for snoring on the prescription of a dentist, as an additional skill, provided the CDT is suitably trained, competent and indemnified. Refer to the GDC Scope of Practice Guidance in their Standards document for further guidance.

1.6.2 Who should interpret and report diagnostic studies?

Ideally the dental practitioner should form a professional working relationship with a specialist Respiratory Physician or Consultant ENT Surgeon so that a multi-disciplinary team is established. Patients with positive diagnostic studies for OSA may then be referred onto the appropriate respiratory team for further investigation and diagnosis. In this way specialist advice can be accessed and leads to an increased knowledge base on all sides.

1.6.2 Definition of experienced:

Dental Practitioners who have undergone documented training.

1.6.3 Acceptable Qualifications:

- Bachelor of Dental Surgery or equivalent.

1.6.4 Who should recommend MRD Therapy?

Specialist respiratory physicians, specialist clinical scientists, respiratory physiologists, respiratory nurse specialists, specialist physiotherapists, trained, dental practitioners, and consultant ENT surgeons.

1.7 Training

Currently there are a number of academically based training programmes specifically for training dentists in patient assessment, screening and appliance provision.

1.7.1 Content

The content of courses/documentated training should include:

- Basic knowledge of sleep physiology/architecture
- Pathophysiology of relevant sleep disorders (including the parasomnias and dyssomnias which in addition to OSA, are causes of excessive daytime sleepiness)
- Sleep disordered breathing, OSA, OSAHS
- Biomechanics of MRD therapy
- Screening for the signs and symptoms of OSA, patient evaluation and assessment
- Potential side effects of MRD therapy (short and long term)
- Varieties of appliance design and manufacture
- Appliance adjustment and patient follow up/recall

The dental practitioner must also be aware of the range of non-dental appliance interventions (both medical and surgical) available for patient treatment as well as an appreciation of the medical co-morbidities associated with OSA, an appreciation of the dangers of excessive daytime sleepiness (EDS), the assessment of EDS and the importance of taking a full and accurate medical and OSA history.

The identification of snoring/OSA predisposing factors needs to be discussed with the patient and along with appliance assessment factors which must also be taken into consideration as these may influence the design of device to be prescribed or even the decision to provide a mandibular repositioning device at all.

1.7.2 Competences

Training courses should be based on the content as outlined in 1.7.1 above

2.0 THE ROLE OF THE DENTIST IN THE SCREENING AND TREATMENT OF SNORING AND OSA – THE LEGAL POSITION

There has been considerable interest in recent years as to the role of dentists in the provision of appliances either for the treatment of snoring or to assist in the treatment of obstructive sleep apnoea. Dentists may be asked to place anti-snoring appliances and a number of enquiries have been made with regard to whether the provision of anti-snoring devices falls within the practise of dentistry and therefore within the scope of assistance normally provided by the GDP's own protection society. See the '*Position statement on the treatment of snoring and sleep apnoea in Dental Practice (Dental Protection (UK) Ltd)*'⁽⁶⁾. It is advisable that every Dental Surgeon involved in this sphere of practice should contact his/her own Dental Protection Society in order to clarify their own individual medico legal position.

Both Dental Protection (UK) Ltd and the Dental Defence Union would indemnify individual members to treat simple, uncomplicated snoring with an MRD following a pre-treatment screening protocol, without the involvement of a medical practitioner, subject to proof of appropriate, formal training. Such cover would be considered on an individual member basis, and application should be made to the relevant underwriting department.

2.1 Study Casts

Due to the possible deleterious side effects that MRDs can have on the occlusion, it is strongly recommended that accurate, hard stone, pre-treatment study casts (preferably orthodontically trimmed) are kept as a record.

2.2 Radiology

Whilst a pre-treatment Ortho-Pantomograph may be useful, it is by no means to be considered as mandatory. Assessment of the dental status of the patient including any radiological investigation is left to the individual GDP to justify. The routine taking of lateral cephalometric radiographs cannot be justified.

2.3 Non-Responders

If the patient is not responding well to treatment, if their medical co-morbidities are increasing in severity, or, if their daytime somnolence (assessed as a result of their SDB) is either not improving or getting worse, then they should be referred back to their own GMP with a request that they should be referred to a specialist respiratory physician or consultant ENT surgeon for further investigation, diagnosis and, perhaps, more appropriate treatment.

2.3 Documentation

Documentary evidence of risk benefit analysis discussion and valid consent must be obtained. This includes informing patients of the short, medium and long-term side effects of wearing a MRD.

3.0 PATIENT ASSESSMENT

3.1 Medical History

A full medical and social history should be recorded with specific notice taken of any co-morbidities which are generally accepted as being linked to OSA or may impact adversely on the provision of an MRD.

These relevant medical issues should be taken into consideration because of their association with OSA, the conditions may be exacerbated by OSA and may limit the use of an MRD. However, they are not in themselves absolute contraindications to treatment other than poorly controlled epilepsy.

3.2 Recent Onset Snoring

Recent onset snoring may be of relevance as it may indicate the onset of hypothyroidism, sudden weight gain, development of a pharyngeal space occupying lesion or the onset of menopause.

3.3 Evidence of Upper Airway Resistance

The patient's oro-pharyngeal airway space must be assessed in case adjunctive surgery may need to be considered.

3.4 Patient Assessment Criteria

3.4.1 Assessment of Excessive Daytime Somnolence

Use of the Epworth Sleepiness Score (≥ 10)

3.4.2 OSA History

Major symptoms:

- Witnessed apnoeas
- Choking during sleep
- Daytime hypersomnolence

Minor symptoms:

- Patients woken by the sound of their own snoring
- Patients having to sleep sitting up
- Frequent nocturia

3.4.3 Assessment and Correction of Snoring/OSA Factors

- Smoking
- Late evening alcohol
- Supine related snoring (positional considerations)
- Use of sedative medication
- Weight loss
- Exercise
- Nasal dilation

3.5 Appliance Assessment Factors

History of:

- Migraine/chronic headaches
- Morning headaches
- Tinnitus
- Pain in or around the Temporo-Mandibular Joints (TMJ)
- Mandibular locking / signs of TMJ dysfunction
- Sleep parafunction (clenching or bruxism)
- Ear pain/stuffiness

Clinical assessment of:

- Limited mandibular opening and/or protrusion
- Skeletal/craniofacial characteristics
- Micrognathia
- Dental status (to include the number, distribution and contour of teeth)
- Periodontal status
- Presence of a pronounced gag reflex

3.6 Patient Recall Regimen

After initial adjustments and assessment, a recall regimen should be employed; for example, review every 6 months for the first 2 years, then yearly thereafter.

It is essential that the patient's response to treatment is evaluated to ensure that, as far as possible, the correct treatment has been prescribed. At these visits, the state of the MRD as well as any possible deleterious effects on, or changes in, the dentition, the periodontium, the TMJ, soft tissues, and occlusion are recorded.

The medical history should be updated as well as rechecking for major or minor symptoms of OSA. The ESS should also be updated.

4.0 APPLIANCES

4.1 Introduction

Minimum standards of acceptable construction and performance of MRDs are essential in order to protect patients from inadvertent or deliberate delivery of devices which are not deemed suitable for purpose.

Equally, minimum standards for MRDs are of no benefit unless the manner of provision of these devices to patients and their subsequent clinical follow up is not also regulated by a similar set of robust minimum standards.

It is only by adopting this strategy that MRD service will be effective and patient safety maintained.

4.2 Essential and desirable features of MRDs

MRDs should be individually, custom-made for each patient from accurate upper and lower dental impressions; with a relevant jaw registration by a General Dental Council registered dental technician working in a dental laboratory registered with the relevant competent medical devices authority. Dental laboratories manufacturing such devices should preferably be affiliated to the Dental Appliance Manufacturing Audit System (D.A.M.A.S).

Non-custom or 'boil and bite' thermoformed appliances are not recommended. Indeed, there is no evidence base for their effectiveness in the treatment of snoring or OSA. There is evidence, however, to show that custom devices are more effective in the treatment simple snoring and OSA^[6]. A non-custom device cannot be recommended as a therapeutic option nor can it be used as a screening tool to select good candidates for custom MRD therapy. Additionally, to avoid medico-legal problems, no mandibular repositioning device should be prescribed for or worn by a patient without prior examination of the patient's dentition, periodontal status and temporo-mandibular joint status. Patients must be made aware that these 'boil and bite' devices, in general, are less comfortable to wear and are more likely to displace during sleep than custom made devices.

Some patients, however, may wish to trial a 'boil and bite', 'off the shelf', non-custom device to see if they can tolerate wearing an intra-oral device and to see if this has any effect on their snoring. In these circumstances the patient must be advised of the limitations of such devices (as outlined above).

Every appliance must be accompanied by a certificate of manufacture under the Medical Devices Directive as well as a patient prescription and custom-made appliance certificate. Such certificates must be retained by the practice; however, a photocopy must be provided at the patient's request.

The debate surrounding whether or not the MRD should involve full or partial coverage of the patient's dentition has yet to be satisfactorily resolved. At present some MRDs cover all the upper and lower teeth whilst others only cover some of the posterior teeth.

The appliance should be made in a rigid or semi-rigid material which conforms to the Medical Directive Standards and is capable of being cleaned and disinfected as per manufacturer's instructions without significant adverse effect on the material itself or any of the component parts. The material should be durable and non-permeable.

An average life expectancy of at least 2 years is considered adequate.

There should be bilateral, flat, even, full arch or posterior contact or, alternatively, some form of anterior single point contact mimicking anterior guidance which permits posterior disclusion in limited lateral mandibular excursion.

The devices should minimally encroach on the Freeway Space (the space between

the occluding surfaces of the maxillary and mandibular teeth when the mandible is in its physiological resting position) and therefore minimally increase the occluso-vertical dimension. There should be minimal encroachment into the tongue space in order to prevent posterior displacement of the tongue further back into the oropharyngeal airspace. There should be minimal soft tissue impingement.

Ideally, some form of compliance monitoring device would be incorporated into the device itself but currently, such innovation is not commercially available.

The ideal device would be suitable for all patients; however, no such appliance exists at present, so it is essential that the trained practitioner is familiar with a range of devices and is able to prescribe the most clinically appropriate.

5.0 REFERENCES

1. N.I.C.E. Health Technology Appraisal of continuous positive airway pressure (CPAP) for the treatment of Obstructive Apnoea Hypopnoea Syndrome (OSAHS) (2008)
 2. S.I.G.N. Management of OSAHS in Adults – a national clinical guideline (2003)
 3. Oral Appliance therapy in Obstructive Sleep Apnea-Hypopnea Syndrome - a clinical study of therapeutic outcomes, Aarnoud Hoekema
 4. Comparison of a Custom-Made and Thermoplastic Oral Appliance for the Treatment of Mild Sleep Apnea, Olivier M Vanderveken, Am J Crit Care Med, vol 178, 197-202, 2008
 5. Snoring and the role of the GDP: British Society of Dental Sleep Medicine pre-treatment screening protocol, J Stradling and R Dookun, British Dental Journal, vol 206, No 6, 307-312, Mar 2009
 6. Olivier Vanderveken et al, American Journal of Respiratory and Critical Care Medicine. vol 178. pp 197 – 202. 2008
 7. Position Statement on the treatment of snoring and sleep apnoea in Dental Practice (Dental Protection (UK) Ltd)
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ARTP Voluntary Code - Sleep Apnoea Services (Mandibular Repositioning Devices)

The aim of this code is to outline key basic standards of service that should be met by service providers for the diagnosis and treatment of obstructive sleep apnoea and snoring. The Voluntary Code will cover the following areas:

- Standards of service and quality
- Accredited Sleep Centres
- Local provision – local networks of care

All patients who have the symptoms of obstructive sleep apnoea (as defined in the SIGN Guidelines 2003) will expect the following level of care within the United Kingdom:

1. They will be referred to a specialist service which will undertake a **sleep study** which as a minimum will measure signals of both respiratory signal and an arousal signal from sleep (e.g. overnight oximetry and upwards). Negative or inconclusive studies should either be repeated or escalated up to more advanced diagnostics (e.g. multi-channel studies).
2. They will have their signs, symptoms and screening sleep study **reviewed by an expert** in sleep apnoea who will have sufficient experience, training and qualifications to provide such an independent professional opinion.
3. They should expect to receive a **treatment pathway** which will give them appropriate treatment for the severity of their sleep apnoea and in accordance with any co-morbidities (cardio-vascular disease, heart failure, stroke, obesity, diabetes or other respiratory disease such as asthma, or COPD). Where appropriate, this may include referral to GDP trained in the provision of MRD therapy for the provision of an intra-oral device.
4. They should have a **titration study** to determine whether (a) CPAP is beneficial and (b) at what level it is optimally beneficial as well as to (c) determine whether the therapy is tolerated.
5. They should be issued, or trialled, with CPAP with a **review** of the intervention within 4 weeks of continual use of the therapy either by remote monitoring (e.g. memory card, phone link or web-based download) or a sleep study seen by an independent expert in sleep apnoea who will have sufficient experience, training and qualifications to provide such an opinion
6. They should have continuous access to **clinical support** in terms of their interface and CPAP device so that they should never need to go without their CPAP treatment for more than 3 consecutive nights due to equipment faults.
7. Support should include an annual review by the CPAP provider or management service and provide routine replacement of interfaces, headsets, filters and other consumables as appropriate.
8. They should have rapid access (1-2 working days max) to a **sleep apnoea expert** who can review their clinical situation and provide advice or improved treatment for their sleep apnoea.

9. They should be seen by a healthcare expert in sleep who can advise on **all aspects of OSAHS interventions** including lifestyle changes, dieting and weight loss, exercise programmes, ENT surgery or assessments, alternative treatments (nasal prongs, mandibular advancement devices, other care).
10. All CPAP services should be provided on a **“value added”** basis which is best for the patient and should not be driven by cost/price.
11. All services should adhere to the ARTP Standards of Care for Sleep Apnoea Services.
12. Given the increased risks to the public and patients, drivers holding Class 1 driving licences, or those who operate trains, buses, planes or other “driven” services should be “fast-tracked” to undergo diagnostic assessment and treatment as a priority, usually within 2 weeks of referral.
13. Sleep apnoea services should be delivered from centres which fulfil criteria which include:
 - a. Safe, clean, environment with patient privacy and access to high quality services.
 - b. Data protection of all patient information and files.
 - c. A selection of CPAP devices (APAP, CPAP, Bi-level, etc) and patient interfaces (nasal masks, full face masks, nasal pillows, etc).
 - d. An option of accessories such as humidifiers, etc.
 - e. Centres staffed with trained and experienced personnel in sleep apnoea diagnostics and therapeutics.
 - f. Centres offering a variety of sleep apnoea diagnostics from simple screening to multi-channel devices.
 - g. Provide a summary report of sleep studies in an easily understandable and readable format written in plain English and explaining technical/medical terms were required.
 - h. Provide reports to general practitioners and relevant specialists in a timely manner.
 - i. Adhere to timely access to therapeutic intervention (e.g. DH 18 Week Pathways for Sleep Services).
 - j. The establishment of multidisciplinary teams comprising trained GDPs and Respiratory Physicians should be encouraged to ensure the appropriate prescription of MRD therapy and effective treatment outcome with these devices.

Summary of National Occupational Standards for Sleep Disorders

Assess patient and recommend action to improve or absolve sleep abnormalities	SS1 recommend diagnostic investigations for the diagnosis of sleep disorder	
	SS2 recommend therapeutic intervention for the treatment of sleep disorders	
	SS3 assess surgery as a treatment option for sleep disorder	
Investigate physiological functions to determine nature and extent of sleep or sleep-related abnormalities	Perform standard tests to investigate physiological function	measure oxygen saturation to determine indications of abnormality – see respiratory phys NOS
		SS4 Measure sleep patterns and factors influencing normal sleep
		SS5 determine degree of sleep disordered breathing using a range of recording sensors and devices
	SS6 investigate sleep and sleep disorders by a range of methods	
	SS7 Investigate daytime sleepiness/vigilance/cognitive function using a range of methods	
Provide therapeutic interventions to achieve improvement in sleep	SS8 Advise patients on behavioural measures to improve sleep disorders	
	SS9 Provide mechanical intervention to improve sleep disordered breathing	
	SS10 Investigate effect of pharmacological interventions on sleep disorder	
<p>Generic Functions</p> <ul style="list-style-type: none"> A – Equipment B – Develop protocols D – Interpret and report E – Health and safety F – Management G – Training and development H – Research and development I – Patient care J – Advise and inform others 		