Scottish Needs Assessment Programme

Obstructive Sleep Apnoea

and

Allied Disorders

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CONTENTS

EXECUTIVE SUMMARY

1 Obstructive Sleep Apnoea (OSA) is a newly recognised condition.

2 Its definition, natural history, and the clinical significance of symptoms and signs are the subject of recent research and development and require refinement and further understanding. Current evidence shows that OSA is an important and common condition, for which there is effective treatment available.

3 The estimated prevalence of the condition is 2% of women and 3.7% of men, aged 30 to 60 - approximately 55,100 people may be affected in Scotland.

4 Daytime sleepiness, unrefreshed sleep and periods of apnoea (breathing pauses) are the most important symptoms. Investigation is carried out by overnight sleep study with polysomnography - a new technique. Most patients diagnosed with OSA can be treated with Continuous Positive Airway Pressure (CPAP), using a machine which blows air through the patient's throat during sleep. Side effects in up to 40% of patients affect compliance with treatment, however. Alternative methods, such as devices to project the jaw and tongue forward, have only modest supporting trial evidence.

5 CPAP therapy is effective. The patient has the potential to improve significantly quality of life, work and social performance and relationships. There is evidence that treatment offers improved sleep for the patient, improved daytime function, mood and prevents accidents caused by drowsiness or sleep. CPAP treatment of OSA may help control hypertension and also prevent some deaths from cardiovascular and cerebrovascular disease, although no direct evidence of mortality benefit is available from cohort studies. Although side-effects of CPAP therapy are not serious, they can be common and affect compliance with treatment.

6 In Scotland presently, there is one designated National Sleep Laboratory. Two hospitals in Glasgow provide services within their Departments of Respiratory Medicine. Several other centres have shown an interest in developing a service, and referrals are making increasing demands on current resources.

7 Funds allocated to the National Sleep Laboratory in 1995/96 are £370,000 plus £150,000 for CPAP machines and heated humidifiers. The likely indicative cost per patient diagnosed with OSA, including prescription of a CPAP machine, is £1500 in the first year, and thereafter £100 per year. Based on estimates of the prevalence of the problem, this suggests that resource allocation of at least £3.1 million may be necessary to establish services nationally and £2.5 million per year thereafter to maintain them.

8 Despite the rapid expansion of existing services, there is a gap between service provision and demand. There is an even wider gap between current provision and estimates of need.

9 Given existing uncertainties over diagnosis and investigation, any local provision of services should be backed by clinical protocols, and by an expert tertiary referral service.

10 Complementary to best practice is a strategy to educate patients, health professionals, and the wider public about OSA, and to encourage health promotion - specifically control of weight and other lifestyle factors. Continuing research and development is necessary to ensure an efficient and effective service for patients.

11 Options for health gain include health promotion elements and service provision. There are several possible models of local provision (8 or 9 centres) with tertiary centres (1 or 2) in teaching hospitals. Health Boards as purchasers, and interested providers, will wish to assess the need for local provision, and how best to deliver care.

RECOMMENDATIONS

Purchasers and providers are invited to consider the following set of recommendations.

Prevention

1 Patient counselling in primary and specialist care should concentrate on reduction of risk factors associated with OSA, especially obesity and the use of alcohol and sedative drugs in appropriate patients.

2 Advice to those drivers with symptoms prior to diagnosis and following effective treatment should be consistent and clear.

Education

3 Resources for health professionals - particularly in primary care - and patients, should be available in a variety of formats including printed and electronic.

4 A programme of general public information should develop, catering for a variety of specific situations, from spouses to the insurance and medical technology industries.

Services

5 Adequate training of health professionals from a range of disciplines should provide an expert service.

6 Provision of facilities should be adequate for the diagnosis and stabilisation on treatment of patients.

7 Part of service provision should be an active research and development programme to increase understanding of the condition and implications for services. Practical implications include the development of protocols for appropriate primary to secondary, and secondary to tertiary referral; appropriate use and development of domiciliary services; and commitment to evaluate the characteristics of diagnostic instruments and their utility for stabilisation on treatment.

8 Local services for diagnosis, treatment and follow-up should develop in consultation with primary care. Medium term options for domiciliary investigation and 'smart' CPAP machines which monitor and deliver effective pressures may develop with the advent of refined diagnostic and treatment methods.

9 Local and regional centres should participate fully in an active programme of evaluation, through audit and multicentre research trials.

Research

The Royal College of Physicians' Report sets out a range of research areas. Early priorities include:

10 Validation of a sleepiness scale, or equivalent disease severity scoring system.

11 Trials of effectiveness of weight loss and other risk factor reduction strategies

12 Maximising compliance with treatment and targeting patient groups most likely to respond and benefit

13 Cohort studies should be established to trace the natural history of disease, the significance of mild/moderate forms of the disease and sub-threshold disease, studies on functional impairment and studies on outcomes.

14 Further health economics studies should identify return in investment in sleep disorders services in terms of health gain.

15 The maximum possible number of diagnosed patients should be evaluated systematically through entry into random allocation controlled clinical trials.

INTRODUCTION

The sleep apnoea syndromes are disorders of breathing during sleep which have daytime consequences. Details of the first clinical series of 62 patients was published in 1976 (Guilleminault - Stradling, 1993). Trends in diagnosis over the past 20 years have reflected increasing medical interest in the pathophysiology of sleep. Further investigation of recognised and new sleep disorders has become possible through technological advances, particularly development of polysomnography.

Since 1985, the National Scottish Sleep Laboratory has offered a small scale, nationally funded service from the City Hospital, Edinburgh. With increased interest in sleep disorders, a gathering body of scientific knowledge to support the epidemiology, diagnosis and management of the conditions, and rising demands on the laboratory, it is timely to address the need for local provision across Scotland. From April 1996, Health Boards make their own purchasing arrangements for respiratory sleep disorder services.

Aim

The aim of this paper is to assess and stimulate discussion on a specific group of sleep disorders centred round the diagnostic process of polysomnography, the scale of disease, the potential for health gain and the need for health services.

2 GLOSSARY

Apnoea
a cessation of ventilatory movement lasting 10 seconds or more.

CPAP (Continuous Positive Airway Pressure)
a constant stream of air directed towards the lungs using apparatus applied to the patient's face, with the intention of maintaining airway patiency.

ECG
Electrocardiograph - measuring instrument which records electrical activity in the heart

EEG
Electroencephalograph - measuring instrument which records electrical activity in the brain

EMG
Electromyograph - measuring instrument which records electrical activity in the muscles

EOG
Electro-oculograph - measuring instrument which records electrical activity in the eyes

Hypopnoea
a 50% reduction in thoracoabdominal movement lasting over 10 seconds (Gould et al, 1988).

OSA Syndrome (working definition)
The occurrence of at least 15 hypopnoeas per hour of sleep in conjunction with two or more major clinical features (Gould et al, 1988).

Characterized by recurrent episodes of cessation of respiratory airflow during sleep, caused by the collapse of the upper airway at the level of pharynx. (Phillipson, 1993).

Multiple sleep latency time
The time delay between adopting a sleeping position and entering a recognised sleep pattern

Oximetry
Continous measurement of oxygen saturation levels in the blood.

Polysomnography
Recording of a number of simultaneous but different physiological measurements during sleep.

3 DEFINITION

Sleep apnoea syndromes and allied conditions are distinct from other sleep-wake disorders. Fifteen per cent of the population complains of chronic poor sleep, and half of the population reports difficulty with sleep in the past (Sedgwick and Yousaf, 1995). Insomnia is the most common sleep complaint and has a variety of causes. It and other predominantly psychological phenomena are not the subject of this study.

There is no agreed definition of the group of conditions under study (RCP, 1993). However, a useful working definition is: a condition characterised by at least 15 episodes per hour of cessation or marked diminution of respiratory airflow (hypopnoea or apnoea - relative or absolute breathing pause lasting ten seconds or more) during sleep, caused by the collapse of the upper airway at the level of the pharynx, in conjunction with two or more major clinical features (Gould et al, 1988; Phillipson, 1993).

The sleep apnoea syndromes are characterised by a group of symptoms and findings on specialist diagnostic apparatus - polysomnography. Such investigation differentiates the main syndrome from a small group of uncommon conditions: restless legs syndrome, narcolepsy and upper airway resistance syndrome.

Pathophysiology

Obstructive sleep apnoea (OSA) results from occlusion of the pharynx (throat) during sleep. During wakefulness, the tendency to narrow the throat by sucking while breathing in is resisted by upper airway dilator muscles, but the tone in these muscles decreases during sleep. In subjects with narrow pharynges, changes brought on by sleep may be sufficient to allow the pharynx to be sucked closed. The underlying mechanism may be genetic or due to fat deposition compressing the airway (Phillipson, 1993).

If the upper airway closes, the subject fights for breath until the increased respiratory effort wakens him. The subject takes in deep breaths and falls asleep again so rapidly that he has no recollection of the episode in the morning.

Once sleep resumes, the pharynx closes again and apnoea recurs. The effect of the many hundreds of brief awakenings (up to 1000) occurring per night is to impair sleep quality and resulting in daytime sleepiness and impaired daytime cognitive function.

Severity of the condition broadly correlates with the frequency of brief awakenings.

4 EPIDEMIOLOGY

The main condition is Obstructive Sleep Apnoea (OSA) which has, more recently, included hypopnoea as a significant component. A memorandum on epidemiology provides more detail in Appendix 1. A summary appears below.

OSA is characterised by a discrete group of symptoms and signs:-

1 Snoring (97%)

2 Day-time sleepiness (88%) (Douglas et al, 1992)

3 Periods of apnoea and/or hypopnoea using standard criteria of frequency.

Associated symptoms in OSA are nocturnal choking (73%), restless or unsatisfying sleep (35%), nocturia, fatigue and exhaustion, irritability, sexual dysfunction, early morning disorientation and headache, and, in a minority, ankle swelling (RCP, 1993; Douglas, 1993; Simonds, 1994). Diagnostic criteria are often not specific to this condition, with a high false positive rate (75-85%) in some series (Stradling, 1993).

Associated Signs, Risk Factors and Disease

Patients are predominantly middle-aged men. OSA is associated with obesity (Young et al, 1993; Jennum and Sjol, 1993; RCP, 1993; Douglas, 1993), increased neck circumference, a short neck and receding chin (Parkes, 1993; Stradling, 1993) and alcohol and tobacco consumption (Stradling and Crosby, 1991; Jennum and Sjol, 1993).

Important effects of OSA include cognitive dysfunction and memory loss which, together with disabling daytime sleepiness, may result in employment difficulties, social disharmony and emotional disturbance.

There are reports of traumatic death due to the condition caused by falling asleep while driving (Parsons, 1986) and of the frequency of road traffic incidents lessened by treatment (Engelman et al, 1995).

Prevalence and Incidence

Estimated prevalence of OSA varies between 0.8% and 4% of men, and approximately 1-2% of women (RCP, 1993; Young et al, 1993).

Projections in this assessment are based on one study in the United States (Young, 1993) and one study on men in the United Kingdom (Stradling and Crosby, 1991).

Incidence of the condition is not clear, depending on awareness of GPs and the public to the condition and the possibilities for treatment.

As the research community learns more about the clinical significance of lower frequencies of apnoea/hypopnoea and the relationship in the elderly between symptoms and abnormal findings on investigation, case definition is likely to relax and the number of potential patients will rise.

Estimated population with the condition in Scotland

1 Assuming the prevalence to be approximately 3.7% in men and 2% in women and making no additional allowance for the prevalence of obesity and high unemployment amongst the Scottish population, an estimated 35,500 men and 19,600 women in the working population aged 30 - 59 have OSA (see Appendix 3 for Health Board guideline figures). The number of affected men and women in the elderly population is not possible to compute on present information but comprises about 5% of the current Scottish caseload. Insufficient information is available on the condition in childhood to assess its importance as a cause of upper respiratory or non-specific complaints.

Given the wide age range and chronicity of the condition but in the absence of accurate incidence figures, the health service implications of such a newly recognised disease are uncertain. If 5% of the projected population presented in any one year, this would represent 2750 patients. The range 2% - 8% would mean 1100 - 4400 patients. However, current referral practice to the Edinburgh Laboratory suggests that 2.1 patients are referred for every one patient diagnosed. This equates to the following number of new patients presenting per year:

upper-estimate	9260
mid-estimate	5780
lower-estimate	2310

2 Alternatively, the 1% prevalence quoted in a UK study (Stradling and Crosby, 1991) for men and women overall provided wide, 12-fold confidence intervals. The indicative figure would equate to 19,400 in the working population. Assuming the same 5% presentation rate but a ratio of 5 patients presenting to each patient diagnosed (the ratio quoted by the RCP report and the experience of Glasgow), the following number of new patients might present each year:

upper-estimate	7760
mid-estimate	4850
lower-estimate	1940

5 CLINICAL MANAGEMENT

Patients presenting with symptoms suggestive of sleep apnoea syndromes are referred for specialist consultation, commonly to a respiratory physician. It is important to take a detailed history (Parkes, 1993; Berrios and Shapiro, 1993). Supporting history from the partner is often useful, as they witness apnoea in 75% of cases (Simonds, 1994). Scoring of symptoms is possible, using either the Stanford or Epworth sleepiness scale. A typical pathway of care is shown in Figure 1 overleaf.

Preliminary daytime investigation may establish abnormally short median sleep latency on repeated testing (Parkes, 1993). Investigation of symptoms for most patients is by sleep study. This can range from pulse oximetry to full polysomnography, the most sophisticated analytical technique available.

Diagnosis

Diagnosis of OSA is based on symptoms and results of overnight sleep study. Two sleepiness scales (Epworth and Stanford) rate severity, although neither has been validated (Stradling, 1993). Frequency rather than reported severity of sleep disturbance may be a better discriminant. Physiological measurements most likely to yield accurate diagnoses are highlighted in Appendix 4, Table 1.

Diagnostic methods complementing the clinical examination are:

1 Polysomnography - the measurement by graphical means of a variety of physiological functions in the respiratory and cardiovascular systems, also movement and arousal/sleep. A recording instrument may measure between 3 and 16 functions (Penzel and Peter, 1992; RCP, 1993). Polysomnography produces a significant paper output. Developing computerised methods are more convenient and efficient (with manual checking by specially trained staff). Polysomnography has no established place in the routine diagnosis of insomnia, depression or dementia.

2 Four or five channel polysomnography. There are currently rapid technological developments. All new devices require validation against full polysomnography (Simonds, 1994). None is capable of quantifying sleep/arousals.

3 Oximetry, with video recording. This diagnostic method was recommended by the British Thoracic Society (1990) but in 50% of studies, the outcome is inconclusive (Douglas, 1993). Pulse oximetry is insuffiently sensitive as a sole diagnostic technique (Simonds, 1994).

4 Day-time studies may identify those with florid disease and rare conditions but is not sufficiently sensitive for lower risk patients (Simonds, 1994).

5 Ambulatory monitoring or investigation at home offers potential and is undergoing further evaluation, with standardisation of values and cost-effectiveness study (NIH Consensus, 1991). Early evidence suggests that findings in a home setting are similar to laboratory conditions (Young et al, 1993; Penzel and Peter, 1992). The main limiting factor is time spent supplying, setting up and retrieving the equipment; also quality of the recording (Simonds, 1994) and false positive results.

Despite the advances of polysomnography, clinical judgement remains central to a firm diagnosis (NIH Consensus, 1991). Interpretation of sleep studies currently lacks robust threshold measurements, and study of test-retest variability has been rare (NIH Consensus, 1991). As the Royal College of Physicians report (1993) states: "The sensitivity, specificity and precise roles of limited sleep studies are still being evaluated and the physicians interpreting the results need to be aware of their limitations". The training needs of technical, scientific and nursing staff are also issues contributing to the quality of a service.

Implications for diagnostic services - configuration of local and specialist referral centres

Given the development stage of all devices, it is important to:

1 Develop a diagnostic service with adequately trained and experienced staff within a structured diagnostic evaluation programme to validate clinical measurements for new 4 and 5 channel polysomnographs. Two such studies are either under way or proposed in Scotland.

2 Retain and develop a research based regional or national laboratory resource to:

a) evaluate new methods against 'gold standard' polysomnography.

b) investigate equivocal, atypical findings in patients undergoing less sophisticated measurement.

c) investigate possible new clinical applications.

d) develop ambulatory monitoring and investigation at home.

e) further develop computerised analysis.

f) ensure leadership in the specialty, and/or coordination and training.

Flexibility of approach is important in the satisfactory diagnosis of these conditions, pending further research evidence.

Treatment

The objective of treatment is restoration of airway patency and normal sleep quality resulting in normal health and social functioning.

1 Lifestyle

As obesity is present in 50% of those referred, weight reduction is one of a number of lifestyle changes commonly recommended for the alleviation of the condition (Smith et al., 1985). Others are avoidance of smoking, alcohol and minor tranquillisers. There have been no trials of weight reduction as the sole intervention in the management of OSA, although experience in alleviating the condition has not been encouraging (Phillipson, 1993; Wooley and Garner, 1994). Advice on driving has not been uniform and is a matter of debate (RCP, 1993; Stradling, 1989). The DVLA advise drivers not to drive pending investigation, treatment and effective relief of symptoms (DVLA, 1994).

There have been no controlled trials proving that lifestyle changes are effective on their own (Albert, 1992). Weight loss for severely obese patients has alleviated the condition, but usually following gastric surgery (Wessex Institute, 1994; Canadian Technology Brief, 1995). For patients with mild to moderate symptoms, advice on sleeping position is a simple treatment option, using a variety of uncomfortable objects (corks, golfballs etc.) to coax the patient away from sleeping on their back (Douglas, 1993; Stradling, 1993). This approach rarely works as most OSA patients have apnoeas in all postures (Douglas - personal communication).

2 Continuous Positive Airway Pressure (CPAP)

For patients with OSA conforming to the current diagnostic criteria the recommended treatment is night-time continuous positive airway pressure (CPAP) therapy. The therapy should be titrated during a second sleep study so that the airflow is sufficient to maintain the patient's airway.

Published evidence supports the view that CPAP is an effective measure (Engelman et al, 1993, 1994 (1,2), 1995) within one to two days (Stradling, 1993) and in over 90% of suitable patients (Douglas, 1993). It does not remove the underlying abnormality, and therapy is required for an indefinite period.

Compliance with treatment bears a relationship to experience of side-effects and severity of the symptoms, but is not related to payment for treatment (Engelman et al, 1994 (2), 1995). "It ... seems likely that the patients titrate their own CPAP use to provide an acceptable balance between the inconvenience of CPAP and the benefits of therapy." (Engelman et al, 1994 (2)).

Side-effects were reported in 41% of one study sample (Engelman et al, 1994 (2)) and include nasal congestion, dry throat and pressure effects of the apparatus. Patient explanation, local therapy and humidification of air may alleviate symptoms and maximise compliance. There are no studies to establish whether reduction in weight or other factors will remove the need for continuing treatment (Eiken et al, 1991).

3 Surgery

Prior to alternative treatment, patients with severe forms of the disease were offered surgery to the uvula, palate and pharynx (Uvulopalatopharyngoplasty - UPPP). This is a major operation carried out on only a few patients (Denholm, 1993) without precise localisation of the obstruction (Douglas, 1993). It is regarded as effective for between 15% (RCP, 1993) and 50% (Crampette et al, 1992) but, again, there have been no controlled clinical trials (NIH consensus, 1991). Mortality following this surgery appears significant but unquantified (He et al, 1988, Rodenstein, 1992) although it is unclear whether the severity of disease, co-morbidity or treatment is responsible. There is no established survival benefit and, while there may be symptomatic benefit, even "cure", objective measures are lacking (Rodenstein, 1992). Later side effects of operation are substantial weight gain and inability to benefit from CPAP when surgery fails (Douglas, 1993). "UPPP can no longer be considered as standard treatment for OSA" (Rodenstein, 1992).

4 Other methods of surgery

None is of proven effectiveness, short of radical surgery to the maxilla and mandible (both upper and lower jaw) - the maxillo-mandibular osteotomy (MMO) - for severe retrognathia (Crampette et al, 1992; Douglas, 1993). In general, surgery for the adult has always been exceptional unless in clearly defined pre-disposing conditions. While it remains important to manage any accompanying nasal and naso-pharyngeal disease, clearance of nasal passages improves snoring, but not OSA (Stradling, 1993).

5 Mechanical Techniques

A variety of intubation and orthodontic procedures have been proposed (including tracheostomy) (Albert, 1992). Recent attention has centred round a group of "mandibular forward positioning appliances" which bring forward the jaw and tongue to help the airway remain open. Early evidence suggests that these appliances can be effective and could offer an alternative to patients unable to tolerate CPAP. However, extensive comparative studies are lacking (Schmidt-Nowara W et al, 1995).

6 Drugs

Some tricyclic antidepressants have been tried (Phillipson, 1993). There is no place for current pharmaceutical agents in the management of these sleep disorders (Stradling, 1993).

Other Diseases

Other diseases amenable to investigation by polysomnography have less promising treatment possibilities. The restless legs syndrome has a range of underlying causes, and a range of interventions of variable effectiveness.

Narcolepsy is rare. Family history and HLA typing are appropriate additional lines of enquiry. General lifestyle advice is important, titration of amphetamines against symptom relief and side-effects may be of benefit (Parkes, 1993), but no treatment of established effectiveness is available.

Education and Development

There remains the important task of education to patients, partners, families, other health professionals and students, the general public, the legal profession, insurance industry, developers of technology and pharmaceuticals, and the research community (NIH consensus, 1991).

Maintenance of Treatment

Long term outpatient review varies between centres. CPAP units are robust and require minimal maintenance other than an annual, electrical safety check. The function of outpatient follow up visits is to service the CPAP machine, check for practical treatment problems, assess benefit, encourage compliance and to reinforce lifestyle advice.

6 EFFECTIVENESS AND OUTCOMES

1 Mortality - there are no sufficiently rigorous cohort studies to substantiate claims of reduced mortality (Partinen and Telakivi, 1992; Redline and Young, 1993, Lavie et al, 1995) as a result of specific intervention. An earlier study (Partinen, Jamieson and Guilleminault, 1988) showed survival advantage with intervention (technology) over life-style advice, but study method leaves many issues unanswered.

OSA is associated with increased mortality from stroke and myocardial infarction. Causation, mechanisms and degrees of risk are unclear. Correcting these associations for obesity and other cardiovascular factors may account for much increased risk. Life-style measures to reduce such factors may be cost effective interventions, in empirical terms, although recent evidence is not encouraging (Wooley and Garner, 1994).

2 Accident Prevention - A retrospective questionnaire survey of Edinburgh patients (Engelman et al, 1995) provides data showing a significant fall in sleepiness symptoms and road traffic incidents with treatment. Reporting frequency in the number of patients (39% to 5%) and occurrence of incidents both decreased. Although recall bias is likely, changes were marked. Other descriptive studies on road accidents suggest that serious incidents are often fatal (Parsons, 1986; Stradling, 1989). There are no further data to support the scale of the problem, although evidence of benefit from treatment is beginning to accumulate.

3 Morbidity - there is evidence of benefit in all three main areas of health function - medical, psychological and social. A placebo controlled study has shown that CPAP improves day-time symptoms, mood, cognitive performance and quality of life (Engelman et al, 1994), both subjectively and objectively. This is supported by descriptive observations of improved work performance, the ability to drive and operate machinery effectively. One study suggests that CPAP therapy helps control of hypertension (Hla et al, 1994), and may prevent depression from developing (Ford and Kamerow, 1989; Reynolds, 1989). Study also suggests that alleviation of the condition has a beneficial effect on the partner (Shapiro and Dement, 1993).

Benefits

The following benefits are established:

- Improved sleep for the patient, probably also the partner
- Improved day-time function - quality of life and cognitive performance and objective sleepiness.
- Improved mood

The following benefits are probable:

- Improved work performance
- Improved driving ability
- Improved relationships, personal and social

The following benefits are possible:

• Lower risk of mortality	Cardiovascular Cerebrovascular Accidental
• Lower risk of morbidity	Hypertension Accidents Depression Partner's well-being

7 THE CURRENT POSITION IN SCOTLAND

1 **Edinburgh** - the National Scottish Sleep Laboratory in the Royal Infirmary of Edinburgh is one of the largest units of its kind in the United Kingdom. Built largely on academic grants and charitable donations and maintained as a centrally purchased service until April 1996, it comprises a suite of four beds running five nights a week. An active research programme continues. Referral of patients has been predominantly from the Lothian and East Scotland areas (see Appendix 4). Referral for the first 80 patients was predominantly from general (38%) and respiratory (20%) physicians, with GPs contributing 29% (Whyte et al, 1989). Recent trends suggest the referral rate from GPs remains around 40%. The ratio of referred to diagnosed cases reflects prior filtering of patients.

2 **Glasgow** - the Gartnavel General Hospital and Glasgow Royal Infirmary provide a service within their departments of respiratory medicine. The Southern General Hospital has discontinued its service. In 1995, both units saw over 170 patients each and are developing domiciliary assessment services. Resources allocated to Edinburgh and Glasgow centres are summarised in Table 1.

3 **Activity** - In summary, the three existing sleep disorders services currently see 534 referred patients, of whom up to 254 could be expected to have OSA, with a further 140 suffering from other ill defined conditions.

4 **Scottish towns and districts** - Hospitals in Dundee, Aberdeen and Inverness have signalled their interest in the specialist referral and investigation of patients with possible sleep apnoea. Some units are investigating patients with pulse oximetry overnight with a view to referral to a specialist centre when the clinical picture supports the diagnosis. Routinely collected data for 1992 and 1993 (ISD - SMR1 series ad hoc request) does not capture the extent of activity.

5 **Surgery** - Review of five year SMR1 data gives no clear indication of any specific surgical procedures undertaken in Scotland such as UPPP (ISD - SMR1 series ad hoc request). In a specialty audit, Denholm et al (1993) identified 16 such operations in six months of activity in 1990 and none in 1988 at the City Hospital, Edinburgh, where interest in the condition might be greatest of any Scottish ENT unit.

Available data show high referral activity for patients living close to centres offering a specialist service. The total of 825 referrals to three centres in Edinburgh and Glasgow (Table 1) represents approximately 1 in 7 of people in Scotland likely, on projected estimates, to need assessment.

TABLE 1
Resources, Activity and Patient Characteristics - Three Scottish Centres, 1995

		GGH	GRI	RIE
Staff	Medical	2 NHS	2 NHS	1 GRANT FUNDED
	Specialist Support Staff	2 WTE	1.2 WTE	4 WTE
	No. Trained	6	3	
	Nursing	6 hrs per week	not designated	0
	A + C	8 hrs per week	8 hrs per week	8 hrs per week
Specific Clinic(s)		Yes	Yes	Yes
Facilities		1 designated bed (2 from March 1996)	1 bed 2 nights per wk	4 designated beds
	Multi-channel	1	1	2
	4/5 channel	2 domiciliary 1 video	2 1 domiciliary 1 video	2
Patients referred		180	170	475
	Overnight studies	138 in-patient 70 home	188	357
	Daytime studies	40		
	CPAP familiarisation		70	140
	MSLTs		9	66
	Waiting list time - referral to investigation	8-10 weeks	8-10 weeks	20 - 30 weeks
	Sex ratio m:f	6:1	5:1	6:1
	Age - mean - range	44 yrs 29-70 yrs	45 yrs 16-75 yrs	45 yrs 8 - 78 yrs

GGH-Gartnavel General Hospital GRI-Glasgow Royal Infirmary
RIE-Royal Infirmary of Edinburgh MSLT-Multiple Sleep Latency Test

All centres report projections of rising activity and additional resources over 3 years.

8 COSTS

The Royal College of Physicians' Report (1993) provides guideline costs of £140,000 to set up a centre and £338,000 to run annually a regional sleep centre (three beds) to serve a population of around three million (Appendix 2, Table 1).

The establishment of a local resource with less sophisticated analytical devices and a small core of trained staff would require proportionately less investment. The two Glasgow centres which provide data differ in their approach to specific allocation of staff. However, based on current activity and making broad assumptions, revenue and capital costs could be scaled down pro-rata for planned activity.

Costs of Existing Service

The National Scottish Sleep Laboratory received £420,000 to provide a service for the financial year 1995/96. This equates to £660 per patient seen.

Although no overall costing is available for the two Glasgow services, one centre costs an overnight sleep study at a fraction of Royal College of Physicians indicative sums.

Cost-Benefits

Studies in the United States for 1988-89 estimated that $78.5 million was spent on sleep centre clinical activity, against the estimated annual cost of (all) accidents relating to sleepiness of between $43 and $56 billion.

In Scotland, the first year cost of an affected patient prescribed a CPAP machine is approximately £1500 with subsequent annual maintenance costs of approximately £100. The estimated cost of a road traffic accident causing serious injury is £20,160 and death is £665,000 (RCP,1993).

Cost Utility

A study (Wessex Institute of Public Health Medicine, 1996) estimates the QALY value of CPAP treatment of OSA at about £1926. Canadian estimates are comparable at $3400 to $9742 (£1634 to £4684).

9 CONSULTATION

The method of enquiry for this needs assessment comprised:

- Literature review
- Consultation with clinicians, in particular Professor Neil Douglas, Director of the National Scottish Sleep Laboratory
- Use of bid documents
- Questionnaire to known providers
- Correspondence with clinicians interested in developing a service, or known to refer patients to the nationally funded laboratory
- Correspondence and consultation with Highland, Lothian and West of Scotland Health Boards
- Opportunistic consultation with GPs
- Patients - Professor Douglas's unit is using patient questionnaires and other evaluation methods as part of an ongoing research and development programme. A broader framework for consultation would be for local determination.

10 GAPS IN PROVISION AND AREAS FOR FUTURE DEVELOPMENT

Based on the likely numbers of the Scottish population affected by the condition, their growing awareness of the condition, expectation, medical investigation and intervention, and professional attitudes towards diagnosis and referral, the need for services is considerably greater than the current provision. The gap is particularly apparent outwith major cities.

The Royal College of Physicians' report recommends one specialist centre for every three million people - approximately two for Scotland. However, patients, in the first instance, could be referred to district hospital units for specialist advice, with investigative facilities on hand to an appropriate level. The specialist laboratory (such as already exists) would then be a local and tertiary referral resource for research and development. There are therefore several options:

1 Maintain the service at present levels, with one specialist regional unit.

2 Retain the existing specialist unit for Scotland but develop additional local providers to address the needs of substantial population centres - up to a further nine.

3 As option two, but develop one Glasgow centre as a regional referral unit along the lines of the Edinburgh laboratory, meeting the recommendations of the RCP report.

4+5 These options rework configurations similar to options 2 and 3 but using different assumptions of population prevalence with the condition and the ratio of patients referred who are subsequently diagnosed. See Appendix 3 for details of assumptions.

11 COSTED OPTIONS AND ESTIMATED EXPECTED BENEFITS

The following options are based on projected full activity of established services.

Option 1

Funding a sole regional laboratory at current activity levels (approximately 560 patients per year)

The current trust bid cost is £520 000

Option 2

This includes a sole regional laboratory as in option 1, but with an augmented activity of 600 patients. Such a laboratory would meet the needs of 6-24% of Scottish patients, based on the upper and lower estimates of patients presenting - see chapter 4.

Local centres, perhaps up to 9 around Scotland would see a mean of 200-300 patients a year, costing pro-rata 30-50% of a full regional centre. CPAP units would each cost £600. Patients on treatment would cost £100 per subsequent year. At a mean activity of 200 new patients per year, the combined service would meet the lower estimate of predicted referral activity. Applying Royal College of Physicians' figures and assuming full capital investment and activity at year 1, the guideline national cost would lie between £3.1m and £4.6m (Appendix 2, Table 1) and between £2.5m and £3.7m in year 2.

Option 3

A second regional centre would provide the same activity of 600 and replace one of the local centres, with additional capital costs. Estimates are contained in Table 2 in Appendix 2. The guideline national cost would lie between £3.7m and £5.1m in year 1, and £3.0m and £4.1m in year 2.

Mean cost per patient for options 2 and 3, including provision for CPAP therapy, would lie approximately between £1450 and £1458. Both options would meet only the lower estimate of need for specialist service provision (2310 patients).

12 MONITORING CRITERIA AND MEASURES

The following list suggests suitable measures:

1 a) staffing
b) staff training/experience
c) facilities, out-patient, in-patient, domiciliary

2 Activity
a) Patient referral
b) Number of overnight full sleep studies
c) Number of CPAP machines prescribed
d) Number of sleep studies undertaken to investigate difficulties in clinical management
e) Number of domiciliary investigations, and proportion of all investigations

3 Waiting time:
a) referral to first appointment
b) referral to sleep study
c) referral to second sleep study with prescribed equipment

4 Lifestyle - changes in weight, alcohol consumption, tranquilliser consumption, etc. of those followed up for all clinical reasons.

5 Compliance with treatment - symptoms, side-effects, time clocks on CPAP machines.

6 Serial effectiveness measures - towards morbidity outcomes

a) Disease specific - Epworth or Stanford sleepiness scale (on validation).
b) General Health Questionnaires-SF 36, also GHQ
c) Patient questionnaires and semi-structured surveys to identify important areas of improved health and other functions, and satisfaction with the services.
d) Questionnaire to partners.

7 Academic output

8 Participation in controlled clinical trials - proportion of patients entered of those appropriate for inclusion.

9 Provision of written materials to patients and referring clinicians.

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Memorandum on the Epidemiology of Obstructive Sleep Apnoea

The main condition is Obstructive Sleep Apnoea (OSA) which has, more recently, included hypopnoea as a significant component. Some authorities term the condition the Sleep Apnoea/Hypopnoea Syndrome (SAHS). It is characterised by a discrete group of symptoms and signs:

1 Snoring (97%)

2 Day-time sleepiness (88%) (Douglas et al, 1992)

3 Periods of apnoea and/or hypopnoea using standard criteria of frequency.

Snoring, however, occurs in up to 45% of the population, habitually in 31% of males and 19% of females (Whyte et al, 1989) but alone does not constitute a clinical problem. With OSA, abnormal day time somnolence usually occurs at least once per day when not in bed, commonly in the early afternoon and evening (and not associated with television watching) (Whyte et al, 1989) but is also not specific for the condition (Phillipson, 1993). Scottish units use the above definitions, while there is ongoing research into whether patients with fewer than 15 apnoea/hypopnoeas per hour have clinical consequences. Therefore, symptom severity presents a continuum, with arbitrary thresholds which currently signify disease. Current diagnostic criteria are sensitive but not specific (15 - 20%) with many false positive cases (75% - 85%) (Stradling, 1993).

Associated symptoms in OSA are nocturnal choking (73%), restless or unsatisfying sleep (35%), nocturia, fatigue and exhaustion, irritability, sexual dysfunction, early morning disorientation and headache, and ankle swelling in a minority (RCP, 1993; Douglas,1993; Simonds, 1994).

Less common disorders which are amenable to similar investigation are the upper airway resistance syndrome, restless legs syndrome (no definitive prevalence data) (Shapiro and Dement, 1993), narcolepsy (prevalence of between 0.03 and 0.16% in the European population - Haraldsson et al, 1992) and central sleep apnoea - a neurological condition with 1% of the frequency of OSA.

There is debate covering association, co-existence and causation. Age and sex associations are well established. OSA is associated with obesity (up to 50% of patients are 30% or more above ideal body weight) (Young et al, 1993; Jennum and Sjol, 1993; RCP, 1993; Douglas, 1993), increased neck circumference, a short neck and receding chin (Parkes, 1993; Stradling, 1993) and alcohol and tobacco consumption (Stradling and Crosby, 1991; Jennum and Sjol, 1993). Hypertension is present in approximately 30% of patients (RCP, 1993), but there is dispute about its significance after correction for other factors (Hla et al, 1994; Jennum and Sjol, 1993). Other associations include increased incidence of stroke, angina and myocardial infarction (RCP, 1993; Phillipson, 1993). OSA is thought to be a cause of pulmonary hypertension and right ventricular failure, with some evidence of successful improvement of (left) cardiac failure through treatment of OSA (Phillipson, 1993). A family study shows predisposition to OSA in relatives with similar variation in bony and soft tissue elements to the upper airway.

Important effects of OSA include cognitive dysfunction and memory loss which, together with disabling daytime sleepiness, may result in employment difficulties, social disharmony and emotional disturbance.

There are reports of traumatic death due to the condition caused by falling asleep at the wheel of a vehicle (Parsons, 1986). In two patient series, 19% and 32% admit to falling asleep at the wheel (Haraldsson et al, 1992; N J Douglas, personal communication) - 25% report this at least once weekly (Shapiro and Dement, 1993). Affected drivers are involved in road accidents two to seven times more often than the general driving population (Findley et al, 1989; Phillipson, 1993; Shapiro and Dement, 1993) and the risk of single vehicle accident may be increased nine-fold (N J Douglas - personal communication). One police survey suggested that sleep disorder may rank second to alcohol as a specific cause of road accidents (RCP, 1993 based on personal communications).

One study (Redline et al, 1992) suggests a familial predisposition which persists after allowing for age, sex and obesity.

In a small minority, the syndrome is associated with disorders of the jaw (mandible), hypothyroidism, acromegaly and Marfan's syndrome (Whyte et al, 1989; Partinen and Telakivi, 1992; Douglas, 1993). There is slight overlap with other chronic chest diseases such as chronic obstructive airways disease (Weitzenblum et al, 1992).

Prevalence depends on the threshold case definition adopted by various studies. These in turn depend on the method of study, eg. investigation only of those with symptoms; type of investigation. Prevalence estimates vary between 0.8% and 4% of men, and approximately 1-2% of women (RCP, 1993, Young et al, 1993), making the condition about as common as asthma. A rigorous population study (Young et al., 1993) found that some of 4% of women and 9% of men had more than 15 apnoea/hypopnoeas per hour (Table 1) with an estimated 2% and 3.7% respectively fulfilling severe symptomatic criteria and five apnoeas/hypopnoeas per hour. Although case definition varies, the findings of this cohort study of U.S. men and women of working age (30 to 60) are likely to reflect prevalence in the UK (Lancet, 1991). A possible explanation for the sex difference may be due to differing patterns of excess fat distribution (Stradling, 1993). Sample population prevalence of obesity is not reported and may be less than in Scotland. The study selected only adults in employment, which tends to suggest a conservative figure. Unemployed adults are more likely to experience conditions which render them unfit for work, and sleep disturbance is no exception (Parkes, 1993).

Several clinical series (Whyte et al, 1989; Douglas, 1993; RCP 1993; questionnaire to Scottish centres, 1993) suggest a wider sex difference in presentation - four or five men to each woman.

Age and prevalence - the prevalence of sleep apnoea syndromes rises with age between 30 and 60, peaking in late-middle age (Partinen and Telakivi, 1992; Young et al, 1993). OSA in children is most often managed effectively by surgery to remove hypertrophic tonsils and adenoids (Jaffa et al., 1993). There is some evidence of precursor conditions to the adult condition in childhood (associated with obesity and enuresis but often without specific symptoms) (Gaultier, 1992). In the elderly, the prevalence of abnormalities on polysomnography rises with increasing age but correlation of these abnormalities with symptoms falls away (Fleury, 1992). Indeed, the correlation at all ages between cardinal symptoms and sleep laboratory abnormality indicates the need for further scrutiny of accepted contemporary case definitions (Partinen and Telakin, 1993).

In a Swedish study (Haraldsson et al, 1992) the prevalence of drivers at risk of sleep apnoea was similar to the total driving population of the same age.

Incidence of the condition is not clear. As a chronic condition, figures are likely to be much lower than those for prevalence. Incidence in terms of presentation to the health service depends on awareness of GPs and the public to the condition.

As the research community learns more about the clinical significance of lower frequencies of apnoea/hypopnoea and the relationship in the elderly between symptoms and abnormal findings on investigation, case definition is likely to slacken and the number of potential patients will rise.

TABLE 1

Specimen Costs of a Specialist Respiratory Sleep Centre

New referral activity per year			384 patients
Revenue*	Total		£338 000
	Staff costs		£150 000
	Equipment depreciation	£28 000	
	Repairs, Disposables +	£39 000	
	Hospital overheads		£121 000
Capital	(Set-up costs)	£140 000	

* CPAP Unit costs excluded

\+ year 1, rising at £100 per patient on CPAP per year

Unit Costs*	New out-patient appointment		£97
	Return out-patient/CPAP follow-up appointment	£73	
	Full Sleep Study		£486
	Limited Sleep Study		£243
	CPAP Unit		c. £600

* with rounding

From: Royal College of Physicians' Report, 1993, Appendix 2

TABLE 2
GUIDELINE NATIONAL COSTS

Prevalence of men 3.7%, women 2%.

For every 2.1 patients assessed, 1 needs a CPAP Machine.

		£	£
		no.	no.
TERTIARY UNIT No.1 (established)	Activity-New Patient Referral	600	
	Revenue costs	528,000	
	CPAP Units	171,000	
	Additional 'return' patient cost (year 1+2)	28,500	
	ANNUAL COST	**727,500**	
TERTIARY UNIT NO.2 (new)	Activity-New Patient Referral	600	
	Capital costs (year 1)	200,000	
	Revenue costs	528,000	
	CPAP Units	171,000	
	Additional 'return' patient cost (year 2)	28,500	
	YEAR 1 COST	**899,000**	
	YEAR 2 COST	**727,500**	
LOCAL CENTRE (new)	Activity-New Patient Referral	200	300
	Capital costs (year 1)	75,000	110,000
	Revenue costs	176,000	264,000
	CPAP Units	57,000	85,800
	Additional 'return' on patient cost (year 2)	9,500	14,300
	YEAR 1 COST	**308,000**	**459,800**
	YEAR 2 COST	**242,500**	**364,100**

OPTION 2

NATIONAL COST (1 Tertiary & 9 Local Centres)

Activity-New Patient Referral	2,400	3,300
	£	**£**
YEAR 1	3,499,500	4,865,700
YEAR 2	2,910,000	4,004,400

OPTION 3

NATIONAL COST (2 Tertiary & 8 Local Centres)

Activity-New Patient Referral	2,800	3,600
	£	**£**
YEAR 1	4,090,500	5,304,900
YEAR 2	3,395,000	4,367,800

Notes

1. Costs contain no training element.
2. In reality a new clinical service might build up to projected activity over 3 to 4 years.
3. Allowing for one return visit.
4. Based on treating 40-60% of the presenting population if 5% present annually.

TABLE 3
GUIDELINE NATIONAL COSTS

Prevalence of 1% in both men & women.

For every 5 patients assessed, 1 needs a CPAP Machine.

		£	£
		no.	no.
TERTIARY UNIT No.1 (established)	Activity-New Patient Referral	600	
	Revenue costs	528,000	
	CPAP Units	72,000	
	Additional 'return' patient cost (year 1+2)	12,000	
	ANNUAL COST	**612,000**	
TERTIARY UNIT NO.2 (new)	Activity-New Patient Referral	600	
	Capital costs (year 1)	200,000	
	Revenue costs	528,000	
	CPAP Units	72,000	
	Additional 'return' patient cost (year 2)	12,000	
	YEAR 1 COST	**800,000**	
	YEAR 2 COST	**612,000**	
LOCAL CENTRE (new)	Activity-New Patient Referral	200	300
	Capital costs (year 1)	75,000	110,000
	Revenue costs	176,000	264,000
	CPAP Units	24,000	36,000
	Additional 'return' on patient cost (year 2)	4,000	6,000
	YEAR 1 COST	**275,000**	**410,000**
	YEAR 2 COST	**204,000**	**306,000**

OPTION 4

NATIONAL COST (1 Tertiary & 7 Local Centres)

Activity-New Patient Referral	2,000	2,700
	£	**£**
YEAR 1	2,652,500	3,597,500
YEAR 2	2,155,500	2,869,500

OPTION 5

NATIONAL COST (2 Tertiary & 6 Local Centres)

Activity-New Patient Referral	2,400	3,000
	£	**£**
YEAR 1	3,276,500	4,086,500
YEAR 2	2,679,000	3,291,000

Notes

1. Costs contain no training element.
2. In reality a new clinical service might build up to projected activity over 3 to 4 years.
3. Allowing for one return visit.
4. Based on treating 20% of the presenting population if 5% present annually.

BASIS OF STATISTICAL ESTIMATES FOR THE PROVISION OF A SLEEP DISORDERS SERVICE

The following assumptions and calculations are for guidance only.

Assume:

1 Calculations based on the 30-59 year age group only - 5% of current referrals in Scotland are older people.

2 Obstructive Sleep Apnoea comprises the major part of service workload.

3 The 'rule of halves' for chronic conditions - half of all cases are known to the health services, and (at least) half are adequately managed.

There are alternative prevalence estimates for OSA. The first results from a more rigorous population study in the United States (see Table 1); the second is men in England.

a) 3.7% in men and 2% in women aged 30-59. For the Scottish working population, this translates to 35 500 men, 19 600 women and 55 100 in total.

b) 1% in both men and women. This translates to an estimate of 19 400 in the Scottish working population.

5% of all cases might be expected to present and be referred each year, although a range from 2% to 8% might be plausible. Lower expectations reflect the 'rule of halves'.

A ratio (or multiplier) of 2.1:1 would reflect referrals for specialist consultation who do not have the condition. A higher multiplier would entail greater cost in all aspects except provision of CPAP units. Efficient use of investigatory resources would not entail higher capital cost for a multiplier of 5.

The expected number of referrals across Scotland per year is between 2310 and 9260 (mid-estimate 5780).

For 8-9 local services seeing between 200-300 patients, and 1-2 regional services seeing 600 patients, provision would meet the needs of patients near the lower estimate.

Ratio patient referred to overnight sleep studies is 1:1 (models).

Sleep Disordered Breathing and Hypersomnolence

Case Definition = Apnoea-Hypopnoea Score ≥ 5; ≥ 2 days per week of Excessive Daytime, Sleepiness, Wakening Unrefreshed, Uncontrollable Sleepiness that interferes with life (all three symptoms).

Women	Men
2%	3.7%

Young et al., New England Journal of Medicine, 1993.

TABLE 1

The Occurrence of Sleep-Disordered Breathing among Middle-Aged Adults
Wisconsin Sleep Cohort Study

Sleep Disordered Breathing

Age-specific estimated percentage (95% C.I.) prevalence, using minimal diagnostic criteria.
Case Definition = Apnoea-Hypopnoea Score ≥15

Age	Women	Men
30-39	4.4 (1.1-7.3)	6.2 (1.9-10)
40-49	3.7 (1.0-6.5)	11 (6.7-16)
50-60	4.0 (0.0-10)	9.1 (6.4-11)
30-60	4.0 (1.5-6.6)	9.1 (6.4-11)

TABLE 1

Polysomnography : Measurements

Respiratory

Airflow (at the nose/mouth)	*
Chest and Abdomen movement	*
Snoring	
Oxygen saturation (oximetry)	*
Snoring Microphone, decibel meter	

Cardiovascular

ECG/heart rate
Blood pressure (arterial)

Movement

Legs

Sleep/wake

EOG - Electroculogram
EMG - Electromyogram
EEG - Electrencephalogram *

Posture

Body Position Monitor (or video) *
Snoring Microphone, decibel meter

* Common and significant recordings.

Adapted from: Penzel and Peter, 1992
Simonds, 1994
Royal College of Physicians' Report, 1993
Douglas, Thomas and Jan, 1992

SLEEP DISORDERS SERVICE - SPECIMEN CONTRACT SPECIFICATIONS

There are two main contract types:

Referral to a ***secondary level*** service - that is, a service based in a DGH under the care, normally, of a Consultant Chest Physician

A ***tertiary service***, based in a teaching hospital under the direction of a Consultant Physician whose main interest is with Sleep Disorders.

1. **Tertiary Service** (amended from NSD contract) - A Sleep Disorders Centre

The primary objective of the Scottish National Sleep Laboratory is to provide a service for the clinical assessment, diagnosis and management of patients with daytime sleepiness or other features of the sleep apnoea/hypopnoea syndrome. The service will provide follow-up of patients only when requested by the referring physician, where the complexity of continuing management is beyond the resources and expertise of a secondary centre. Normally, a patient would be referred back to secondary level care following diagnosis and initial management.

A second objective of the service is that of the investigation and management of patients with nocturnal hypo-ventilation. Although these patients do not have the sleep apnoea/hypopnoea syndrome (SAHS), their investigation and management is closely analogous.

An anticipated 10 to 20% of all patients referred for clinical assessment to all Scottish centres would be referred on to a tertiary centre. The main clinical indications would be continuing diagnostic uncertainty, or for the detailed analysis of diagnoses which are not SAHS.

The tertiary centre would also receive “data referrals” of diagnostic data for further elucidation.

Co-ordinating Centre for Units

The tertiary centre would co-ordinate national clinical audit and research programmes relating to sleep disorders. Commitment to multi-centre audit and research would be integral to every centre’s clinical activity. The centre would devise and co-ordinate an external quality assurance programme in collaboration with Scottish units.

i) Staffing

a) *Director* - the Director of a tertiary sleep disorder service would be expected to have a joint NHS and academic appointment. The majority of NHS sessions would be committed to the sleep disorder service, and the postholder would be expected to have an appropriate higher professional training and research track record.

b) *Nurse and technical staffing* - both staff groups would be expected to have at least one member with full-time commitment and recognised training and trainer status in the analysis/management of sleep disorders.

ii) Facilities

A tertiary centre would be expected to have the following:

a) A dedicated and soundproofed bed-suite with at least two beds
b) A 16-channel polysomnograph
c) A range of less sophisticated equipment for assessment, comparison and trial, both on loan from companies and as part of the establishment
d) CPAP titration facilities
e) Follow-up availability/helpline staff - there will be 24-hour availability of qualified staff to give advice through a recognised helpline.

iii) Activity Levels/Throughput

The indicative activity level for the year would be at least 300 new patient referrals. There would be facilities for overnight and daytime assessment, and the provision of a full range of CPAP machines, masks and heated humidifiers.

iv) Referral

Referrals would normally come from hospital consultants, commonly physicians but also ENT surgeons.

v) Information and Materials

The tertiary centre would be expected to develop, pilot and evaluate information materials, and relate them to patient understanding and compliance.

vi) Research and Audit Capability

Research and audit would be a major component of the tertiary unit's work. Research and development funding schemes would be expected to be a significant part of the unit's activity and income.

vii) Contract Exclusions

Following diagnosis, the provision of BiPAP apparatus where this is indicated according to the diagnosis. Provision of CPAP apparatus would be a matter for individual determination between the service, secondary centre and purchaser.

viii) Monitoring - clinical audit of referrals which may be inappropriate for a tertiary centre

There should be continuous feedback of data to referring clinicians and purchasers to gauge appropriateness of care. However, for the purposes of research, the tertiary centre may reach an arrangement with the secondary centre, but at no financial penalty to the purchaser and on terms which favour the patient's interest.

ix) Tariff of Charges

Referral from a secondary centre where there is diagnostic uncertainty, on the following basis:

a) Of the patient
b) Of computer or paper data on a patient for expert opinion
c) For conditions unlikely to be SHAS, but appropriately referred to benefit from the sophisticated diagnostic apparatus and management capabilities of the tertiary centre.

x) Research and Development

As budget holder for a programme of research topics, possibly with its own portfolio of research.

2. Secondary Service - A Sleep Disorders Unit

i) Definition of service

The primary objective of the sleep service would be to provide a facility for the clinical assessment, diagnosis and management of patients with daytime sleepiness or other features of sleep apnoea/hypopnoea syndrome for a defined local population or purchaser. The service will provide follow-up for patients when requested by the referring practitioner.

A second objective of the service is that of the investigation and management of patients with nocturnal hypoxaemia and hypercapnia due to the nocturnal hypo-ventilation. Although these patients do not have the sleep apnoea/hypopnoea syndrome, the investigation and management is closely analogous.

The purchaser would expect that between 10 and 20 percent of patients, despite adequate assessment, would still present diagnostic uncertainty. It would be appropriate then to refer on for tertiary assessment.

ii) Research and Audit

As a new health technology, it would be integral to the sleep disorder unit to participate fully in nationally derived clinical audit and research into sleep disorders.

iii) Staffing

a) The service would normally be under the direction of a Consultant with a commitment to chest diseases for the majority of their time. Sleep disorders, however, would be a recognised part of their higher professional training prior to taking up a consultant appointment, or the result of a long standing interest supplemented by periods of study and continuing professional development in the area of sleep disorders.

b) *Technical and Nurse Staffing* - both technical and nurse staff, while not necessarily full-time committed to sleep disorders, should have a recognised period of specialised training in sleep disorders, should regularly update their skills and knowledge, and develop a system of external quality assurance in association with the tertiary centre.

iv) Equipment

At minimum, the sleep disorders service should have access to at least one quiet room equipped for the purposes of sleep disorder management.

Diagnostic apparatus should include:

a) At least one four-channel polysomnograph
b) The service should possess the skills and equipment to enable CPAP titration
c) Follow-up/helpline staff - help should be available during office hours
d) Ward night staff should be familiar with potential patient complications and queries at home, and should be able to deal with or refer enquiries on a 24 hour basis.

v) Activity Level/Throughput

The indicative activity level should be at least 100 new patients referred per year (2 per week). Facilities should be available primarily for overnight studies, but also for a number of daytime studies as necessary. At least 50% of overnight studies should take place on a domiciliary basis.

vi) Referral

The usual means of referral would be through a General Practitioner but there may also be cross-referral from the hospital physician or surgeon (with the knowledge and consent of the GP). Normally, a patient referred to the tertiary service would be returned to the secondary local unit following elucidation of the diagnosis, with a recommendation for further treatment. Referral to the tertiary centre can be on four grounds - that of diagnostic uncertainty, sending the patient or a computer/paper record, for atypical conditions and for research purposes by mutual agreement (see later).

vii) Research and Audit

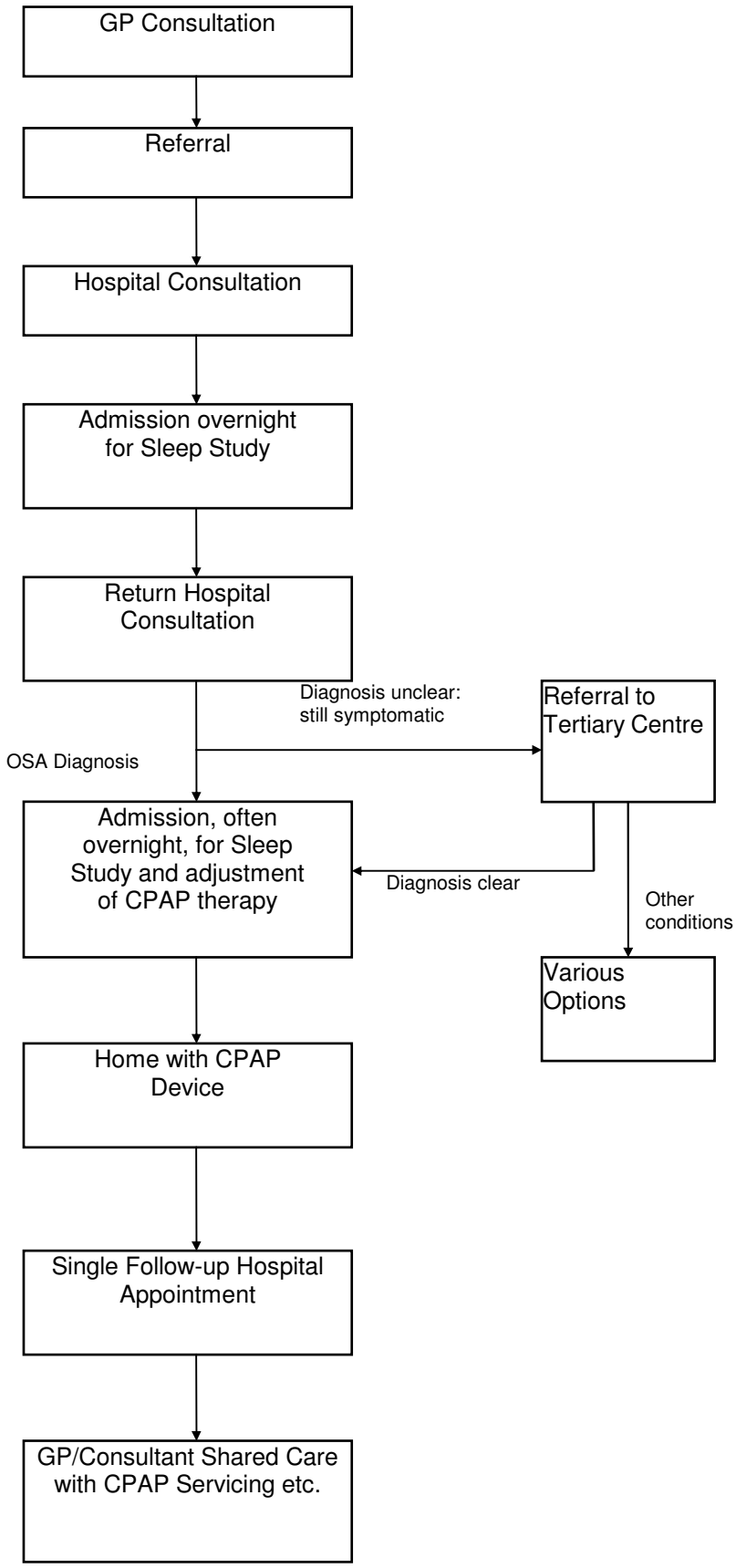
The secondary service would be expected to engage fully with clinical audit and research. While it may hold its own research projects, it would be expected to contribute fully to research on a multi-centre basis, including the identification of control patients. There should be continuing assessment of levels of patient understanding, relating to compliance with treatment.

viii) Contract Exclusion

Following diagnosis, the provision of BiPAP apparatus where this is indicated according to the diagnosis. Secondary units may reach agreement with the tertiary unit to refer on patients for the purposes of research. This arrangement should have no financial penalty to the purchaser and should be with the informed consent of the patient.

FIGURE 1

Typical pathway of care for a patient with Obstructive Sleep Apnoea



ix) Tariff

Units would be expected to include within the contract price the supply of a CPAP machine. It is recognised that only a proportion of patients with a suitable diagnosis will require such apparatus.

The pricing policy would be either:

a) Diagnosis and clinical advice
b) Diagnosis and management of SAHS, including the provision of CPAP machines and onward management
c) A single rate recognising the probability of a certain proportion of patients requiring CPAP machines.

Sleep Disorders Service - Monitoring Information

1. Statement of activity:

- number of new patients seen -total
  -by Health Board of residence/purchaser
- number of night sleep studies -diagnostic
  -treatment
  -hospital/home
- number of day-time studies
- number of CPAP units issued
- waiting time at mid-year -referral to new patient appointment
  -referral to diagnostic study
  -referral to treatment (CPAP)
- number of patients referred to tertiary centre/retained by tertiary centre

2. Comment on any material variance from contracted activity.

3. Comment on any trends in results of which the purchaser should be aware.

4. Results of clinical audit work, to include:

- multi-centre audit
- patient compliance and understanding
- symptom relief/functional improvement
- dietary advice and weight management

5. Research work to include:

-multi-cente commitment - new patients enrolled
- number of studies

- single-centre research (outline)