

NORTH WESTERN HEALTH

**CLINICAL EPIDEMIOLOGY & HEALTH SERVICES
EVALUATION UNIT**

CPAP Service Development Project

Final Report

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Foreword

The CPAP Service Development Project was conducted by the Clinical Epidemiology and Health Services Evaluation Unit, Royal Melbourne Hospital on behalf of the Victorian Department of Human Services. Dr Renee Manser and Associate Professor Donald Campbell coordinated the project and were responsible for writing this report.

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Abbreviations

- CPAP Continuous Positive Airway Pressure
- AHI Apnoea Hypopnoea Index
- SD Standard Deviation
- ESS Epworth Sleepiness Scale
- SWAI Sleep-Wake Activity Inventory
- SAQLI Sleep Apnoea Quality of Life Index
- ANOVA Analysis of Variance
- BMI Body Mass Index
- ICC Intraclass Correlation Coefficient
- REM Rapid Eye Movement (sleep)
- NREM Non Rapid Eye Movement (sleep)

Nomenclature

- For the purposes of consistency throughout the report, consumers of CPAP services will be referred to as patients or participants.
- The term “sleep disordered breathing” will be used. This is a broader category which includes obstructive sleep apnoea, central sleep apnoea and sleep apnoea-hypopnoea syndrome.
- The term “CPAP providers” refers to those institutions/hospitals responsible for administering CPAP services to patients under the CPAP pilot scheme.
- The term “CPAP supplier” refers to those companies whose services are tendered to provide CPAP equipment to patients.
- The CPAP service provided by the department of human services will be referred to throughout as the “CPAP pilot scheme”.

Executive summary and recommendations

Background

The CPAP pilot program was introduced in Victoria on the 1st of July 1997. One of the objectives of this program is to provide high quality and cost effective CPAP services to patients. Under the scheme patients with severe obstructive sleep apnoea who are financially disadvantaged are eligible for one CPAP device and are required to make 10% co-payment towards the cost of their CPAP machine. The patient purchases consumable items (such as masks) associated with the use of CPAP devices.

The current CPAP pilot scheme provides a service for a small proportion of patients estimated to have sleep disordered breathing in Victoria. To be eligible for CPAP services, patients must be managed by a participating sleep centre. The scheme is intended for those with severe obstructive sleep apnoea. Patients with less severe disease are eligible for the scheme if they have co-morbidities such as cardiovascular, neurological or pulmonary disease.

The CPAP pilot scheme provides funding on an annual basis to approved CPAP providers who are required to collect demographic and compliance data on patients and to forward these to the Department of Human Services.

A tendering process is open to CPAP suppliers. Suppliers of CPAP equipment are also expected to provide a follow up phone call service to collect compliance data and offer advice where difficulties with treatment are encountered. This information is forwarded to the CPAP provider.

Overview and Aims

The CPAP Service Development Project has been conducted by a collaborative research team involving 5 of the major sleep centres currently responsible for providing CPAP services under the current CPAP scheme. Western Hospital, Alfred Hospital, Latrobe Regional Hospital, Austin and Repatriation Medical Centre and Monash Medical Centre. These hospitals are the largest providers for the CPAP Pilot Program. Based on the 1998/1999 budget for the CPAP services these centres were responsible for 76% of participants in the CPAP pilot program. The collaborative involvement of the sleep disorders services will assist in developing local versions of best practice protocols.

The CPAP Service Development Project aims to enhance the existing CPAP scheme by assessing current levels of satisfaction with the scheme and health outcomes, such as quality of life. In addition to the evaluation of patient satisfaction, clinician satisfaction with CPAP suppliers and the service provides insight into operational aspects of the scheme. The findings will be made available to CPAP providers and suppliers with a view to improving the current scheme.

The project was conducted between February 1999 and March 2000. The study was conducted in 2 phases, during the first part of the project a retrospective review of the service was undertaken involving the following components:

- Qualitative assessment of clinician satisfaction with the service and suppliers.
- A review of the characteristics of patients using the service.
- Evaluation of patient satisfaction using focus groups.

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- A survey of sleep laboratories throughout Victoria.
- A review of hospital bed utilisation by participants before and after treatment using the Victorian Inpatient Minimum Database.

During the second phase of the project a prospective study was undertaken in order to:

- Assess health-related benefits of the treatment including daytime sleepiness and quality of life.
- Survey patient satisfaction (using a written questionnaire).
- Examine the utility of disease-specific and generic quality of life instruments for assessing the response to treatment.

The research findings have been used to make recommendations for improved performance of the CPAP pilot scheme in relation to:

- The performance of suppliers of CPAP equipment.
- The selection of subjects for treatment with CPAP.
- The conduct of sleep studies.
- Additional management issues relevant to enhancing compliance with treatment for sleep disordered breathing.

The findings may be used to inform the development of locally adapted clinical practice guidelines for the management of sleep disordered breathing.

Study methods

1 Qualitative review of the service:

Staff interviews

A series of key informant interviews were conducted with 3 physicians at different institutions currently involved in the CPAP pilot program to evaluate referring practitioners' experience of, and satisfaction with, the performance of the current CPAP scheme and CPAP suppliers.

Patient focus groups

Four separate focus groups (with an emphasis on service delivery, outcome, side effects, reasons for presentation and barriers to compliance) were held at 4 institutions involved in service delivery in order to examine patient perceptions of the CPAP Pilot Program. The purpose was to generate hypotheses for subsequent research work, inform the development of a patient satisfaction survey and validate the researchers understanding of the research agenda from the viewpoint of patients. All participants in the program at these 4 centres who were referred between October 1998 and December 1998 were invited to attend the groups.

2 Performance review of the clinical service for the diagnosis and management of sleep disordered breathing.

Data on patients referred to the program between October 1998 and December 1998 were reviewed. Patient demographics, polysomnographic findings and CPAP compliance data were analysed.

3 Survey of laboratory equipment and methods for scoring sleep studies.

A survey of laboratory equipment and scoring methods was undertaken using a self-complete written questionnaire constructed following literature review and interviews with staff at 3 separate sleep laboratories. The purpose of the survey was to examine the sources of variability in the measurement of sleep disordered breathing (as defined by the Apnoea-Hypopnoea Index) between laboratories. The survey was sent to all Victorian laboratories listed by the Australasian Sleep Association in 1998.

4 Comparison of scoring criteria for sleep studies

Currently there is a lack of data available about which definitions of hypopnoea best predict health status or short and long term outcomes such as cardiovascular morbidity. This study examines the effect that variations in practice have on the prevalence of disease in the population of patients involved in the CPAP pilot scheme and the level of agreement between the different sleep laboratory methods for scoring sleep studies. The Chicago criteria¹ have been proposed as a 'gold standard' for scoring sleep studies, however none of the laboratories surveyed are currently using this method exactly. The study compared this method with the criteria used by 2 of the larger providers for the CPAP pilot scheme.

5 Prospective evaluation of health outcomes of participants.

The purpose of this research was to determine the outcome measures that may be most useful for evaluating this population, and assess the magnitude of health benefit from treatment with CPAP in this highly selected population. An uncontrolled prospective cohort study was undertaken. Participants in the CPAP pilot scheme between June 1999 and November 1999 at the 5 centres involved in the project were offered participation in the study. Quality of life was measured using a generic quality of life measure and a disease specific questionnaire. Subjective daytime sleepiness was measured using 2 validated measures. Patient satisfaction with all aspects of the CPAP pilot scheme was evaluated using a written self reported survey instrument. All questionnaires were administered at baseline prior to the commencement of CPAP and after 1 and 3 months of treatment.

6 Examination of hospital bed day utilisation by patients with sleep disordered breathing prior to and after commencement of CPAP treatment.

Participants in the CPAP pilot program referred between July 1997 and June 1998 who were admitted to hospital between a 3 year period (1996/1997 -1998/1999) were identified on the Victorian Inpatient Minimum Database (VIMD) using hospital UR numbers. The search was limited to patients at Monash Medical Centre, The Alfred Hospital, Western Hospital and Austin and Repatriation Medical Centre. For each patient the database was searched for admissions 12 months prior to and 12 months after the date that CPAP therapy commenced. All admissions during this period were included and length of stay was also recorded.

¹ This data is unpublished, source: American Sleep Disorders Association, Discussion document.

Conclusions

- The findings from staff interviews suggest that while CPAP providers believe the CPAP pilot scheme provides a much needed service to patients with sleep disordered breathing, the scheme could be improved. The major concerns raised by staff include:
 - The current guidelines for inclusion in the scheme lack clarity.
 - Physicians expressed some concerns about the limitations to the current eligibility criteria.
 - Physicians currently do not have ready access to compliance reports submitted by CPAP suppliers at the time of clinical review.
 - The expanding scheme has resulted in a growing administrative burden for CPAP providers and at present there is no specific funding allocated for this purpose.
- The results of patient focus groups suggest that most patients are happy with the CPAP pilot scheme however additional technical support following implementation of CPAP would be appreciated. Some patients were concerned about the cost of consumable items.
- Review of data collected on patients referred to the CPAP pilot scheme between October 1998 and December 1998 at the 5 centres found that there were no clinically or statistically significant differences in the rates of compliance between different CPAP providers or different CPAP suppliers. In terms of contacting patients at follow up, some CPAP suppliers performed better than others. Statistically and clinically significant differences exist in the reported Apnoea-Hypopnoea Index and prescribed CPAP pressure of patients entering the CPAP scheme at different institutions. None of the baseline variables measured were good predictors of compliance.
- A laboratory survey sent to sleep laboratories throughout Victoria has documented the extent of variation in the methods used to record and report polysomnography (sleep study results). There were no standard measures used to define or measure hypopnoeas in Victorian sleep laboratories.
- The extent to which the different methods used to define hypopnoeas for the purposes of reporting sleep study results may influence the comparability of reported results between different laboratories was assessed in a study comparing three different methods for scoring hypopnoeas. This study found that while the overall level of agreement between the different methods was high, some differences were noted in the point prevalence of disease when different thresholds were used to define disease in relation to the total Apnoea-Hypopnoea Index. These findings suggest that different methods may influence eligibility and access to the CPAP pilot scheme at different centres.
- In the prospective phase of the study we found that CPAP treatment significantly reduced all measures of daytime sleepiness. In addition small but statistically significant improvements were noted in self-reported health status measured by the SF-36. The Sleep Apnoea Quality of Life Index was also used to assess disease specific quality of life, the results of this survey suggest that in this group of patients, improvement in quality of life was limited by treatment related side effects. Consistent predictors of outcome were not identified from the baseline data collected in this study.

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- The results of the written patient satisfaction survey suggest that patients were happy with the overall service, however responses to individual questions provided some interesting insights into the current scheme, in particular:
 - Satisfaction with the CPAP equipment was generally low compared with service delivery.
 - The majority of participants had experienced difficulties with masks.
 - Many respondents did not find the phone call follow up provided by suppliers helpful.
 - The majority of participants indicated that they would like more information about their condition and how CPAP works.
 - The majority of participants are concerned about the cost of consumable items but not the co-payment made towards the cost of the CPAP machine.
- The findings from the study of hospital bed day utilisation by patients with sleep disordered breathing are interesting. A preliminary analysis shows that in patients managed within the CPAP pilot scheme there is no reduction in hospital bed days or hospital admissions subsequent to the commencement of CPAP therapy for sleep disordered breathing. When extreme cases are removed from the analysis however, there is a significant reduction in both admissions and hospital bed days post CPAP implementation. The findings should be further evaluated using a prospective study design.

Recommendations

Selection of patients for the CPAP pilot scheme.

- The current guidelines need to be revised to include greater clarity and specificity with respect to inclusion criteria.
- Clinical practice guidelines (as outlined in section 10.5) could be used to guide this process.

Assessment of sleep disordered breathing

- Local guidelines for standardising the measurement and reporting of sleep studies should be developed.
- In the absence of such guidelines, specific criteria for scoring respiratory events should be outlined in the CPAP pilot scheme guidelines.

Performance of suppliers

- Follow up requirements for suppliers should be standardised.
- The requirement for suppliers to collect routine compliance meter readings should be reviewed.
- Periodic review of the performance of suppliers could be undertaken by providers using the satisfaction survey developed in this project, once this has been validated.

Enhancing compliance and outcome

- Among subjects selected for the current scheme specific factors influencing compliance or outcome could not be identified.
- A common theme throughout the findings was the need for greater technical support for patients following commencement of CPAP.
- Methods for providing additional technical support to participants should be explored. This might include a shift in the focus during the phone call follow up provided by suppliers (from the collection of meter readings to the provision of advice) or the use of CPAP clinics.

Role of clinical practice guidelines

Locally adapted evidence based guidelines for the management of sleep disordered breathing could form the basis for guidelines for the scheme and would represent a compromise between flexibility for clinicians and equity and access for patients. Our research suggests the scope of guidelines should include:

- Diagnostic and treatment criteria
- CPAP implementation
- Technical support
- Follow up procedures
- Alternative treatment options

Administration of the CPAP pilot scheme

Alternative methods for administering the scheme should be explored, these might include:

- A centralised administrative process
- Additional funding for current providers to cover administrative costs

Support for patients

- Patients need education regarding their condition and treatment and this should take account of their sociodemographic background and cultural diversity. This might involve for example the development of literature in languages other than English.
- Some participants would benefit from additional financial support for the cost of consumables in specific circumstances.

Research and development

- Further research and development is required into CPAP technology and its application to clinical practice.

1 Introduction

1.1 Background

The clinical syndrome of sleep apnoea has been increasingly recognised in medical practice in the last three decades. The prevalence of the disorder in the general population is estimated to be between 2 and 4% (1). The prevalence increases with age, and with increasing obesity. Thus obstructive sleep apnoea is about as prevalent as diabetes mellitus in women and systemic hypertension in men. The public health significance of sleep disordered breathing has been likened to that of smoking (2).

Complications of the condition are numerous. Sleep disordered breathing frequently results in neuropsychological and behavioural sequelae including mood disorders, impaired cognitive function and daytime sleepiness (3). Moreover, systemic and pulmonary hypertension, right heart failure and cardiac arrhythmias as well as increased risk of premature mortality have been linked to the condition (4,5). Currently nasal CPAP is recognised as the treatment of choice for the management of sleep disordered breathing. Numerous studies have demonstrated the effectiveness of nasal CPAP therapy in eliminating apnoeas and symptoms referable to sleep disordered breathing. In addition mortality associated with sleep apnoea may be reduced by nasal CPAP treatment (6).

Patients with sleep disordered breathing have been shown to be heavy users of medical services prior to initiation of treatment (7). Furthermore, treatment with nasal CPAP has been shown to be effective in reducing hospitalisation with cardiovascular and pulmonary disease (8). Despite this, concerns have been raised internationally that direct costs to the patient may be limiting factor in the initiation of treatment with nasal CPAP when economic resources are constrained (8).

The CPAP pilot program was introduced in Victoria on the 1st of July 1997. One of the objectives of this program is to provide high quality and cost effective CPAP services to patients. Under the scheme patients with severe obstructive sleep apnoea who are financially disadvantaged are eligible for one CPAP device and are required to make 10% co-payment towards the cost of their CPAP machine. The patient purchases consumable items (such as masks) associated with the use of CPAP devices. The co-payment is usually about \$70 while consumables cost usually at least \$150.

The current CPAP pilot scheme provides a service for a small proportion of patients estimated to have sleep disordered breathing in Victoria. To be eligible for CPAP services patients must be managed by a participating sleep centre. The scheme is intended for those with severe obstructive sleep apnoea with an Apnoea Hypopnoea Index (AHI) of 20 or more events per hour. Patients with less severe disease ($AHI \geq 15$) are eligible for the scheme if they have co-morbidities such as cardiovascular, neurological or pulmonary disease. Eligible subjects must either be a health care card or equivalent concessional card holder or otherwise demonstrate financial disadvantage. Participants within the scheme are expected to comply with CPAP usage requirements.

The CPAP pilot scheme is structured such that funding is provided on an annual basis to approved CPAP providers. Patients must be managed by one of the participating centres. The providers are required to collect demographic and compliance data on patients and to forward this to the Department of Human Services.

A tendering process is open to CPAP suppliers. Suppliers of CPAP equipment are also expected to provide a follow up phone call service to collect compliance data and offer advice where difficulties with treatment are encountered. This information is forwarded to the CPAP provider.

The CPAP Service Development Project aims to enhance the existing CPAP scheme by assessing current levels of satisfaction with the scheme and health outcomes such as quality of life. In addition to the evaluation of patient satisfaction, clinician satisfaction with CPAP suppliers and the service will provide insight into operational aspects of the scheme. The findings will be made available to CPAP providers and suppliers with a view to improving the current scheme.

The project examines the utility of disease-specific and generic quality of life instruments for assessing the response to treatment. It provides a mechanism for the development of a local audit of the performance of the CPAP pilot scheme. This will guide future refinements to the CPAP pilot scheme. The collaborative involvement of the various sleep disorders services will help in developing local versions of best practice protocols. This is seen to be a critical element in enhancing the implementation of research findings into practice (9).

1.2 Overview

The CPAP Service Development Project has been conducted by a collaborative research team involving 5 of the major sleep centres currently responsible for providing CPAP services under the current CPAP scheme. The project was conducted between February 1999 and March 2000.

The study was conducted in 2 phases, during the first part of the project a retrospective review of the service was undertaken involving the following components:

- Qualitative assessment of clinician satisfaction with the service and suppliers.
- A review of the characteristics of patients using the service.
- Evaluation of patient satisfaction using focus groups
- A survey of sleep laboratories throughout Victoria.
- A review of hospital bed utilisation by participants before and after treatment using the Victorian Inpatient Minimum Database.

During the second phase of the project a prospective study was undertaken in order to:

- Assess health-related benefits of the treatment including daytime sleepiness and quality of life.
- Survey patient satisfaction using a written survey.

The research findings have been used to make recommendations for improved performance of the CPAP pilot scheme in relation to:

- The performance of suppliers of CPAP equipment
- The selection of subjects for treatment with CPAP
- The conduct of sleep studies
- Additional management issues relevant to enhancing compliance with treatment for sleep disordered breathing.

The findings may be used to inform the development of locally adapted clinical practice guidelines for the management of sleep disordered breathing.

1.3 Participating Centres

There were 5 CPAP providers involved in the study; Western Hospital, Alfred Hospital, Latrobe Regional Hospital, Austin and Repatriation Medical Centre and Monash Medical Centre. These hospitals are the largest providers for the CPAP pilot program. Based on the 1998/1999 budget for the CPAP services these centres were responsible for 76% of participants in the CPAP pilot program (10).

Throughout the report participating centres will be referred to by number and the codes are listed below:

Hospital code:	Hospital
1	Western Hospital
2	Alfred Hospital
3	Latrobe Valley
4	Austin and Repatriation Medical Centre
5	Monash Medical Centre

At the time this project commenced there were only 3 suppliers in the CPAP pilot program and these were chosen following a tendering process. Throughout the report suppliers are also referred to by code as displayed below:

Supplier Code:	Supplier
A	Air Liquide
B	Fisher and Paykel
C	Sunrise Medical

2 Qualitative review of the service: staff interviews

2.1 Aims

To evaluate experience of and satisfaction with the current CPAP pilot scheme and suppliers from the point of view of referring practitioners and sleep laboratory staff.

2.2 Methods

A series of key informant interviews were conducted with 3 physicians at different institutions currently involved in the CPAP pilot program. The interviews were conducted by Dr Renee Manser using a semi-structured format. Interviews were transcribed at the time of the meetings. The transcripts of the interviews were then analysed to identify common themes.

In addition when the laboratory survey (refer to Appendix A) was sent to all laboratories throughout Victoria respondents were given an opportunity to respond to the following question 'If you any comments or recommendations regarding the current CPAP pilot scheme please list below'.

A series of informal and unstructured interviews were held with sleep laboratory staff at each of the centres involved in this study.

2.3 Results

2.3.1 Key informant interviews

The major findings are summarised below

2.3.1.1 Eligibility criteria and access to the scheme

Some concerns were raised in relation to the current eligibility criteria:

- The AHI does not necessarily reflect disease severity.
- Other measures such as marked desaturation or findings from oesophageal balloon studies should be included in the criteria.
- The program does not specify a method for determining the AHI.
- One physician thought the AHI cut off should not only apply to the total AHI but also should cover patients with sleep disordered breathing occurring predominantly in a particular sleep stage or body position. It was noted that the guidelines are not clear on this issue.
- The term 'financially disadvantaged' lacks clarity.
- Consideration to symptoms could be included in the criteria.
- One physician felt that access should not be limited to patients managed by participating centres.

2.3.1.2 Supplier performance

- 1 physician had noted that the adequacy of follow up varies with different suppliers but the others had not made any assessment of the adequacy of follow up by different suppliers. None of the centres had methods for systematically evaluating the adequacy of the service provided by suppliers.
- 2 of the physicians did not usually have the opportunity to view the compliance reports provided by suppliers and a third found the reports helpful but only had access to them at the time of patient review about 20 % of the time.

2.3.1.3 Clinical review

- Routine follow up arrangements for clinical review vary at the different centres. Follow up sleep studies at 3 months are rarely performed due to long waiting lists for sleep studies.
- Physicians tended to manage poorly compliant patients on an individual basis and try to assist with measures to improve adherence in the first instance. In general they did not specify daily rates of CPAP usage considered to indicate inadequate compliance.
- Physicians felt that poorly adherent patients could best be dealt with in the context of clinical review.

2.3.1.4 Administration of the scheme

Concerns raised about the administration of the current scheme include:

- Changes to the tendering process once the pilot scheme tendering process ceases (fairness, competition and pricing).
- The growing and long term administrative load of the program for hospitals (the workload will continue to increase as the scheme expands to include new patients)
- Two physicians suggested that alternative methods for administration of the scheme should be explored.
- Concern regarding the lack of funding provided for CPAP technologists/nurse by hospitals acting as providers for the scheme.
- Concerns about ownership of the machine and implications for maintenance.

2.3.2 Survey results

- Several laboratories indicated that they were happy with the scheme and believed it had provided a significant benefit to patients.
- One sleep laboratory not currently involved in the CPAP scheme was concerned that patients who were assessed initially at their laboratory and were subsequently found to be eligible for the CPAP scheme had to be referred elsewhere for repeat studies or clinical review possibly resulting in delays to treatment and unnecessary duplication.

2.3.3 Informal and unstructured interviews

There was general uncertainty about what was meant by the term 'managed by a participating centre'. At some centres patients are referred and followed up by physicians not working directly at that institution.

The centres involved in this study have slightly different procedures for implementing CPAP and following up patients. Only 2 CPAP providers offer routine access to a CPAP clinic.

All centres raised concerns about the growing administrative burden of the scheme under the current system and the lack of specific funding for this purpose.

2.4 Discussion

We have sampled a relatively small number of physicians and all physicians were from tertiary institutions involved in this study. Therefore the findings may not reflect the views of all referring physicians to the program. In addition however, comments were invited from all sleep laboratories in Victoria at the time of the laboratory survey.

Although staff members believe the CPAP pilot scheme provides a much-needed service to patients with sleep disordered breathing, there are concerns about the limitations of the service, the clarity of the guidelines and the administration of the scheme. Of significant concern is the fact that compliance data being collected by suppliers of CPAP equipment is not readily accessible to treating physicians at the time of clinical review. A mechanism for allowing physicians access to compliance reports at the time of review should be developed. Alternatively treatment adherence could be assessed at the time of clinical follow up. For example some centres routinely ask patients to bring their CPAP machines with them at review and check compliance meters at that time. Another option would be to omit the requirement for checking compliance meters in favour of following patient reports of compliance and symptoms. The results of follow up from a large CPAP service in the United Kingdom have recently been published. At this centre compliance meter readings were monitored and pumps were reclaimed if they were used for less than 2 hours per night. Only 4 % of pumps were reclaimed, while a further 15% of patients in this scheme stopped treatment independently (11). These results suggest that the many poorly adherent patients will decide to stop treatment voluntarily. Therefore a system of regular clinical review may be most appropriate.

All physicians interviewed expressed some concerns about the current eligibility criteria for the scheme. Eligibility criteria may best be based on diagnostic and treatment criteria developed in the context of locally adapted evidence based clinical practice guidelines. If CPAP providers uniformly adopted such guidelines then this would provide a mechanism for balancing the competing interests of flexibility and clinical discretion with equity of access to the scheme.

Concerns raised in relation to administration of the scheme require further evaluation. The expanding scheme has resulted in a growing administrative burden for CPAP providers and at present there is no specific funding allocated for this purpose. The provision of additional funds for administration would be one way of addressing this problem. Another suggestion made was to develop a centralised administrative process.

2.5 Conclusions

- The current guidelines for the CPAP pilot program lack clarity.
- Procedures for follow up are not standardised and the system for monitoring compliance could be improved.
- CPAP providers are concerned about the growing administrative burden of the scheme.

2.6 Recommendations

- The current guidelines for the CPAP scheme should be reviewed to include greater specificity and clarity with respect to inclusion criteria and follow up requirements.
- The procedure for monitoring compliance should either be improved or alternative methods for managing poorly adherent patients examined.
- Alternative methods for administering the scheme could be explored.

3 Qualitative review: Patient focus groups

3.1 Background

Since the introduction of the CPAP pilot scheme there has been no formal evaluation of patient satisfaction. Searches of the medical literature failed to identify any tools that were available for assessing patient satisfaction with CPAP services. Therefore focus groups were used as a means of exploring further patient experiences of the current system and to identify problems encountered with the treatment or the service.

3.2 Aims

To examine patient perceptions of the CPAP Pilot Program with an emphasis on service delivery, outcome, side effects, reasons for presentation and barriers to compliance. The purpose was to generate hypothesis for subsequent research work, inform the development of a patient satisfaction survey and validate the researchers understanding of the research agenda from the viewpoint of patients.

3.3 Method

Four separate focus groups were held at 4 institutions involved in service delivery for the CPAP pilot program (Hospitals 1,2,3 and 5). All participants in the program at these 4 centres referred between October 1998 and December 1998 were invited to attend the groups. The subjects were chosen from the same cohort of patients reviewed in section 4. Subjects were initially sent a letter and this was followed by a phone call specifying the purpose of the groups and the available time. There were 33 (33 %) respondents who indicated they would be available to attend at the nominated times.

The procedures for the conduct of the focus groups followed the recommendations laid down in Thomas et al. (12). A trained independent observer conducted the groups. The discussions were recorded using a Marantz Superscope recorder with external Sony electret microphone onto audio cassettes.

The following questions were used as the basis for stimulation of the discussion for each group. As discussed in Thomas et al, unlike in the case of structured individual interview, focus group participants modify the agenda to follow their own interests. Therefore, the discussions, while including discussion of the participants' views concerning the following questions, also involved consideration of other matters raised by the participants. This is a standard feature of the focus group method.

The concepts for the questions were developed following review of the literature related to CPAP compliance and satisfaction and discussions with clinicians in the field. The questions were structured by Thomas and Associates, based on written and verbal briefings concerning the study aims. The questions used in the discussions appear below.

- How did you come to be on the sleep apnoea program?
- Did you decide to come yourself or did someone else suggest that you come?
- What happened when you came on the program?
- Do you have difficulty with sleepiness during the day?

- Do you snore?
- What do you think of CPAP? Does it work for you?
- Does it have any side effects?
- What do you think about the CPAP program?
- What are the good things about the program?
- What are the bad things about the program?
- How could it be improved?

After conduct of the groups, the recordings were professionally transcribed by a transcription service. Shane Thomas performed minor editing on the transcripts. Following finalisation of the transcript documents, the text within them was subjected to thematic analysis. This involves the parsing of the transcription into text units and then encoding of these units into categories. Unlike in some aspects of quantitative method, there is no single universally approved method for thematic analysis (13).

The selection of coding themes reflects the outlook of the coder. The readers of this document because of their different outlooks and theoretical perspectives may have quite different priorities. It is important for the purposes of this exercise as specified in the activity brief that independent analysis of the transcripts occurs. Each separate goal may require a different use of the information contained in and generated by the interviews and transcripts.

3.4 Results

24 subjects attended the meetings (73% of those who indicated they were available). The majority of participants were from the same cohort used in the retrospective analysis of patients (see section 4) and therefore demographic and compliance data was available. Both adherent and non-adherent users of CPAP attended. Table 3.1 compares the characteristics of participants who attended the focus groups with the remainder of the cohort from which they were selected.

Table 3.1: Characteristics of focus group participants and non-participants

	Non Participants Mean (95% CI)	Participants Mean (95% CI)	P-value independent sample T test
% Female	20%	25%	0.743 [†]
Age (years)	57 (55-59)	61 (53-69)	0.324
BMI (kg/m/m)	36 (34-37)	34 (30-38)	0.427
AHI (events per hour)	40 (35-45)	39 (28-54)	0.832
CPAP Pressure (cm H₂O)	10.4 (9.8-11)	9.4 (7.8-11.4)	0.303
Compliance (hours/day)	4.8 (4.3-5.3)	4.5 (3.3-5.6)	0.616

[†] Fisher's exact test

Outcomes of transcript analysis

In the coding approach used in this exercise, the following themes were identified.

- Three main triggering events were mentioned by patients in terms of their decisions to enter the program. These were:
 - A bad experience with driving
 - Family pressure to attend, and
 - Tiredness.
- Many patients mentioned long periods before correct diagnosis had occurred.
- Sleepiness was a common symptom.
- Many participants noticed an improvement in daytime sleepiness with CPAP treatment but some did not.
- Most participants reported snoring was a major problem for them.
- Most respondents reported positive experiences with CPAP and many reported major changes for the better.
- Many respondents mentioned difficulties with the operation of their mask (nasal or full face) including soreness from local pressure and problems related to air escape.
- Most respondents had positive views about the CPAP program.
- Participants felt the program could be improved by additional technical support to assist with mask and related problems.
- Cost related to consumables and running costs was an issue for some respondents.

3.5 Discussion

This study provides some important insights into the patient perspectives on the current CPAP program. The use of focus groups is a valuable method for exploring people's knowledge and experiences. As with other types of qualitative research interviewing and coding is somewhat a subjective process however in this case the focus groups were conducted by someone independent from the research team and so biases at the stages of interview conduct and coding were minimised but not eliminated.

Including focus groups in the evaluation process means that respondents with poor literacy skills are able to participate. There are some limitations with the sample however, a few patients from non-English speaking backgrounds were unable to attend because interpreters were not available. In addition those subjects who were referred for CPAP but withdrew from the program prior to receiving treatment are not listed and therefore have not been provided the opportunity to attend these groups.

The results suggest that patients within the program are relatively happy with the delivery of the service and its outcomes. This could be the result of sample bias with respondents with negative experiences failing to attend the groups however, there was no significant difference in levels of compliance between those who attended the groups and those who did not.

Other studies have also found that side effects related to the mask are common (14). Additional technical support may be required for participants within the CPAP program. Recent research suggests that CPAP use may be improved by a nurse-led intensive CPAP education and support program (15).

Exploring triggering factors for presentation may provide further insights to factors that influence compliance and outcome. For example previous research suggests that those who are self referred are more compliant than those who are referred by their partners (15). Our findings suggest that it may be possible to classify triggers for presentation into three main categories.

The costs incurred for consumable items some patients found restrictive.

3.6 Conclusions

- Most participants are happy with the current CPAP program however additional technical support would be well received.
- The findings have been used to develop a survey to further evaluate levels of patient satisfaction.
- Future research may help to establish whether improved technical support results in better outcomes and examine the relationship between triggering factors for presentation, outcome and compliance.

3.7 Recommendations

- Following implementation of CPAP additional technical support is required with respect to running of equipment and operation of masks.

4 Review of the performance of the clinical service: patient characteristics

4.1 Background

The routine data collected under the guidelines of the CPAP pilot scheme has not been reviewed since the scheme began in 1997. Participants in the scheme are expected to consent to consumer level data being forwarded to the Department of Human Services. Information including sleep study variables, demographics and compliance measures are collected by the CPAP providers. Suppliers of CPAP equipment also contribute to data collection by following patients up with phone calls to obtain CPAP meter readings (a measure of compliance). The data was reviewed in order to assess the performance of CPAP providers, suppliers and the overall service.

4.2 Aim

To review the performance of the clinical service for the diagnosis and management of sleep disordered breathing at 5 sleep centres involved in the CPAP Pilot Scheme.

4.3 Methods

Data on patients referred to the program between October 1998 and December 1998 was reviewed. Patient demographics, polysomnographic findings and CPAP compliance were analysed. Compliance data was collected by the suppliers or hospitals by phone call follow up (CPAP meter readings). Statistical analysis was performed using SPSS version 8 for windows. Comparisons were made between different centres and suppliers using one-way ANOVA. Variables that were non-normally distributed have been logarithmically transformed (using natural logarithms) to a gaussian distribution. Multiple linear regression was used to assess the relationship between baseline variables and compliance.

4.4 Results

Of 140 patients referred to the program, 137 commenced CPAP. 93 patients were known to be using CPAP at between 1 and 6 months, 32 could not be contacted at follow up and 12 were known to have stopped treatment within the first 6 months.

The findings are presented in a series of tables below. For continuous data results are summarised with mean values and 95% confidence intervals (CI) for the mean unless otherwise stated. For the following variables; Apnoea-Hypopnoea Index, Oxygen saturation nadir, CPAP pressure the mean values presented represent the geometric mean.

Table 4.1: Summary statistics for entire patient group

Variable	Number of patients with data available	Mean, median, (95% CI)
Gender (% female)	140	29
Age (mean, median, range)	140	57,58 (24-85)
Body Mass Index kg/m/m	131	35.4, 35, (34 – 36.8)
Apnoea-Hypopnoea Index (events/hour)	131	39.8,41.0 (35.4-44.8)
Oxygen saturation nadir	132	76, 76, (73.8-78)
CPAP pressure recommended (mmH ₂ O)	135	10.3, 10.0, (9.7-10.8)
Compliance (hours per day)	98	4.7, 5.0 (4.3 – 5.2)

Table 4.2: Summary data by hospital

Hospital	1	2	3	4	5	P value (ANOVA)
Number of patients	30 (21%)	29 (21%)	25 (18%)	41 (29%)	15 (11%)	
Age (mean, range)	55 (30-85)	50 (36-80)	58 (30-77)	57 (24-84)	57 (35-75)	0.712
Body Mass Index kg/m/m	36.8 (33.6-40.0)	35.3 (31.4-9.1)	33.9 (30.7-37.0)	35.9 (33.4-38.4)	34.6 (30.4-38.9)	0.769
Apnoea-Hypopnoea Index (events/hour)	52.5 (42.5-64.7)	32.3 (24.8-42.4)	34.0 (27.0-42.8)	44.3 (34.2-57.2)	34.9 (22.3-54.6)	0.033*
Oxygen saturation Nadir	78 (72.5-82.4)	76.6 (72.1-80.4)	77.6 (72.0-82.0)	73.1 (68.4-77.2)	75.8 (67.4-82.0)	0.459
CPAP pressure (mmH ₂ O)	11.9 (10.7-13.2)	8.9 (8.0-9.9)	10.0 (9.1-11.1)	11.2 (10.2-12.4)	8.1 (7.0-9.4)	<0.0005 [†]
Contacted at follow up (%)	81.5	79.3	60	73.2	100	0.057 [‡]
Compliance (hrs/day)	4.4 (3.6-5.2)	5.2 (4.2-6.2)	5.7 (4.3-6.9)	4.2 (3.3-5.1)	4.6 (3.0-6.2)	0.271

* Statistically significant at the 0.05 level of significance.

[†] Hospitals 2 and 5 prescribed significantly lower CPAP levels even after adjusting for the effect of disease severity and BMI using multivariate analysis.

[‡] Chi Square

Table 4.3: Summary data by supplier

	Supplier A	Supplier B	Supplier C	P value (ANOVA)
Number of patients	35	82	20	
BMI (kg/m/m)	35.4 (32.2-38.6)	34.9 (33.4-36.4)	35.1 (30.9-39.2)	0.953
AHI (events/hour)	37.5 (30.8-45.6)	38.3 (32.6-45.0)	44.8 (30.3-66.0)	0.625
Oxygen saturation nadir	78.3 (73.9-82)	74.4 (71.5-77.1)	78.2 (71.6-83.3)	0.195
CPAP pressure (mmH₂O)	10.0 (9.0-11.0)	10.2 (9.6-10.8)	11.0 (9.0-13.5)	0.510
Compliance (hrs/day)	5.0 (3.8-6.3)	4.9 (4.3-5.4)	3.4 (1.7-5.1)	0.11
Contacted at follow up (%)	54	88	72	< 0.005* [‡]

*Statistically significant difference.

[‡] Chi Square

Compliance:

Within the first 6 months of treatment 61% of patients were using CPAP for more than 2 hours per night and 50% were using CPAP more than 3.5 hours per night.

None of the variables recorded were good predictors of compliance, using multiple linear regression only 9% of the variance was explained and in this selected patient group compliance varied inversely with disease severity. (AHI; β -0.27, p 0.025, Oxygen nadir; β 0.31, p 0.011) Other variables (Age, BMI, hospital and gender) were not statistically significant.

There were no clinically or statistically significant differences between compliant and non-compliant users for the variables measured (As outlined in table 4.4). For the purposes of this analysis non-compliant users were defined as those who could not be contacted or those who were known to have stopped treatment.

Table 4.4: Comparison between compliant and non-compliant subjects

	Compliant users Mean (95%CI)	Non-compliant Mean (95% CI)	P value Independent- samples T test
Number	93	44	
Age (mean, median, range)	57, 59 (30-84)	57, 58	0.798
BMI (kg/m/m)	35.6 (33.9-37.3)	34.6 (31.9-37.3)	0.532
Gender (% female)	21.5%	20.5%	0.663 [‡]
AHI (events/hr)	39.9 (34.3-46.4)	37.3 (30.8-45.2)	0.576
Oxygen saturation nadir	75.6 (72.8-78.1)	76.8 (72.8-80.3)	0.589
CPAP pressure (mmH₂O)	10.3 (9.6-11.0)	10.1 (9.2-10.9)	0.687

[‡] Chi Square

Polysomnographic variables before and after CPAP

Two hospitals supplied further data on CPAP studies and the Epworth Sleepiness Score at baseline. Following treatment with CPAP there was a clinically and statistically significant reduction in both the number of apnoeas or hypopnoeas per hour and the minimum oxygen saturation.

Table 4.5: Polysomnographic variables before and after CPAP

	Hospital 1	Hospital 2	P value for difference between hospitals using Independent-samples T test.
Pre-treatment AHI	52.5 (42.5-64.7)	32.3 (24.8-42.4)	0.006
Post-treatment AHI (CPAP)	12.3 (7.6-19.5)	3.9 (2.1-6.6)	0.002
<i>P value (before and after CPAP using paired T test)</i>	<0.0005***	<0.0005***	
Pre-treatment Oxygen nadir	78 (72.5-82.4)	76.6 (72.1-80.4)	0.674
Post-treatment Oxygen nadir	88.6 (84.6-91.6)	88.8 (86.1-90.9)	0.955
<i>P value (before and after CPAP using paired T test)</i>	<0.0005	<0.0005	
Epworth Sleepiness Scale at baseline	13.1 (10.7-15.5)	11.0 (8.3-13.8)	0.249

*** In a combined analysis (hospitals 1 and 2) multivariate analysis (using the difference as the outcome) was used to adjust for hospital and baseline severity and the improvement was still statistically significant (p <0.0005). There was a suggestion that the hospital may be a predictor but this did not reach statistical significance (p = 0.1).

4.5 Discussion

The median compliance is comparable to that seen at other centres with CPAP schemes (11). The losses to follow up in this group are high and this may bias the results.

Long term follow up has yet to be performed, however McArdle et al have found that CPAP use during the first 3 months is predictive of long term compliance (11).

The comparative analyses performed in this study are exploratory only. The groups are not randomised and differences between groups may be the result of unknown or unrecorded characteristics related to patients, centres or suppliers.

Differences in disease severity between different centres may reflect variations in the methods used to score sleep studies.

Differences in the prescribed CPAP pressure may indicate variation in clinical practice. There are no guidelines currently for the implementation of CPAP and different laboratories may chose to use different end points for CPAP titration studies.

There were no clinically or statistically significant differences in the rates of compliance between the various hospitals and suppliers. Some suppliers were better at contacting patients however and therefore selection bias may affect this finding.

Some suppliers were better than others at contacting patients. The different suppliers do have different protocols for following up patients. We have found in this research that some participants within the scheme are difficult to contact due to multiple factors. Problems include limited access to telephones, language barriers and frequent changes of address.

Assessing the adequacy of compliance is difficult because there is no consensus currently about what levels of daily usage may be sufficient to improve patient outcomes (16). Some centres have used a cut off of less than 2 hours per night however there is no such cut off within this scheme. Some clinical trials have found improvements in daytime sleepiness with compliance levels as low as 3.2 hrs per night (17).

In general other studies have also found that baseline variables such as disease severity measured by the AHI are only weak predictors of compliance (11,18).

4.6 Conclusions

- Rates of compliance with CPAP did not differ between different centres or CPAP suppliers.
- Some suppliers were better at contacting patients at follow up.
- Statistically and clinically significant differences exist in the reported AHI and prescribed CPAP pressure of patients entering the CPAP scheme at different institutions. These findings warrant further evaluation.

4.7 Recommendations

- Criteria for scoring sleep studies and the impact on the reported prevalence of sleep disordered breathing have been explored in further studies (As outlined in sections 5 and 6).
- Clinical practice guidelines should include information about CPAP titration and management of CPAP levels post implementation.
- Procedures for follow up by suppliers could be standardised or reviewed.

5 Survey of laboratory equipment and scoring methods

5.1 Background

Eligibility for the CPAP pilot scheme is based on the severity of sleep disordered breathing. Disease severity is determined by performing overnight polysomnography (sleep study), the results are analysed for respiratory events and an overall Apnoea-Hypopnoea Index (AHI) is calculated. Methods for recording sleep variables and defining respiratory events measured by polysomnography are thought to vary between different sleep laboratories. We developed a laboratory survey in order to document current methods used for recording and analysing overnight polysomnography in sleep laboratories in Victoria.

5.2 Aim

To assess sources of variability in the measurement of sleep disordered breathing (as defined by the Apnoea-Hypopnoea Index) between different sleep laboratories throughout Victoria.

5.3 Methods

A self-complete written questionnaire was constructed following literature review and interviews with staff at 3 separate sleep laboratories. The survey was sent to all laboratories listed in Victoria by the Australasian Sleep Association in 1998. The first part of the survey related to the type of equipment used to record sleep and other variables during overnight polysomnography and the second part to the definitions and methods used for the reporting of the results. The mail out was followed by phone call reminders where required. The survey is displayed in appendix A.

5.4 Results

The response rate was 94% (17 of the 18 laboratories returned the surveys). Several centres have satellite laboratories in rural areas and the sleep studies are scored centrally, consequently for the second part of the survey there are 15 responses.

The survey was quite extensive and only some of the findings are summarised below.

Equipment

All laboratories monitor chest and abdominal wall movements to assess changes in respiratory effort/ventilation. 76% of laboratories use inductive devices while the remainder use strain gauge devices.

Methods used for monitoring airflow are displayed in Table 5.1.

Table 5.1: Airflow

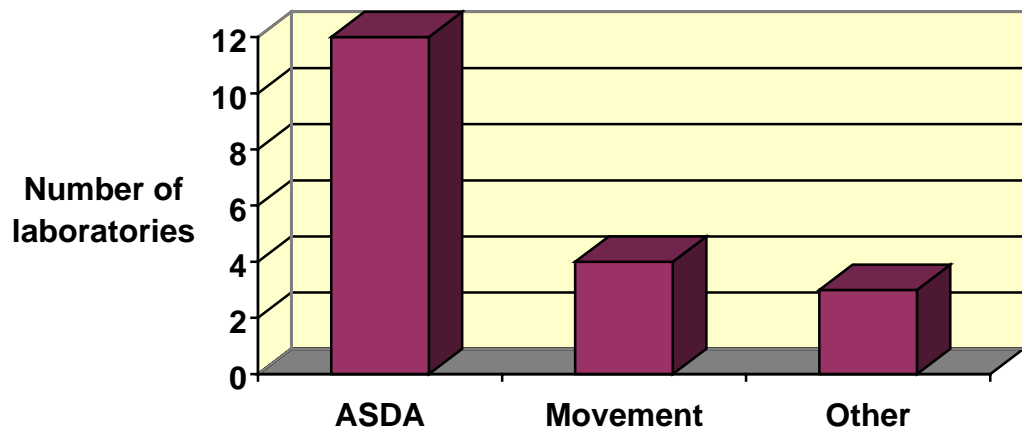
Method for airflow monitoring	Percentage of laboratories
Thermistors	64
Thermocouples	18
Thermistor and nasal pressure transducer	12
Nasal pressure transducer alone	6

Minor variations exist in the methods used for monitoring other variables such as oxygen saturation, EEG, leg movements, body position.

Arousals and micro-arousals

Some laboratories use more than one method to score arousals. The responses are displayed in Figure 5.1. ASDA refers to the American Sleep Disorders Association definition (19). Movement arousals refer to those described by Rechtschaffen and Kales (20). The other category includes the 'Cheshire definition' (3) and non-'standard' definitions.

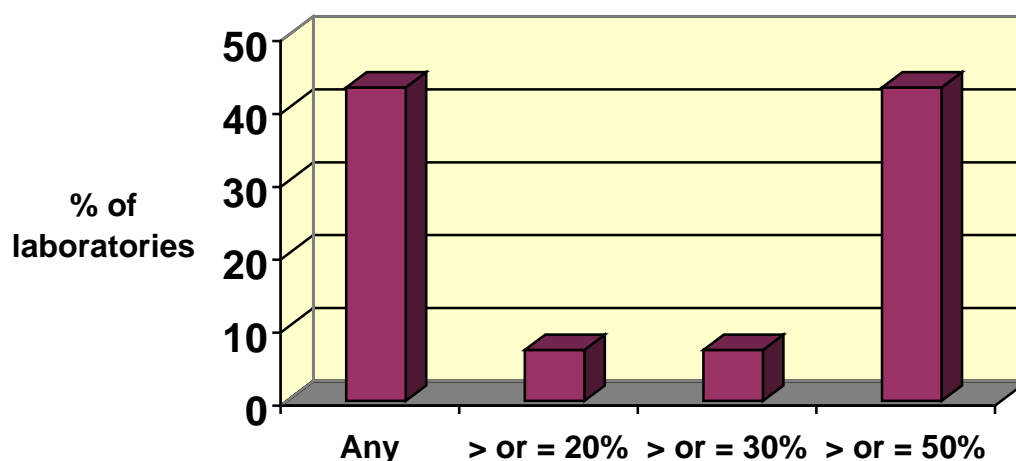
Figure 5.1: Criteria used for scoring arousals



Hypopnoeas

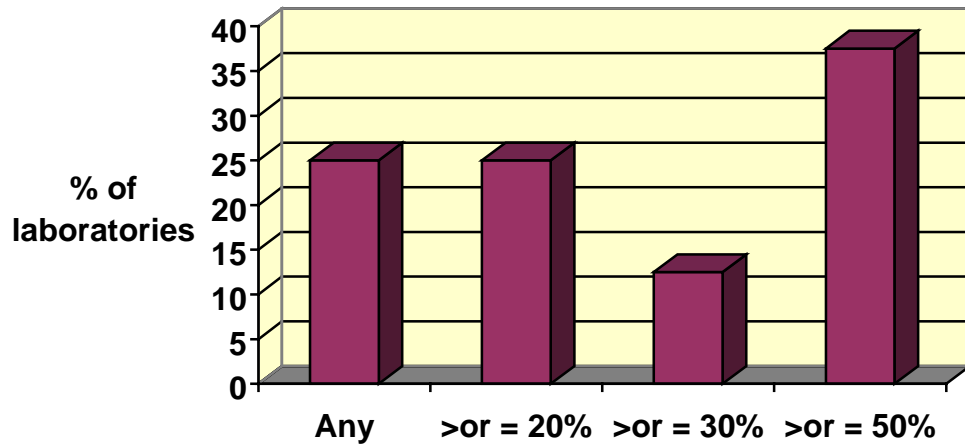
- None of the centres use the same definition of hypopnoea
- 47% of laboratories require reductions in 2 out of 3 respiratory signals (airflow, abdominal or thoracic wall movement).
- 53% of laboratories require changes in 1 of 3 signals (airflow, abdominal or thoracic wall movement).
- 80% of laboratories include oxygen desaturation as part of the definition of hypopnoea (two thirds of these use desaturation alone and one third use either desaturation or arousal).
- 20% of laboratories do not require either changes in oxygen saturation or arousal as part of the definition hypopnoea.
- Where oxygen desaturation is included in the definition of an hypopnoea 50% of laboratories require a reduction of 2 % or greater and 50% require a reduction of 3% or greater.
- All but one laboratory indicated that a reduction in airflow must be present as part of the definition of hypopnoea.
- Those using airflow changes to define hypopnoeas required that the duration of airflow reduction lasts at least 10 seconds.
- The amount of airflow reduction required to score an hypopnoea varies between different centres as displayed in figure 5.2.

Figure 5.2: Percentage reduction in airflow used to define hypopnoeas



- 53% of laboratories indicated that a reduction in thoracoabdominal movement forms part of the definition of hypopnoea. However the amount of reduction varies between centres as displayed in figure 5.3.

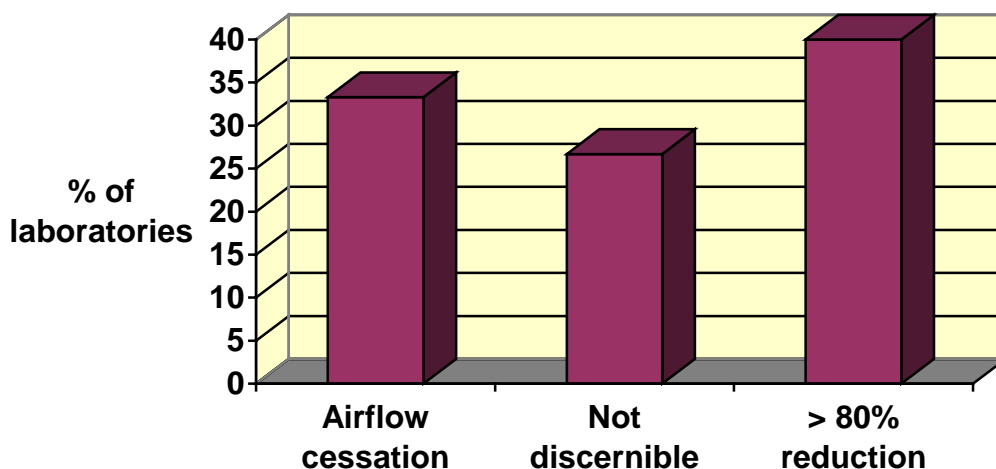
Figure 5.3: Hypopnoeas - percentage reduction in thoracoabdominal movement



Apnoeas

- All laboratories reported using a minimum duration of 10 seconds for the definition of an apnoea.
- 73% of laboratories require an associated oxygen desaturation for the definition of an apnoea. The amount of oxygen desaturation varies between laboratories (1-3%).
- The terminology used to define apnoeas (airflow changes) varies between centres. For this question 4 possible responses were provided; complete cessation of airflow (flat line), reduction in airflow signal such that breaths are not discernible, a greater than 80% reduction in airflow from baseline, other. The results are displayed in figure 5.4.

Figure 5.4: Apnoeas - required airflow changes



- Considerable variation was also noted in the description of changes in thoracoabdominal movement used to distinguish obstructive from central apnoeas.

5.5 Discussion

The survey has documented the extent of variation in the methods used to record and report polysomnography in sleep laboratories in Victoria. Respondent bias has been minimised by the high participation rate.

The greatest diversity exists in the criteria used to define hypopnoeas. Similar results have previously been documented in a survey of North American sleep laboratories (21). In addition we have shown that variation also exists in the criteria used to score apnoeas and arousals.

The development of standards for measuring and assessing sleep-disordered breathing is not only an important consideration within the context of the CPAP pilot scheme but also would provide benefits for clinical practice and scientific and public health research.

5.6 Conclusions

- There are no standard methods used to define or measure hypopnoeas in sleep laboratories in Victoria.
- Variations in methods for scoring apnoeas and arousals have also been demonstrated.
- The extent to which these variations may affect the comparability of reported results between different laboratories requires further research (refer to section 6).

5.7 Recommendations

- The findings suggest there is a need to develop guidelines for standardising recording and reporting of polysomnographic findings at the local level.

6 Comparative study of scoring criteria for sleep studies

6.1 Background

Currently there is a lack of data available about which definitions of hypopnoea best predict health status or short and long term outcomes such as cardiovascular morbidity (22). A large prospective study being conducted in the United States will help to identify the most valid definitions of respiratory events by examining long-term cardiovascular effects (23). The results of this study are likely to be helpful in informing the development of guidelines on the scoring of polysomnographic data. The results of the laboratory survey (section 5) suggest that there is a need to assess the impact that variations in criteria for scoring sleep studies has on the diagnosis of disease. This study will examine the effect that variations in practice have on the prevalence of disease in the population of patients involved in the CPAP pilot scheme. The level of agreement between the different sleep laboratory methods for scoring sleep studies will also be assessed.

6.2 Aims

To explore the effect of using different scoring criteria for hypopnoeas in the scoring of polysomnographic studies:

- Firstly by estimating the level of agreement between different scoring methods.
- Secondly by examining the effect on the point prevalence of disease in this population.

6.3 Methods

48 sleep study records were retrospectively selected at random from a sleep study database. This database included all studies performed on patients at a tertiary sleep centre during a 6-month period. The random number sequence was computer generated. Randomisation was stratified so that studies were selected according to disease severity. There were 6 categories (AHI 0-10, AHI 10-20, AHI 20-30, AHI 30-40, AHI 40-50 and AHI > 50) based on the reported results for that sleep laboratory. Each sleep record was re-scored by the same staff member in a random sequence using 3 different criteria for scoring hypopnoeas. The Chicago criteria¹ have been proposed as a 'gold standard' for scoring sleep studies however none of the laboratories surveyed are currently using this method exactly. We compared this method with the criteria used by 2 of the larger providers for the CPAP pilot scheme.

Sleep staging and scoring

Sleep stages were scored according to the criteria of Rechtschaffen and Kales (20). For each method apnoeas were defined as cessation of oronasal airflow for 10 seconds or longer and a 2% or greater oxygen desaturation. For each method arousals were scored according to the ASDA criteria (19). The 3 different methods for scoring hypopnoeas were as follows:

¹ Unpublished data, source: American Sleep Disorders Association, discussion document.

Method A: A reduction ($\geq 50\%$) in one or more of the 3 respiratory signals (airflow, thoracic or abdominal respiration) compared with baseline breathing level, for more than 10 seconds and desaturation $\geq 2\%$ compared with baseline.

Method B: Chicago criteria

Criteria (either 1 or 2 plus 3)

- 1) A clear decrease from baseline in the amplitude of a validated measure. For inductive signals the amplitude of reduction should be 50% or more using both channels individually or the best one of 2 signals.
- 2) A clear amplitude reduction that does not reach the above criterion but is associated with either an oxygen desaturation of greater than or equal to 3 % or an arousal.
- 3) Event lasts 10 seconds or longer.

The arousal should occur within three seconds of termination of the respiratory event.

Method C: Any discernible reduction in airflow lasting 10 or more seconds associated with a 3% or greater oxygen desaturation (with or without arousal).

Equipment and instrumentation

For each sleep study polysomnographic data was recorded using a computerised polysomnographic system (Compumedics). The montage consisted of 2-channel electroencephalograms, bilateral electrooculograms, a submental electromyogram, and bilateral leg piezo-electric sensors. Nasal and oral airflow was measured using a thermister. Respiratory effort was detected by inductance changes on plethysmography (Respiration). Oxygen saturation was recorded with a finger probe (Radiometer OXI).

Statistical Analysis

Data was analysed using SYSTAT for Windows version 9. Descriptive analysis was performed on the raw data. Apart from NREM and REM sleep times all sleep variables were non-normally distributed. For the purposes of calculating the repeated measures analysis of variance (ANOVA) and an Intra-class Correlation Coefficient (ICC) the AHI for each of the three methods were transformed towards normal using complimentary natural logarithms. The method for calculating an ICC is described in Streiner and Norman (24).

6.4 Results

Table 6.1: Patient summary characteristics

Variable	
Gender (% female)	8 %
Age, years(mean, median, range)	52, 54 (20-86)
BMI, kg/m/m (mean, 95% CI for mean)	31.5 (30-33)

Table 6.2: Summary characteristics of sleep studies

	Mean	Median	Standard deviation	95% CI for mean	Range
NREM sleep time (minutes)	234	232	44	221-247	120-331
REM sleep time (minutes)	53	52	25	46-61	8-107
Arousal Index	37	32	20	31-43	5-87
Apnoea Index	7.3	1.6	11.9	3.9-10.8	0-55
AHI method A^Φ	37.5	37.3	22.8	30.1-44.1	0.4-90.8
AHI method B^Φ	42.0	43.1	21.1	35.8-47.9	4.1-92.4
AHI method C^Φ	30.5	25.9	22.3	24.2-37.2	0.3-86.9
HI method A[†]	30	29	21	24.1-36	0-81
HI method B[†]	35	33	19	29.3-40.4	4-83
HI method C[†]	24	20	20	17.8-29.1	0-83

^Φ Total Apnoea-Hypopnoea Index

[†] Total Hypopnoea Index

6.4.1 Effect of scoring criteria on measured disease prevalence

Table 6.3: Disease prevalence - Method A vs. Method B

		METHOD B			
METHOD A	If AHI \geq 20 events/hr		Ineligible	Eligible	Total
		Ineligible	7	6	13
	*Fisher's Exact Test (2 Sided $p < 0.0005$)	Eligible	0	35	35
		Total	7	41	48
	If AHI \geq 15 events/hr	Ineligible	5	8	13
		Eligible	0	35	35
	*Fisher's Exact Test $p = 0.001$	Total	5	43	48
	If AHI \geq 5 events/hr		Normal	Disease	Total
		Normal	1	1	2
	*Fisher's Exact Test $p = 0.042$	Disease	0	46	46
		Total	1	47	48

Table 6.4: Disease prevalence - Method A vs. Method C

		METHOD C			
METHOD A	If AHI \geq 20 events/hr		Ineligible	Eligible	Total
		Ineligible	13	0	13
	*Fisher's Exact Test (2 Sided $p < 0.0005$)	Eligible	5	30	35
		Total	18	30	48
	If AHI \geq 15 events/hr	Ineligible	13	0	13
		Eligible	1	34	35
	*Fisher's Exact Test $p < 0.0005$	Total	14	34	48
	If AHI \geq 5 events/hr		Normal	Disease	Total
		Normal	2	0	2
	*Fisher's Exact Test $p = 0.009$	Disease	3	43	46
		Total	5	43	46

Table 6.5: Disease prevalence - Method B vs. Method C

		METHOD C			
METHOD B	If AHI ≥ 20 events/hr		Ineligible	Eligible	Total
		Ineligible	7	0	7
	*Fisher's Exact Test (2 Sided p<0.0005)	Eligible	11	30	41
		Total	18	30	48
	If AHI ≥ 15 events/hr	Ineligible	5	0	5
		Eligible	9	34	43
	*Fisher's Exact Test p=0.01	Total	14	34	48
	If AHI ≥ 5 events/hr		Normal	Disease	Total
		Normal	1	0	1
	*Fisher's Exact Test p=0.042	Disease	4	43	47
		Total	5	43	48

Tables 6.3 to 6.5 illustrate the effect of using different threshold values of AHI to determine the presence of disease or eligibility for the CPAP pilot scheme. An AHI of more than 5 events per hour is usually considered abnormal.

6.4.2 Kappa statistics using different thresholds for diagnosis/eligibility

Tables 6.6 to 6.8 display simple agreement and kappa statistics for the comparisons between different scoring methods when different threshold values of AHI are applied.

Table 6.6: Agreement and Kappa statistics – Method A vs. Method B

Method A vs. B		
Threshold	Kappa	Agreement
> 5 events per hour	0.66	97.9%
> 15 events per hour	0.48	85.4%
> 20 events per hour	0.63	87.5%

Table 6.7: Agreement and Kappa statistics – Method A vs. Method C

Method A vs. C		
Threshold	Kappa	Agreement
> 5 events per hour	0.54	93.8%
> 15 events per hour	0.95	97.9%
> 20 events per hour	0.77	89.7%

Table 6.8: Agreement and Kappa statistics – Method B vs. Method C

Method B vs. C		
Threshold	Kappa	Agreement
> 5 events per hour	0.3	89.2%
> 15 events per hour	0.44	81.3%
> 20 events per hour	0.44	77.1%

6.4.3 Agreement and correlation between different scoring methods for hypopnoeas

An Intraclass correlation coefficient (ICC) was calculated using the three different methods for scoring hypopnoeas. ICC = 0.95. This is a ratio of the variance between patients to the error variance. The result suggests that 95% of the variance in scores arises from true variance in the scores. This ICC is equivalent to a weighted kappa (using quadratic weights) and reflects strong agreement between the different methods. (25).

6.4.4 Repeated measures ANOVA

The differences in mean AHI scores between the three methods for scoring hypopnoeas were statistically significant using repeated measures ANOVA, $p < 0.005$.

6.5 Discussion

This study has compared three different methods for scoring hypopnoeas when analysing polysomnographic results. When the threshold for inclusion in the CPAP pilot scheme is an $AHI \geq 15$ or 20 the prevalence of disease is significantly different between the different methods used. However the Intraclass Correlation Coefficient which looks at the overall agreement between the three methods was high consistent with strong agreement.

The studies were scored in a random order to avoid an order effect. A single experienced polysomnographer undertook all the scoring so that interobserver variability will not affect the results.

The studies used in this analysis were selected based on categories of disease severity and the findings relate to this selected population. The predictive value of the methods used will depend on the prevalence of disease in the population to which they are applied.

6.6 Conclusion

- The overall agreement between the three methods for scoring hypopnoeas examined in this study was strong.
- When the point prevalence of disease was examined around the threshold levels (of AHI) used to determine eligibility for the CPAP pilot scheme there were significant differences between the three methods.
- These findings suggest that different methods may influence eligibility and access to the CPAP pilot scheme at different centres.

6.7 Recommendations

- Local guidelines for standardising the measurement and reporting of sleep studies should be developed.
- Guidelines could incorporate more than one method for scoring hypopnoeas but the level of agreement between methods should be specified. Sleep study reports should specify the particular method used by the laboratory concerned.
- In the absence of such guidelines specific criteria for defining hypopnoeas should be included in the guidelines for the CPAP pilot scheme.

7 Prospective study

7.1 Background

There is now high level evidence in support of the use of CPAP for sleep disordered breathing from randomised controlled trials (17, 26-32). These trials have shown benefits in terms of objective and subjective measures of daytime sleepiness and quality of life. However trials have also shown that the treatment is not acceptable for some patients (17), (30) and there are not always consistent improvements in symptom scores. The CPAP pilot scheme provides CPAP services for a limited and highly selected section of the population only. Often the results of randomised controlled studies are not generalisable to the population at large because of the selection process for participants in clinical trials. In addition patients in clinical trials tend to be offered high levels of support through out the treatment period. This aspect of the project has evaluated the adequacy of the provision of CPAP services by examining health-related outcomes in participants in the CPAP pilot scheme. Factors that might influence outcome have been examined. The health gain of the treatment was assessed using generic quality of life tools so that the relative benefit can be compared with that seen in other disorders.

7.2 Aims

To prospectively evaluate health outcomes of participants in the CPAP pilot scheme. The purpose of this research was to:

- Assess the magnitude of health benefit from treatment with CPAP in this highly selected population.
- Identify any differences in outcome/performance between different providers for the program.
- Identify any factors that may influence outcome.
- Determine the outcome measures that may be most useful for evaluating this population.
- Identify aspects of service delivery that could be improved.

7.3 Method

7.3.1 Design

We conducted an uncontrolled prospective cohort study. Participants in the CPAP pilot scheme between June 1999 and November 1999 at the 5 centres involved in the project were offered participation in the study. There were no specific exclusion criteria, however patients with poor English verbal skills or limited literacy were not included because of the requirement for follow up with written surveys. Baseline data was collected on demographics.

Quality of life was measured using a generic quality of life measure the MOS 36-Item Short-form Health Survey (SF-36), Australian Version (33) and a disease specific questionnaire; Sleep Apnoea Quality of Life Index (SAQLI) (34). The SF-36 measures self-reported health status. There are two summary scores calculated; the physical component summary (PCS) which represents physical functioning, while the mental component summary (MCS) reflects emotional wellbeing. The scores are transformed onto a scale of 0 (worst possible health) to 100 (best possible health). The scores are standardised such that a mean score of 50 reflects the mean score of the general population (we used the US population data) (35). The SAQLI has 5 domains; daily functioning, social interactions, emotional functioning, symptoms and treatment related symptoms. The treatment related domain is weighted according to the impact of the treatment-related side effects relative to the perceived benefit of the treatment on overall quality of life. For the first 4 domains the summary scores have a range of 1 to 7 where 1 represents the worst possible health and 7 the best. The total score is obtained by subtracting the summary score for the treatment related side effects from the summed mean scores of the other 4 domains. Thus where the impact of treatment related side effects are high negative scores are possible. Higher total scores reflect better quality of life.

Subjective daytime sleepiness was measured using 2 validated measures; the Epworth Sleepiness Scale (ESS) and the Excessive Daytime Somnolence (EDS) domain of the Sleep-Wake Activity Inventory (SWAI) (36, 37). For the ESS a score of 16 or more represents a high level of daytime sleepiness, while scores of 10 or more are generally taken to indicate abnormal levels of sleepiness (36) (38). With respect to the EDS component of the SWAI scores of 40 or less are highly indicative of sleepiness, scores between 40-50 are considered to be a gray area, and scores of 50 or more are unlikely to represent pathological levels of sleepiness (39).

All questionnaires were administered at baseline prior to the commencement of CPAP and after 1 and 3 months of treatment. The SAQLI was administered with the aid of an interviewer but the other surveys were completed by the participants without assistance. Compliance was recorded at 1 and 3 months. Compliance data was obtained by asking participants to give the CPAP meter readings at the time of phone call follow up. Follow up questions were asked in relation to hypertension and employment. Polysomnographic data was collected from the referring CPAP providers. The questionnaires used in this study are included in the appendices (B-E).

7.3.2 Statistical analysis

Data analysis was performed using SYSTAT for windows 9 version. Tests for normality were performed on continuous variables using the Kolmogorov-Smirnov (Lilliefors) test. Those that are not significantly different from normality have been analysed using parametric tests. For variables that are non-normally distributed comparisons have been made using non-parametric tests. For baseline data one-way analysis of variance (ANOVA) was performed to assess for significant differences between hospitals. Questionnaire data was analysed using repeated measures ANOVA. To analyse the influence of other variables hospital was fitted in the repeated measures ANOVA model as a factor and CPAP pressure, compliance, baseline sleepiness (using the SWAI scores) and AHI were fitted as covariates. The p values quoted are based on the Huynh-Feldt Epsilon adjustment for repeated measures.

7.3.3 Recruitment

There were 246 patients referred to the program between mid June 1999 and November 1999 at the 5 centres involved in the study. A number of subjects were not eligible either because they had been using CPAP for some time or were referred to us after treatment had commenced. The reasons for exclusion from the study are listed in table 7.1. There were 68 subjects enrolled in the study (47% of those who were eligible).

Table 7.1: Reasons for exclusion

Reason	Number	Percentage
Poor English or literacy	34	19
Already on CPAP e.g. hired pump	26	15
Patient declined	20	11
Not informed in time by participating centre	42	24
Researcher unable to contact	56	31

Even though the recruitment rate was poor those selected appear to be a representative sample.

Table 7.2: Characteristics of included and excluded patients.

Variable	Included	Excluded	P value
Number	68	178	
Gender (% female)	22 %	23 %	0.87 [†]
Age years (Mean, median, range)	56, 59 (19-78)	57, 59 (21-85)	0.697 [‡]
BMI kg/m/m (Median, range)	32 (20-60)	35 (20-57)	0.33 [€]
AHI events/hr (Median, range)	36 (5-145)	37 (5-131)	0.84 [€]
Oxygen Nadir % (Median, range)	75 (42-92)	75 (22-96)	0.17 [€]

[†] Chi square

[‡] t-test

[€] Mann-Whitney

7.4 Results

Of the 68 participants enrolled in the study, 59 (87%) were available for follow up, 4 patients did not commence treatment during the study period, 3 were lost to follow up, 1 was unable to continue to take part due to psychiatric illness and 1 subject died.

7.4.1 Demographics and co-morbidities

Employment: 40% of participants were retired, 26% permanently unable to work due to chronic illness, 14% were employed either full or part time, 6% unemployed, 12% home duties and 2% students.

Table 7.3: Occupation (usual occupation e.g. when employed)

Occupation category	Number	Percent
Professional	7	11.3
Management	8	12.9
Clerical	6	9.7
Manual labour	22	35.5
Sales assistant	5	8.1
Driver	11	17.7
Home duties	3	4.8
Non responders	6	9

- *Education:* 1.5% of participants have no formal education, 6.1% completed some primary school, 10.6% completed primary school, 36.4 % have some secondary school education, 22.7% completed secondary school, 19.7% have a diploma or partial degree, 3% completed a university degree.
- 83% of respondents reported an annual income of less than \$25,000 (net family income) however only 46 participants completed this question.
- *Marital status:* 10.6 % never married, 68.2% married, 12.1 % divorced or separated, 1.5% de facto, 7.6 % widowed.
- *Co morbidities:* 78% of participants have 1 or more co-morbidities, 52% have 2 or more co-morbidities and 25% 3 or more co-morbidities. (not including hypertension)
- *Hypertension:* 59% of participants have a history of hypertension and 53% had been prescribed medication for hypertension, at some time in the past.
- 21% of respondents spoke a language other than English at home. 36% Italian, 14% French, 14% Maltese and 36% other languages including Greek, Arabic, Estonian, Persian and Dutch.
- 62% have smoked tobacco for as long as one year, 21% were current smokers.

- *Alcohol consumption:* The mean alcohol consumption was 6 standard drinks per week (SD 11, Range 0-50).

7.4.2 Comparison between baseline data for different CPAP providers

Table 7.4 compares the baseline demographics, sleep study variables, baseline questionnaire data and compliance at 3 months for participants at each of the centres involved in this study.

Table 7.4: Comparison between hospitals: baseline demographics and sleep study variables

Hospital	1	2	3	4	5	P value
Number	10	11	24	20	3	
% of patients recruited	27 %	22 %	41 %	22 %	27%	0.14 [†]
% female	30 %	18 %	35 %	10 %	0	0.28 [†]
BMI kg/m/m (Median, range)	32 (23-42)	33 (20-55)	32 (23-60)	34 (25-58)	32 (26-42)	0.96 [‡]
AHI (events/hr) (Median, range)	46 (12-80)	65 (13-100)	39 (21-124)	30 (5-96)	32 (9-47)	0.15 [‡]
Age (mean ± SD)	53.7 ± 8.3	52.7 ± 12.4	56.6 ± 12.8	58.3 ± 14.2	58.3 ± 7.5	0.753 ^Φ
CPAP pressure (mean ± SD)	9.7 ± 1.5	10.6 ± 3.2	11.4 ± 2.9	10.0 ± 2.8	N/A	0.520 ^Φ
Compliance at 3 months (mean ± SD)	4.3 ± 2.2	4.4 ± 2.9	5.0 ± 2	5.4 ± 2.6	N/A	0.762 ^Φ
Baseline SAQLI (mean ± SD)	3.22 ± 1.04	3.76 ± 1.00	3.64 ± 1.09	3.97 ± 1.04	3.54 ± 1.46	0.511 ^Φ
Baseline PCS (mean ± SD)	35.5 ± 6.5	34.6 ± 13.4	36.2 ± 11.4	38.2 ± 13.7	32.9 ± 10.1	0.916 ^Φ
Baseline MCS (mean ± SD)	39.3 ± 9.6	44.3 ± 14.3	42.8 ± 9.9	40.8 ± 12.8	46.8 ± 12.96	0.754 ^Φ
Baseline SWAI (mean ± SD)	36.3 ± 13.7	53.7 ± 14.8	45 ± 18	53.3 ± 14.8	24.7 ± 16.3	0.08 ^Φ
Baseline ESS (mean ± SD)	15.4 ± 5.1	12.3 ± 4.2	14.4 ± 4.4	10.95 ± 4.5	19.0 ± 3.6	0.025 ^Φ

[†] Chi square

[‡] Kruskal-Wallis Test

^Φ One-way ANOVA

For both measures of daytime sleepiness there were statistically significant difference between the hospitals at baseline. For all the other variables measured at baseline there were no significant differences between CPAP providers.

7.4.3 Main results; questionnaire data

The mean prescribed CPAP pressure was 10.1 ± 2.6 range 6-17, (CI 9-11).

Compliance

At the time of writing this report objective compliance data was only available on 50% of participants therefore the following figures may be influenced by a selection bias.

1 month (mean \pm SD, range): 5.3 ± 2.9 , 1.5-13.6

3 months (mean \pm SD, range): 4.98 ± 2.3 , 0.43 – 8.9.

Of the outcome measures used the SWAI and ESS were completed by most participants with little difficulty. On the whole participants were able to complete the SF-36 without difficulty. Several patients had difficulty with some aspects of the SAQLI even with the help of an interviewer. For those participants where questions frequently needed repeating this questionnaire was quite time consuming. Participants often were confused by section F of the SAQLI where they were required to rate the impact of treatment and treatment related side effects on quality of life.

Table 7.6: Results of questionnaire data (presented as mean \pm SD and range)

Questionnaire	Baseline	1 month	3 months	P value*
SAQLI				
Daily functioning	3.7 \pm 1.3 (1.3-6.9)	4.7 \pm 1.2 (1.2-6.9)	4.8 \pm 1.3 (1.6-7.0)	< 0.0005
Social interactions	4.6 \pm 1.5 (1.5-6.8)	5.4 \pm 1.3 (2.0-7.0)	5.6 \pm 1.3 (1.5-7.0)	< 0.0005
Emotional functioning	4.1 \pm 1.3 (1.6-6.6)	4.7 \pm 1.3 (1.3-6.6)	4.8 \pm 1.3 (1.4-6.8)	< 0.0005
Symptoms	2.4 \pm 1.2 (0.8-6.2)	4.1 \pm 1.6 (0.8-7.0)	4.2 \pm 1.7 (0.4-7.0)	< 0.0005
Treatment related symptoms	Not applicable	2.9 \pm 1.6 (0.4-5.4)	2.3 \pm 1.5 (0.4-6.0)	0.03 [†]
Total SAQLI	3.7 \pm 1.1 (1.45 – 6)	2.5 \pm 2.5 (-4.6 – 6.4)	3.3 \pm 2.5 (-2.8 – 6.8)	0.010**
SF-36				
PCS	36.4 \pm 11.7 (11.2-61.4)	37.5 \pm 11.4 (15.3-61.4)	38.7 \pm 11.8 (15.9 –63.9)	0.006***
MCS	42.1 \pm 11.5 (21.6-68.3)	45.9 \pm 10.4 (20.9-63.1)	43.5 \pm 10.9 (18.4-64.6)	0.024***
Daytime sleepiness measures				
ESS	13.2 \pm 4.9 (3-24)	10.1 \pm 5 (2-21)	10.8 \pm 5.7 (3-22)	< 0.0005
SWAI	47 \pm 17 (9-81)	59 \pm 16 (16-79)	59 \pm 16 (23-81)	< 0.0005

[†] t test

**Note trend represents a decrease in overall disease specific quality of life from baseline to one month (p=0.001 paired t-test), but no change between baseline and 3 months (Paired t-test, p=0.288).

***With hospital included in the model as a factor.

The results of the sleepiness questionnaires are consistent with the responses to the global question asked at 1 month “Rate the total change that you have experienced in your general level of daytime sleepiness in the past 1 month. Compared to your condition 1 month ago how much have you changed?.” Eighty percent of respondents indicated they were either slightly better, much better or extremely better.

7.4.4 Side effects of treatment

The most commonly reported side effects in section on treatment related side effects from the SAQLI survey at 1 month are listed in Table 7.7.

Table 7.7: Side effects of treatment

Side effect	Percentage
Stuffed or congested or blocked nose	53%
Excessive dryness of the nose or throat passages especially upon awakening	45%
Waking up frequently during the night	45%
Air leakage from the nasal mask	36%
Discomfort from the nasal mask	36%
Runny nose	30%
Complaints from partner about the noise of the CPAP machine.	25%
Marks or rash on your face	23%
A sense of suffocation	21%
Eye irritation	19%
A change in voice quality	15%
Feeling self conscious	15%
Difficulty returning to sleep after awakening	15%

7.4.5 Predictors of outcome

The effect of hospital on outcome was evaluated using repeated measures ANOVA for each of the questionnaires with hospital as a factor. Hospital was not a significant predictor of improvement for the following measures; SAQLI total ($p=0.117$) or ESS ($p=0.144$). With respect to the SWAI the effect of hospital may have been a factor however this did not reach statistical significance ($p=0.053$).

For both components of the SF-36 hospital was a predictor of change; MCS ($p=0.033$) and PCS ($p=0.023$). For the MCS component hospitals 2 and 4 showed a significant improvement (repeated measures ANOVA, $p=0.031$ for the combined analysis) compared with hospitals 1,3 and 5 (repeated measures ANOVA $p=0.41$). For the PCS component hospital 2 showed a significant improvement when analysed separately (repeated measures ANOVA, $p=0.03$, compared with the remainder of the hospitals (repeated measures ANOVA, $p=0.5$).

For each outcome the influence of covariates including CPAP pressure, compliance, AHI and baseline sleepiness (using the SWAI scores) was included in the ANOVA model, however none of these factors significantly affected the change in scores ($p > 0.08$). The effect of a CPAP clinic on compliance or outcome could not be examined independently of hospital. CPAP clinic services are routinely offered at hospitals 4 and 5 however for hospital 5 there was only 1 patient who completed the study.

7.4.6 Hypertension and weight loss

Hypertension

59% of participants had been diagnosed with hypertension at some stage and 53% had been prescribed medication for hypertension in the past. 50% of subjects had been taking medication to control high blood pressure in the last 3 months and 47% in the last 1 month (prior to starting CPAP). Of those who were taking antihypertensive medication at the time of commencing CPAP only 1 reported a reduction in medication use after CPAP was commenced, while 5 reported an increase in blood pressure medication.

Weight loss

There was no significant weight reduction during the follow up period ($p=0.50$) The mean weight at baseline 99 ± 25 kg compared with 97 ± 25 at 3 months.

7.5 Discussion

Demographics of participants in the program are consistent with the eligibility criteria for the CPAP pilot scheme (based on financial status). Most of the participants are not actively employed and more than 50% had not completed secondary school education. The majority of patients have co-existing medical conditions in addition to the high rates of hypertension and obesity. Baseline measures indicate poor quality of life amongst most subjects relative to the general population.

The most consistent finding relates to improvement in daytime sleepiness. All 3 measures of subjective sleepiness showed significant improvement (ESS, SWAI and global question about sleepiness). The scales are complimentary: the ESS tends to measure sleep propensity in certain situations while the SWAI measures sleep behaviour. The changes in both measures are clinically significant however the mean post treatment SWAI score falls within the normal range, while the mean post treatment ESS score is still just above the normal range. Although there were overall significant improvements, some patients did not improve despite adequate compliance. Possible reasons for this might include treatment failure, subtherapeutic levels of CPAP or air leaks due to poorly fitted equipment or co-existing sleep disorder. Most centres were not performing routine review sleep studies on participants after 3 months, and we did not have access to clinical records so that reasons for poor response could not be assessed further.

Overall quality of life in this group of patients was poor. The mean baseline value of 42.1 for the MCS is 0.8 SD below the population mean (based on US general population) while the baseline value of 36.4 for the PCS scale is 36.4 which is 1.4 SDs below the population mean (35).

The improvements in PCS and MCS scores of the SF-36 are statistically significant however the magnitude of the benefit is relatively small. When compared to the US general population the change in MCS represents an increase from the 20th to the 22nd percentile. For the PCS component the improvement reflects an increase from the 12th to the 16th percentile (35).

There was no overall improvement in quality of life measured by the SAQLI, in fact at 1 month there was a significant decline in quality of life but by 3 months there was no significant difference compared with baseline. The individual domains; daily functioning,

social interactions, emotional functioning and symptoms did show significant improvements however. The data suggests that the lack of benefit can be attributed to the impact of the treatment on quality of life. The treatment related symptom domain however did show an improvement between 1 and 3 months suggesting that the impact of treatment related symptoms improved over time.

Although differences in outcome were noted between hospitals for the SF-36 summary measures, these were not consistent with the other outcomes and their significance is uncertain. Factors such as level of baseline sleepiness, CPAP pressure, AHI and compliance did not appear to influence the outcome.

Although this study is uncontrolled and uses subjective outcome measures the data can be used to compare the magnitude of the health benefit from this treatment with treatments for other conditions where similar studies have been conducted. Clinical trials have usually limited follow up periods to 4-6 weeks our results show that the benefits of treatment are maintained at 3 months.

A concern of this study is that a large number of comparisons were made due to multiple outcome measures. This would be expected to increase the type 1 error rate. The conservative Bonferroni correction would define significance as occurring when $p < 0.05$ divided by the number of tests (in this case there were 10 tests and therefore $p < 0.005$) while the results for the SF-36 fall short of this level of significance other results are highly significant ($p < 0.0005$) and therefore satisfy this definition.

The findings demonstrate a treatment benefit for patients in the current program however they also suggest that there are opportunities to improve outcome further compared with the results of controlled clinical trials.

7.6 Conclusions

- Treatment with CPAP consistently improves subjective measures of daytime sleepiness.
- Treatment with CPAP results in statistically significant but small improvements in self reported health status measured by the SF-36.
- Improvements in quality of life were limited by treatment-related side effects.
- There were no consistent differences in the performance of different CPAP providers.
- Factors such as baselines sleepiness, CPAP pressure and disease severity were not predictors of outcome in this selected group.

7.7 Recommendations

- Greater technical support post implementation of CPAP may help to reduce the negative impact of treatment related side effects on quality of life and therefore enhance the magnitude of health benefit of participants in the CPAP program. The program could be re-evaluated following the introduction of such support.
- Treatment benefits may also be enhanced with additional emphasis placed on weight loss for participants with an elevated BMI. Although significant weight loss is difficult to achieve in this group (32).

8 Patient satisfaction

8.1 Background

In the short history of the CPAP pilot scheme there has not been a mechanism developed for systematically evaluating patient satisfaction with the overall service or specific aspects such as CPAP suppliers. Assessing patient satisfaction can provide useful information about how the quality of care can be improved. Although the results of patient focus groups (presented in section 3) suggest that participants are happy with the service, some deficiencies were identified. The information obtained from these focus groups has been used to develop a written patient satisfaction questionnaire that will measure satisfaction quantitatively in a larger sample. The survey could be developed further for use as a tool to periodically assess the performance of the scheme.

8.2 Aim

To evaluate patient satisfaction with all aspects of the CPAP pilot scheme.

8.3 Method

A written self reported satisfaction survey was constructed. The survey was developed using information obtained from focus groups conducted with patients (as outline in section 3). In addition the literature on patient satisfaction was reviewed. The survey was sent to participants in the prospective study after 3 months of treatment (n=59).

Survey design

The survey was divided into 4 sections; medical care, equipment, CPAP suppliers and overall satisfaction. For each statement there were 4 possible responses (Likert-type scale):

- 1 = strongly agree
- 2 = somewhat agree
- 3 = somewhat disagree
- 4 = strongly disagree

To reduce the chance of bias in answering the questions, a mixture of positive and negative statements were used. The survey is displayed in appendix F.

8.3.1 Statistical analysis

Descriptive statistics for the results are presented. Analysis was performed using SPSS for Windows version 8. For the summary statistics responses to questions with negative statements were recoded.

8.4 Results

There were 38 responses to the satisfaction survey (response rate 64%). The results for each section of the survey are summarised below. For each of the summary tables below, percentile values are presented for absolute date. In addition, proportional values out of 100 are added so that comparisons can be made between different sections.

8.4.1 Medical care

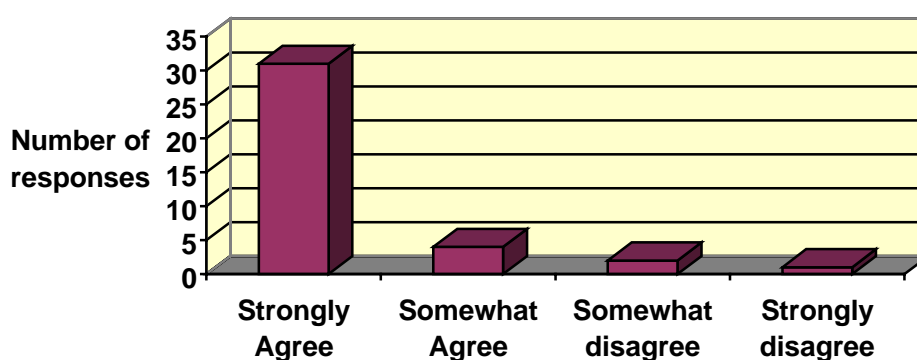
For this section, there were 4 questions giving a maximum possible score of 16 (lowest level of satisfaction) and a minimum of 4 (highest level of satisfaction).

Table 8.1: Summary statistics for medical care domain

			Percentiles						
Mean	SD	Range	5%	10%	25%	50%	75%	90%	95%
7.4	2.5	4 -13	4	4	5.75	7.5	9	11	12
Proportional score out of 100			25	25	36	47	56	69	75

The responses to the question: *If I had to do the whole thing all over again I would choose the same doctors*, are displayed in Figure 8.1.

Figure 8.1 Medical care



Despite the relatively high levels of satisfaction demonstrated in this section, 53% of patients indicated they would like more information about how CPAP works and 63 % agreed that they would like more information about their condition.

8.4.2 CPAP Equipment

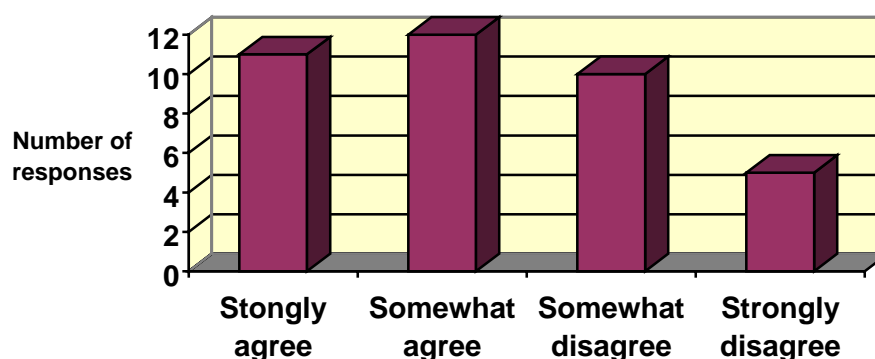
For this section there were 6 questions with a maximum score of 24 (lowest level of satisfaction) and a minimum of 6 (highest level of satisfaction).

Table 8.2: Summary statistics for equipment domain.

			Percentiles						
Mean	SD	Range	5%	10%	25%	50%	75%	90%	95%
13.7	3.2	9-21	9	9.9	11	13	16	18	20
Proportional score out of 100			38	41	46	54	67	75	83

The responses to the question: *I have experienced difficulties with my mask such as air leak, sore nose or poorly fitting mask (at any point since starting treatment with CPAP)*, are displayed in Figure 8.2.

Figure 8.2 Side effects related to the mask



Responses to a number of questions in this section are summarised below:

*The noise my CPAP machine makes **does not** disturb either my partner or myself.* 37% of respondents strongly or somewhat disagreed with this statement.

*I **am not** concerned that I may have to use CPAP for the rest of my life.* 42% of respondents strongly or somewhat disagreed with this statement.

I was unhappy about the payment I had to make towards the cost of the CPAP machine. 34% respondents strongly or somewhat agreed with this statement.

57% of participants strongly or somewhat agreed with the statement; *I was unhappy about the cost of attachments for the CPAP machine such as masks, head straps, tubing etc.*

8.4.3 Suppliers

For this section there were 4 questions with a maximum score 16 (lowest level of satisfaction) and a minimum of 4 (highest level of satisfaction).

Table 8.3: Summary statistics for supplier section

			Percentiles						
Mean	SD	Range	5%	10%	25%	50%	75%	90%	95%
7.3	2.7	4 -13	3.9	4	5	7	10	11	11.1
Proportional score out of 100			24	25	31	44	63	69	69

Responses to a number of questions in this section are summarised below:

I knew who I should contact for advice if I was experiencing difficulty using my CPAP machine at home. 97% of respondents agreed with this statement.

40% of respondents either agreed or strongly agreed with the statement; *I did not find the phone call follow up provided by CPAP suppliers helpful.*

When I had problems with my CPAP machine, mask fitting or other technical factors I was able to obtain helpful advice easily. 24% of respondents either strongly or somewhat disagreed with this statement.

8.4.4 Overall care

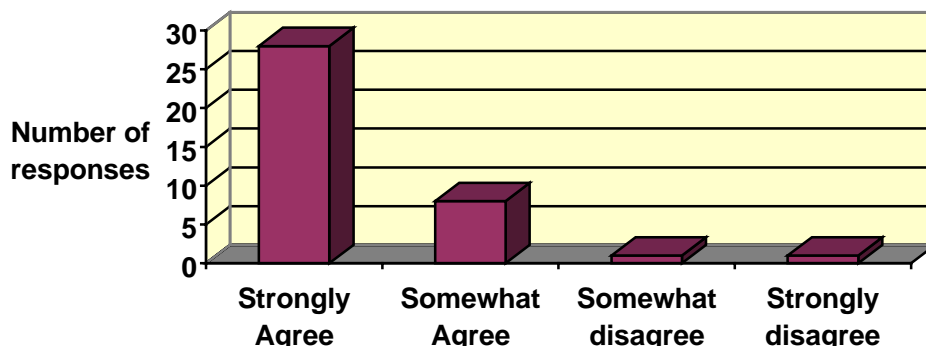
For this section there were 3 questions giving a maximum score of 12 and a minimum score of 3.

Table 8.4: Summary statistics for overall care section

			Percentiles						
Mean	SD	Range	5%	10%	25%	50%	75%	90%	95%
4.3	1.9	3 -12	3	3	3	3	5.25	6	9.2
Proportional score out of 100			25	25	25	25	44	50	77

The responses to the statement: Overall (*thinking about all aspects of your care*) I am satisfied with the treatment I have received for my condition (*obstructive sleep apnoea*), are displayed in Figure 8.3.

Figure 8.3 Overall care



8.4.5 Summary results for whole survey

A summary score was calculated for the entire survey by summing the results of each question. A maximum score of 68 represents a maximum level of dissatisfaction whereas a minimum score of 17 represents the highest level of satisfaction.

Table 8.5: Summary statistics for composite score

			Percentiles						
Mean	SD	Range	5%	10%	25%	50%	75%	90%	95%
32.5	7.4	20-51	22.9	24	26	33	37	43	50
Proportional score out of 100			34	35	38	49	54	63	74

8.5 Discussion

The results suggest that levels of satisfaction with the overall service are high. However the results should be viewed in the context of the fact that most patient satisfaction surveys report high levels (75-90% satisfied) of satisfaction (40).

There are several limitations to this study. The response rate was 64%, while this would be a typical response rate for many surveys, it does introduce the possibility of bias with either more or less satisfied patients declining to return the survey. As yet the validity and reliability of the survey has not been assessed. Ideally further surveys should be collected and factor analysis performed on the results in order to assess how the individual items relate to each other and evaluate what factors are being measured. In addition the internal consistency could be assessed with a view to removing redundant items. It is worth noting

that although questions have been grouped under certain headings it is possible that these groupings are not appropriate and factor analysis may reveal that items should be grouped according to other dimensions of patient care.

Despite the limitations described the results of individual questions can be examined and provide interesting insights into specific aspects of the CPAP pilot scheme. For example the responses to the question about side effects related to the mask are consistent with the findings in the focus groups and the prospective study (as outlined in sections 3 and 7). Questions relating to the CPAP equipment generally had less positive responses. The findings also suggest that there may be a need to review the phone call follow up provided by suppliers and to provide patients with more education regarding their condition and CPAP equipment.

This research should be seen as the initial phase in the development of a patient satisfaction survey for participants in the CPAP pilot scheme. Once the survey has been validated it could be used to periodically evaluate patient satisfaction with different aspects of the CPAP pilot scheme and therefore help to inform the process of quality improvement.

8.6 Conclusion

- Patient satisfaction with the overall service was high.
- Satisfaction with the CPAP equipment was generally low compared with service delivery.
- Many respondents did not find the phone call follow up provided by suppliers helpful.
- The majority of participants had experienced difficulties with masks.
- The majority of participants indicated that they would like more information about how CPAP works and their condition.
- The majority of participants are concerned about the cost of consumable items but not the co-payment made towards the cost of the CPAP machine.

8.7 Recommendations

- The current CPAP program could be improved by focusing on the follow up particularly with respect to difficulties experienced with the equipment.
- It may be better for the phone call follow up provided by suppliers to focus on specific difficulties being experienced by participants rather than the CPAP meter readings.
- Additional education regarding sleep disordered breathing and CPAP equipment may be helpful to patients.
- This information needs to take into account the sociodemographics of the population for example literature for patients from non-English speaking backgrounds may be helpful.
- Greater research and development of CPAP technology is required.
- There could be a mechanism within the scheme to provide additional financial support to patients towards the cost of consumable items in specific financial circumstances.

9 Utilisation of hospital bed days by CPAP users

9.1 Background

The results of the prospective study (see section 7) indicate that patients treated within the CPAP pilot scheme commonly have co-morbid medical conditions. Previous research has found that patients with sleep disordered breathing are heavy users of health care services (7). Research conducted overseas has shown that treatment with CPAP may reduce the need for acute hospital admissions due to cardiovascular or pulmonary disease in patients with sleep disordered breathing (8). It is unclear whether these findings apply to the Victorian health care system and in particular to participants in the CPAP pilot scheme. We designed a study to evaluate the effect of CPAP treatment within the CPAP pilot scheme on hospital admissions for all causes.

9.2 Aim

To examine hospital bed day utilisation by patients with sleep disordered breathing prior to and after commencement of treatment with CPAP.

9.3 Methods

The Victorian Inpatient Minimum Database (VIMD) records details of all public hospital inpatient admissions for the State of Victoria (41). Participants in the CPAP pilot program referred between July 1997 and June 1998 who were admitted to hospital between a 3 year period (1996/1997 -1998/1999) were identified on the VIMD using hospital UR numbers. The search was limited to patients at Monash Medical Centre, The Alfred Hospital, Western Hospital and Austin and Repatriation Medical Centre. (Participants at Latrobe Regional Hospital were excluded because many did not live in the local area and were assigned UR numbers at the time of referral to the program.) For each patient the database was searched for admissions 12 months prior to and 12 months after the date that CPAP therapy commenced. All admissions during this period were included and length of stay was also recorded. Patients are routinely admitted for diagnostic and implementation sleep studies at the Western and Alfred Hospitals and for these records 2 admissions were subtracted from the pre treatment figures.

9.3.1 Statistical analysis

Data was analysed using SPSS version 8 for windows. Admission rates and hospital bed days before and after treatment with CPAP were compared using paired t-tests.

9.4 Results

There were a total of 298 patients entering the CPAP pilot scheme during the specified time period. From the VIMD search 65 patients had admissions to hospital during the 12 months prior to or 12 months after the commencement of CPAP.

Table 9.1: Summary of raw data

	Mean ± SD	Percentiles								
		1%	5%	10%	25%	50%	75%	90%	95%	99%
Admissions before CPAP	5.96 ± 6.6	0	0	0	1	4	9	15	18	33
Admissions after CPAP	6.01 ± 12.7	0	0	0	1	3	12	12	13	93
Hospital bed days before CPAP	23.6 ± 35	0	0	0	2	14	29	50	64	207
Hospital bed days after CPAP	31.9 ± 72	0	0	0	1	7	28	73	188	467

Table 9.2: Summary of data with extreme cases removed

	Mean ± SD	Percentiles								
		1%	5%	10%	25%	50%	75%	90%	95%	99%
Admissions before CPAP	4.96 ± 4.8	0	0	0	1	3	8	12	15	18
Admissions after CPAP	3.8 ± 3.7	0	0	0	1	2.5	6	9	12	13
Hospital bed days before CPAP	17.3 ± 17.3	0	0	0	2	12.5	28	43	50	64
Hospital bed days after CPAP	11.8 ± 15.3	0	0	0	1	5.5	15	37	44	68

There were a total of 387 admissions before treatment and 394 after treatment, the paired t-test for the difference between admission rates was not significant ($p = 0.95$). There were 1532 bed days before treatment and 2072 after treatment the Paired t-tests for the difference in length of stay per patient was not significant ($p=0.39$).

The data was not normally distributed and there were several outliers/extreme cases. A repeat analysis was performed with extreme cases removed. Patients with more than 20 admissions per year either before (3) or after (3) treatment were excluded (for paired analysis $n = 59$) and those patients with a total number of bed days of more than 70 were also excluded (3 before and 7 after, for paired analysis $n = 56$). Repeat t tests showed a significant reduction in both number of admissions and total bed days after treatment with CPAP ($p=0.04$, $p=0.03$, respectively).

9.5 Discussion

Our findings suggest that when less extreme cases are considered there is a fall in the rates of hospitalisation and hospital bed days following the introduction of CPAP in patients referred to the CPAP pilot scheme. These results are consistent with the experience overseas (8).

There are several limitations to this study. It is estimated that 5-10% of admissions may be missed using the VIMD. Private hospital admissions are not included in the database however we anticipate that this group will not be heavy users of the private health system given the eligibility criteria for the CPAP pilot scheme. Admissions at other public hospitals may be missed. Nonetheless these limitations will apply to both the before treatment and after treatment parts of this analysis. A further limitation is that this research was performed retrospectively and as such there are many unknown factors, for example if patients died after treatment then admission rates would fall. In addition we did not have figures on how many patients were still using CPAP during the 12-month period post implementation.

The findings should be further evaluated using a prospective study design. Such a study could define in advance clinical criteria for defining extreme cases. In addition patients could be followed up so that compliance and other outcomes could be monitored. Hospital bed day utilisation may be an important factor to consider when conducting cost effectiveness or cost benefit analyses of CPAP therapy and for this reason it would be important to confirm this finding.

9.6 Conclusions

A preliminary analysis of the data shows that in patients managed within the CPAP pilot scheme there is no reduction in hospital bed days or hospital admissions subsequent to the commencement of CPAP therapy for sleep disordered breathing. When extreme cases are removed from the analysis however there is a significant reduction in both admissions and hospital bed days post CPAP implementation. These findings warrant further evaluation with prospective studies.

10 Recommendations

10.1 Selection of patients for the CPAP pilot scheme.

- The current guidelines need to be revised to include greater clarity and specificity with respect to inclusion criteria.
- Clinical practice guidelines (as outlined in section 10.5) could be used to guide this process.

10.2 Assessment of sleep disordered breathing

- Local guidelines for standardising the measurement and reporting of sleep studies should be developed.
- In the absence of such guidelines, specific criteria for scoring respiratory events should be outlined in the CPAP pilot scheme guidelines.

10.3 Performance of suppliers

- Follow up requirements for suppliers should be standardised.
- The requirement for suppliers to collect routine compliance meter readings should be reviewed.
- Periodic review of the performance of suppliers could be undertaken by providers using the satisfaction survey developed in this project, once this has been validated.

10.4 Enhancing compliance and outcome

- Among subjects selected for the current scheme specific factors influencing compliance or outcome could not be identified.
- A common theme throughout the findings was the need for greater technical support for patients following commencement of CPAP.
- Methods for providing additional technical support to participants should be explored. This might include a shift in the focus during the phone call follow up provided by suppliers (from the collection of meter readings to the provision of advice) or the use of CPAP clinics.

10.5 Role of clinical practice guidelines

Locally adapted evidence based guidelines for the management of sleep disordered breathing could form the basis for guidelines for the scheme and would represent a compromise between flexibility for clinicians and equity and access for patients. Our research suggests the scope of guidelines should include:

- Diagnostic and treatment criteria
- CPAP implementation
- Technical support

- Follow up procedures
- Alternative treatment options

10.6 Administration of the CPAP pilot scheme

Alternative methods for administering the scheme should be explored, these might include:

- A centralised administrative process
- Additional funding for current providers to cover administrative costs

10.7 Support for patients

- Patients need education regarding their condition and treatment and this should take account of their sociodemographic background and cultural diversity. This might involve for example the development of literature in languages other than English.
- Some participants would benefit from additional financial support for the cost of consumables in specific circumstances.

10.8 Research and development

- Further research and development is required into CPAP technology and its clinical application.

11 Dissemination of results

The following abstracts have been accepted for presentation at the Thoracic Society of Australia and New Zealand Annual Scientific Meeting, April 2000:

Manser R, Rochford P, Roebuck T, Pierce R, Naughton M, Campbell D. Survey of Victorian Sleep Laboratories: Equipment, Staging and Scoring Criteria.

Manser R, Teichtahl H, Ho M, Sasse A, Cherry G, Copland J, Campbell D. Outcomes of the Victorian CPAP pilot program patient focus groups.

The following abstracts have been accepted for presentation at the Australasian Sleep Association Annual Scientific Meeting, April 2000.

Manser R, Hurlbut D, Campbell D. Retrospective Review of CPAP Services at 5 Different Centres.

Manser R, Rochford P, Roebuck T, Pierce R, Naughton M, Campbell D. Survey of Victorian Sleep Laboratories: Equipment, Staging and Scoring Criteria.

Manser R, Teichtahl H, Ho M, Sasse A, Cherry G, Copland J, Campbell D. Outcomes of the Victorian CPAP pilot program patient focus groups.

The following abstract has been accepted for presentation at the Australasian Sleep Technologist Association Annual Meeting, April 2000:

Rochford P, Manser R, Pierce R, Campbell D. Impact of different criteria for defining hypopnoeas on the Apnoea-Hypopnoea Index.

The abstracts listed above have been submitted to the Royal Melbourne Hospital Research Week and will be presented in June 2000.

The findings will be presented at the Melbourne Sleep Meeting and Repatriation Hospital (Daw Park) Adelaide.

Publications:

We intend to submit for publication the findings documented in sections 3,4,5,6 and 7.

12 Performance

12.1 Reporting against aims and objectives described in the protocol

The aims and objectives outlined in the project proposal are listed below:

To review the performance of the CPAP pilot scheme in the context of a treatment program for the management of obstructive sleep apnoea

II to make recommendations for improved performance of the CPAP-PS in relation to:

- (a) the performance of the suppliers of CPAP equipment*
- (b) the conduct of sleep studies*
- (c) the selection of subjects for treatment with CPAP*
- (d) additional management issues relevant to enhancing compliance with treatment for sleep disordered breathing.*

III to examine:

- (a) hospital bed day utilisation by patients with sleep apnoea prior to and after commencement of treatment with CPAP*
- (b) the responsiveness to change of disease specific and generic quality of life measures in patients with sleep apnoea treated with CPAP*

IV to develop a minimum data set (including clinical and sleep study variables) which might form the basis of clinical practice guidelines for management of sleep disordered breathing.

Apart from III (b) all of these aims have been met and are addressed in section 10. The responsiveness to change of disease specific and generic quality of life measures in patients with sleep disordered breathing treated with CPAP could not be adequately assessed. The method we intended to use for this study required us to collect repeated baseline survey data prior to the commencement of CPAP, however most patients commenced treatment with CPAP within a few days of enrollment in the study and therefore there were too few patients in this aspect of the study for a meaningful analysis (n=4).

Our findings did not identify specific sleep study or clinical variables that could be used to predict outcome in this selected group of patients and therefore we have not proposed a minimum data set which might form the basis of clinical practice guidelines for the management of sleep disordered breathing. We have identified those issues that should be covered by clinical practice guidelines and these are outlined in section 10.

12.2 Variations from the original protocol

- As discussed in section 12.1, there was insufficient data available to perform the analysis on the responsiveness to change of disease specific and generic quality of life measures.
- In addition to assessing patient satisfaction using qualitative methods (as described in section 3), we developed a patient satisfaction questionnaire which was sent to participants during the follow up period of the prospective study.
- Preliminary analysis of the laboratory survey (refer to section 5) showed there was considerable variation in the methods used by different sleep laboratories to define respiratory events for the purposes of analysing polysomnography results. We therefore

developed a study to assess the level of agreement between different scoring methods (as outlined in section 6).

12.3 Performance against targets

Key performance indicators outlined in the original project protocol include:

- The extent of uptake by eligible centres and participants for involvement in the study.
- To achieve the time lines for the project.
- To achieve the deliverables for the project.

12.3.1 Uptake by eligible centres

This was discussed in the introduction (refer to section 1.2).

12.3.2 Uptake by eligible participants

- **Focus groups:** 73% of participants who initially were available to attend these group discussions attended on the day of the meeting. Both compliant and non-compliant users have attended (refer to section 3).
- **Performance review - patient characteristics:** At each of the 5 institutions involved in the study retrospective data was collected on all patients entering the scheme during the 3 month period from the 1st of October 1998 to 31st of December 1998. There were 140 participants during this time period. For each variable being assessed in this study data was available on at least 70% of participants (reported in section 4).
- **Laboratory Survey:** The response rate to the survey of Victorian sleep laboratories was 94% (reported in section 5).
- **Prospective Phase:** The uptake rate (47%) for this part of the study falls short of the targets set out in the project proposal. Difficulty with recruitment was encountered largely because of the need to recruit patients from multiple sites removed from the coordinating centre. Many patients could not be contacted by the research team prior to the commencement of CPAP. The reasons for exclusion from this study are summarised in Table 7.1 (refer to section 7).

12.3.3 Timelines

The timelines proposed in the original protocol were subject to the availability of suitable research personnel. A research assistant with adequate experience and expertise was not available to commence work on the project until February 1999 and therefore revised timelines were developed based on this commencement date. Performance was assessed against the revised timelines (details of revised timelines are listed in appendix G).

Retrospective review

Final report of the CPAP Service Development Project

Due to delays in the approval by ethics committees the data collection for the retrospective phase of the study did not commence until late April 1999 (Appendix H outlines the procedures undertaken in relation seeking approval from ethics committees). Data collection for this aspect of the study was completed by the 1st of July 1999. All but one of the responses to the laboratory survey was received by the end of June 1999. The difficulties encountered in obtaining approval from multiple different ethics committees was outlined in the interim progress report.

Prospective phase – recruitment

Recruitment for the prospective phase, in keeping with timelines, began during June 1999, however delays have been experienced at some centres as detailed below:

Alfred Hospital	14/6/99
Austin and Repatriation Medical Centre	23/6/99
Latrobe Regional Hospital	30/6/99
Western Hospital	07/7/99
Monash Medical Centre	12/7/99

Delays were experienced at the Western Hospital due to a shortfall of pumps towards the end of the financial year. Once the short fall was met patients were supplied with pumps but some eligible participants had been on hired pumps while waiting (and were therefore ineligible). Similar delays were experienced at the Austin and Repatriation Medical Centre. Delay was experienced at Monash Medical Centre due to a combination of the workload of staff administering CPAP pilot scheme and annual leave.

Additional delays in recruitment were experienced for reasons outlined in section 12.3.1. Recruitment ceased on the 30th November 1999. Follow up ceased in March 2000.

Final Report

We requested an extension to the submission date for the final report in December 1999 and the date was extended to April 7th 2000. Data analysis and report writing were delayed subsequent to the delays experienced with recruitment for the prospective study (see above).

12.3.4 Deliverables

Deliverable 1 – Progress Report submitted July 1999 as requested by the Department of Human Services on the 19th April 1999.

Deliverable 2 – Final Report submitted April 2000.

13 Bibliography

1. Young T, Palta M, Dempsey J, Skatrud J, Weber S, Badr S. The occurrence of sleep-disordered breathing among middle age adults. *New Eng J Med* 1993;328:1230-1235.
2. Phillipson E. Sleep apnoea: A major public health problem. *N Engl J Med* 1993;328:1271-1273.
3. Cheshire K, Engleman HM, Deary IJ, Shapiro C, Douglas NJ. Factors impairing performance in patients with sleep apnoea/hypopnoea syndrome. *Arch Int Med.* 1992;152:538-541.
4. Polo Mea. Management of obstructive sleep apnoea/hypopnoea syndrome. *Lancet* 1994;334:656-660.
5. Partinen M, Guileminault C. Daytime sleepiness and vascular morbidity at seven year follow up in obstructive sleep apnoea. *Chest* 1990;97:27-32.
6. Westbrook P, Millman RP. Controversies in the treatment of snoring and obstructive sleep apnoea. In: Saunders N, Sullivan CE., editor. *Lung biology in health and disease.* New York: Marcel Dekker. p. 529-555.
7. Kryger M, Roos L, Delaive K, Walid R, Horrocks J. Utilisation of health care services in patients with obstructive sleep apnoea. *Sleep* 1996;19:S111-S116.
8. Pecker Yea. Reduced hospitalisation with cardiovascular and pulmonary disease in obstructive sleep apnoea on nasal CPAP treatment. *Sleep* 1997;20:645-653.
9. Haines A. Making better use of research findings. *Br Med J* 1998;317:197-199.
10. Department of Human Services. Continuous positive airway (CPAP) services, 1998/1999, policy and project guidelines. Victoria; 1998.
11. McArdle N, Devereux G, Heidarnejad H, Engleman HM, Mackay TW, Douglas NJ. Long-term use of CPAP therapy for sleep apnoea/hypopnoea syndrome. *Am J Respir Crit Care Med* 1999;159(4):1108-1114.
12. Thomas SA, Steven I., Browning CJ, Dickens E, Eckermann L, Carey L, Pollard S. Focus groups in health research: A methodological review. *Annual Review of Health Social Sciences* 1992;2:7-20.
13. Polgar S, Thomas SA. Introduction to research in health sciences. 3rd ed. Edinburgh: Churchill Livingstone; 1995.
14. Pepin J, Leger P, Veale D, Langevin B, Robert D, Levy P. Side effects of nasal continuous positive airway pressure in sleep apnoea syndrome. Study of 193 patients in two French sleep centres. *Chest* 1995;107:375-381.
15. Hoy C, Vennelle M, Kingshot, R, Engleman H, Douglas N. Can intensive support improve Continuous Positive Airway Pressure use in patients with the Sleep Apnoea/Hypopnoea Syndrome? *Am. J. Respir. Crit. Care Med.* 1999;159:1096-1100.
16. McNicholas W. Compliance with nasal CPAP therapy for obstructive sleep apnoea: how much is enough? *Eur Respir J* 1997;10:969-970.
17. Engleman HM, Martin SE, Deary IJ, Douglas NJ. Effect of CPAP therapy on daytime function in patients with mild sleep apnoea/hypopnoea syndrome. *Thorax* 1997;52(2):114-9.
18. Meurice J, Dore P, Paquereau J, Neau JP, Ingrand P, Chavagnat JJ, Patte F. Predictive factors of long term compliance with nasal continuous positive airway treatment in sleep-apnoea syndrome. *Chest* 1994;105:429-433.
19. American Sleep Disorders Association. EEG arousals: scoring rules and examples. A preliminary report. *Sleep* 1992;15:174-184.
20. Rechtschaffen A, Kales A. A manual of standardised terminology and scoring system for sleep stages of human subjects. Los Angeles: BIS/BRI, UCLA; 1968.
21. Moser N, Phillips BA, Berry DT, Harbison L. What is hypopnoea anyway? *Chest* 1994;105:426-428.
22. Redline S, Sanders M. Hypopnoea, a floating metric: Implications for prevalence,

- morbidity estimates and case finding. *Sleep* 1997;20(12):1209-1217.
23. Quan S, Howard BV, Iber C et al. The Sleep Heart Health Study - Design, Rationale and methods. *Sleep* 1997;20:1077-1085.
 24. Streiner D, Norman GR. Reliability. In: Health measurement scales: a practical guide to their development and use. Second ed. New York: Oxford University Press; 1995. p. 104-127.
 25. Morton A, Dobson AJ. Assessing agreement. *Med J Australia* 1989;150:384-387.
 26. Redline S, Adams N, Strauss ME, Roebuck T, Winters M, Rosenberg C. Improvement of mild sleep-disordered breathing with CPAP compared with conservative therapy. *Am J Respir Crit Care Med* 1998;157(8):858-865.
 27. Wright J, White J. Continuous positive airways pressure for obstructive sleep apnoea: cochrane review. Oxford: Update software; 1998.
 28. Engleman H, Martin SE, Deary IJ, Douglas NJ. Effect of continuous positive airway pressure treatment on daytime function in sleep apnoea/hypopnoea syndrome. *Lancet* 1994;343:572-575.
 29. Engleman H, Martin SE, Kingshott RN, Mackay TW, Deary IJ, Douglas NJ. Randomised placebo controlled trial of daytime function after continuous positive airway pressure (CPAP) therapy for the sleep apnoea/hypopnoea syndrome. *Thorax* 1998;53:341-345.
 30. Engleman H, Kingshott RN, Wraith PK, Mackay TW, Deary IJ, Douglas NJ. Randomised placebo-controlled crossover trial of continuous positive airway pressure for mild sleep apnoea/hypopnoea syndrome. *Am J Respir Crit Care Med* 1999;159:461-467.
 31. Jenkinson C, Davies RJO, Mullins R, Stradling JR. Comparison of therapeutic and subtherapeutic nasal continuous positive airway pressure for obstructive sleep apnoea: a prospective parallel trial. *Lancet* 1999;353:2100-2105.
 32. Ballester E, Badia JR, Hernandez L, Carrasco E, de Pablo J, Fornas C, Rodriguez-Roisin R, Montserrat JM. Evidence of the Effectiveness of Continuous Positive Airway Pressure in the Treatment of Sleep Apnoea/Hypopnoea Syndrome. *Am J Respir Crit Care Med* 1999;159:495-501.
 33. Ware J, Sherbourne CD. The MOS 36-item Short Form Health Survey (SF-36): I. Conceptual framework and item selection. *Med Care* 1992;30:473-483.
 34. Flemons W, Reimer MA. Development of a disease-specific health related quality of life questionnaire for sleep apnoea. *Am J Respir Crit Care Med*. 1998;158:494-503.
 35. Ware J, Kosinski M, Keller SD. SF-36 Physical and Mental Health Summary Scales: A Users Manual. Boston: The Health Institute, New England Medical Centre; 1994.
 36. Johns MW. A new method for measuring daytime sleepiness: the Epworth sleepiness scale. *Sleep* 1991;14(6):540-5.
 37. Rosenthal L, Roehrs TA, Roth T. The Sleep-Wake Activity Inventory: A self-report measure of daytime sleepiness. *Biological Psychiatry* 1993;34:810-820.
 38. Johns M, Hocking B. Daytime sleepiness and sleep habits of Australian workers. *Sleep* 1997;20(10):844-9.
 39. Rosenthal L, Bishop C, Guido P, Syron ML, Helmus T, Rice FM, Roth T. The sleep/wake habits of patients diagnosed as having obstructive sleep apnoea. *Chest* 1997;111:1494-1499.
 40. Carr-Hill R. The measurement of patient satisfaction. *Journal of Public Health Medicine* 1992;14:236-249.
 41. Department of Human Services. The Victorian Inpatient Minimum Database: An overview. Melbourne: Health and Community Services; 1994.

14 Appendices

APPENDIX A: Laboratory Survey

The CPAP Pilot Scheme was introduced in Victoria on 1 July 1997. The aim of the scheme is to provide accessible, high quality and cost effective CPAP services to patients with sleep disordered breathing who are financially disadvantaged.

The CPAP Service Development Project is a study funded by the Victorian Department of Human Services. The project will include a review of the performance of the CPAP Pilot Scheme, and make recommendations concerning improved performance of the CPAP-PS in relation to suppliers of the CPAP equipment and selection of subjects and conduct of the sleep studies. The project will develop a minimum data set of clinical and sleep study variables which might form the basis of a clinical practice guideline for the management of OSA.

As part of this study we are conducting a survey of all sleep laboratories that currently conduct sleep studies for patients entering the CPAP pilot program. The survey will ask questions about the equipment used for the conduct of sleep studies in your laboratory and the criteria used to stage and score studies.

Please note that this is not a test. There are no right or wrong answers. Surveys overseas have shown that different laboratories use a wide array of criteria for scoring studies. We understand that you may not be able to answer all the questions please answer those that you can and return the survey when you have finished.

Date: ____/____/____

Hospital/Sleep laboratory: _____

Doctor in charge of Laboratory: _____

Chief Scientist/technologist: _____

Name and Role of person completing this survey: _____

Part One – Equipment

1. Please state the brand of sleep study equipment and model number if applicable e.g. Compumedics:

Describe the type of equipment used to measure the following variables:

2. Do you use a pulse oximeter to monitor oxygen saturation?

1. No
2. Yes
3. Don't know

3. **If you answered yes to question 2** please indicate the site of probe placement:

1. Finger
2. Ear lobe
3. Other, please specify: _____
4. Don't know

4. **If you answered yes to question 2** what averaging time have you selected on the oximeter (if you are not sure write don't know):

5. **If you answered yes to question 2**, what brand of oximeter do you use (if you are not sure write don't know):

6. Please specify the method used to monitor airflow:

1. Thermister
2. Thermocouples
3. Nasal pressure – pressure transducer
4. Pneumotachometer
5. Other, please specify: _____
6. Don't know

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7. Please specify the location of airflow monitoring

1. Nasal only
2. Nasal-oral
3. Other, please specify: _____
4. Don't know

8. With respect to the monitoring of respiratory effort which of the following do you routinely record:

1. Chest and Abdominal signals
2. Chest signal only
3. Abdominal signal only
4. Other, please specify: _____
5. Don't know

9. Please specify the method used to monitor chest or abdominal movements:

1. Inductive device, e.g. respitrace
2. Strain guage device
3. Other, please specify: _____
4. Don't know

10. Please specify the location of EMG leads for monitoring EMG for sleep staging:

1. Chin
2. Mandible
3. Other, please specify: _____
4. Don't know

11. Please specify the location of EEG leads (you may circle more than one answer):

1. C3
2. C4
3. O1
4. O2
5. Other please specify: _____
6. Don't know

12. Electro-oculogram – Please specify the location of the leads for recording extraocular movements:

1. Outer canthus of the eye
2. Other, please specify: _____
3. Don't know

13. With respect to the recording of extraocular – circle the appropriate statement below:

1. Left and right eye movements are recorded on separate channels
2. Left and right eye movements are recorded on a single integrated channel.
3. Other please specify: _____
4. Don't know

13. Do you routinely record an ECG during the study:

1. No
2. Yes
3. Don't know

If yes, please specify the leads that are routinely applied:

15. Please specify the method of body position monitoring:

1. Position sensor
2. Direct observation and manual recording
3. Video monitoring, observation and manual recording
4. Other, please specify: _____
5. Don't know

16. Do you routinely record leg movements?

1. No
2. Yes
3. Don't know

17. **If you answered yes to question 16**, what method is used for recording leg movements?:

1. Muscle EMG recording
2. Piezo-electric sensor
3. Other, please specify: _____
4. Don't know

16. **If you answered yes to question 16**, do you monitor both legs or one leg?:

1. One leg only
2. Both legs
3. Don't know

19. Please specify the method used for monitoring airway pressure during CPAP studies (i.e. how you know what pressure the patient is on):

1. External pressure transducer
2. Water filled manometer
3. CPAP pump signal
4. Other, please specify: _____
5. Don't know

20. Which of the following **sites** is used to monitor the CPAP pressure?:

1. At the mask
2. At the pump
3. Other, please specify: _____
4. Don't know

21. Does your laboratory undertake video monitoring routinely during sleep studies?

1. No
2. Yes
3. Don't know

22. Do you routinely record oesophageal pressure during diagnostic studies:

1. No
2. Yes
3. Don't know

23. Do you routinely record surface diaphragm EMG during diagnostic studies:

1. No
2. Yes
3. Don't know

23. Do you routinely record transcutaneous CO2 during diagnostic studies:

1. No
2. Yes
3. Don't know

25. If you record any of the items mentioned in **questions 22, 23 and 24** in specific circumstances only please briefly describe below:

26. Are there any other variables routinely recorded during sleep studies in your laboratory?

1. No
2. Yes

If yes, please specify:

Part two – Staging and Scoring Criteria

For the questions below please **circle the number of your answer**:

Sleep Staging and Arousals

1. Please indicate below whether the following categories of sleep studies are staged and scored in your laboratory? **If you answer yes** to any of the categories below please indicate in the second column whether these studies are staged and scored manually or whether you use an automated staging and scoring protocol.

- | | | |
|--|-----------------|--|
| A) Routine diagnostic studies | 1. No
2. Yes | 1. Manual
2. Automated
3. Semi-automated |
| B) Routine CPAP implement studies | 1. No
2. Yes | 1. Manual
2. Automated
3. Semi-automated |
| C) Diagnostic studies of patients
utilising the CPAP pilot scheme | 1. No
2. Yes | 1. Manual
2. Automated
3. Semi-automated |
| D) CPAP implement studies of patients
utilising the CPAP pilot scheme | 1. No
2. Yes | 1. Manual
2. Automated
3. Semi-automated |

Please note: The term *manually* refers to studies that are entirely staged and scored manually. The term *automated* refers to studies that are entirely staged and scored by a computer. The term *semi-automated* refers to studies that are partially staged and scored by a computer and partially staged and scored manually including those studies that are staged and scored by a computer and then manually checked.

If you answered yes to any of the categories in question 1, please answer the series of questions below:

2. Do you use the Rechtschaffen and Kales (1968) scoring system for staging sleep?

1. No
2. Yes

3. For each of the categories of sleep studies below please indicate whether you score *any types* of **arousals**:

If you have any comments regarding the scoring of arousals please describe below:

Respiratory Events:

7. Do you use the same criteria to define respiratory events for CPAP pilot scheme patients and non-CPAP pilot scheme patients?

1. No
2. Yes

For the following questions please refer to the criteria used for studies of patients entering the CPAP pilot scheme. For each the questions circle the number of your answer. You should provide only a single response for each question except where otherwise indicated.

Criteria for hypopnoeas

The questions 8 to 18 below relate to any **mandatory requirements** used in your laboratory when scoring hypopnoeas (of any type).

8. Must a reduction in airflow be present?

- 3 1. No
- 4 2. Yes

9. If you answered yes to question 8, please indicate below the percent of airflow reduction from baseline required:

1. Any discernible reduction
2. 20% or greater reduction
3. 25% or greater reduction
4. 30 % or greater reduction
5. 40% or greater reduction
6. 50% or greater reduction
7. other, please specify: _____

10. If you answered yes to question 8, please indicate below whether there must be a minimum duration of airflow reduction for the hypopnoea to be scored:

1. Minimum duration of 10 seconds
2. Other minimum duration: _____ seconds.
3. No minimum duration.

11. Must a reduction in thoracoabdominal movement/ respiratory effort be present?

1. No
2. Yes

12. If you answered yes to question 11, please indicate below which signals this reduction applies to:

1. A reduction in both signals
2. A reduction in either signal
3. A reduction in the best one of the 2 signals
4. A reduction in abdominal signal only
5. A reduction in thoracic signal only
6. Other, please specify: _____

13. If you answered yes to question 11, please indicate below the percent of thoracoabdominal movement reduction from baseline required:

1. Any discernible reduction
2. 20% or greater reduction
3. 25% or greater reduction
4. 30 % or greater reduction
5. 40% or greater reduction
6. 50% or greater reduction
7. Other, please specify: _____

14. If you answered yes to question 11, please indicate below whether there must be a minimum duration of thoracoabdominal movement reduction for the hypopnoea to be scored:

1. Minimum duration 10 seconds
2. Other minimum duration: _____ seconds
3. No minimum duration.

15. Must there be a reduction in oxyhaemoglobin saturation?

1. No
2. Yes

16. If you answered yes to question 15, please indicate below the % reduction in oxyhaemoglobin saturation from baseline required:

1. Any discernible reduction
2. 1 % or greater reduction
3. 2% or greater reduction
4. 3 % or greater reduction
5. 4 % or greater reduction
6. 5 % or greater reduction
7. Other, please specify: _____

17. Must there be an associated arousal?

1. No
2. Yes

18. If you answered yes to question 17, which of the following criteria are used to score arousals? (If necessary you may circle more than one answer)

1. ASDA criteria (1992)
2. Movement arousals (R and K)
3. Other, please specify:

Some laboratories use an *either/or* system to define hypopnoeas. For example a 10 second discernible reduction in airflow **and either** a 2% oxyhaemoglobin desaturation **or** a 50% reduction in amplitude of thoracoabdominal movement.

19. Do you score hypopnoeas using an *either/or* approach?

1. No
2. Yes

20. If you answered yes to question 19, please describe below the set of criteria used:

21. Do you, *where possible*, distinguish between central and obstructive events when scoring *hypopnoeas*?

1. No
2. Yes

22. If you answered yes to question 21, please indicate below the criteria used to define the following hypopnoeas:

(A) Obstructive hypopnoea:

(B) Central hypopnoea:

(C) Mixed hypopnoea:

23. If you have any comments regarding the scoring of hypopnoeas please specify below:

Criteria for apnoeas

The questions 24 to 27 refer to any types of apnoeas

24. How do you define airflow changes for the purposes of scoring apnoeas?

1. Complete cessation of airflow (flat line)
2. Reduction in airflow signal such that breaths are not discernible
3. Greater than 80% reduction in airflow from baseline
4. Other, please specify: _____

25. Please indicate below whether there must be a minimum duration of airflow reduction for the apnoea to be scored:

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1. Minimum duration of 10 seconds
2. Other minimum duration: _____ seconds
3. No minimum duration.

26. Must there be a reduction in oxyhaemoglobin saturation for an apnoea to be scored?

1. No
2. Yes

27. If you answered yes to question 26, please indicate below the % reduction in oxyhaemoglobin saturation from baseline required:

1. Any discernible reduction
2. 1 % or greater reduction
3. 2% or greater reduction
4. 3 % or greater reduction
5. 4 % or greater reduction
6. 5 % or greater reduction
7. Other, please specify: _____

28. For each of the following types of apnoeas please indicate how changes in *thoracoabdominal movement/ respiratory effort* are defined for the purposes of classifying these respiratory events in your laboratory. In addition if there are any other criteria used not already covered please specify:

(A) Obstructive apnoea:

For example any respiratory effort present for the duration of the apnoea in either signal or discernible movements on one or both signals for the duration of the apnoea.

(B) Central apnoea:

For example respiratory effort completely absent in both abdominal and thoracic signals for the duration of the apnoea or respiratory effort reduced by greater than 80% from baseline in both abdominal and thoracic signals for the duration of the apnoea.

(C) *Mixed apnoea:*

For example both central and obstructive criteria are met at some stage during the event or respiratory effort is absent in both abdominal and thoracic signals for at least 5 seconds preceded or followed by discernible movements on one or both effort signals for at least 5 seconds.

29. Do you **record** the duration of apnoeas?

1. No
2. Yes

30. If you answered yes to question 29, please specify:

31. If you have any comments regarding the scoring of apnoeas please specify below:

Leg Movements:

32. Please indicate for each of the categories of sleep studies below whether you routinely score leg movements:

- | | |
|---|-----------------|
| A) Routine diagnostic studies | 1. No
2. Yes |
| B) Routine CPAP implement studies | 1. No
2. Yes |
| C) Diagnostic studies of patients
utilising the CPAP pilot scheme | 1. No
2. Yes |
| D) CPAP implement studies of patients
utilising the CPAP pilot scheme | 1. No
2. Yes |

33. If you answered yes to any of the categories in question 13, do you calculate a PLM index?

1. No
2. Yes

34. If you answered yes to any of the categories in question 32 please specify below the criteria and method used:

35. If you have any comments regarding the scoring of leg movements please list below:

APPENDIX B: Prospective study – baseline demographics and medical details

Date: ___/___/___

Initials

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Participant identification no.

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PART ONE: Medical History

The following is a series a questions about your health.

(1) Do you or have you ever had any of the following medical conditions (please circle):

1. Diabetes Mellitus
2. Thyroid disease
3. Depression
4. Asthma
5. Lung disease other than asthma e.g. emphysema or fibrosis.
6. Heart attack
7. Angina
8. Heart Failure
9. Heart disease other than a heart attack, heart failure or angina
10. Stroke
11. Mini-stroke (Transient Ischaemic Attack)
12. Epilepsy
13. Other, please specify:

(2) Do you or have you ever had high blood pressure (hypertension)? **Circle the number of your answer?**

1. No
2. Yes

(3) Has your doctor ever prescribed medicine for high blood pressure?

1. No
2. Yes

(4) Have you been taking medicine for high blood pressure at any time in the last 12 months?

1. No
2. Yes

(5) Have you been taking medicine for high blood pressure at any time in the last 1 month?

1. No
2. Yes

(6) Have you ever smoked tobacco for as long as a year?

1. No
2. Yes

(7) Do you *now* smoke as of one month ago?

1. No
2. Yes

(8) How many standard drinks of alcohol do you *normally drink per week*? _____

Note: One standard drink (approximately) = A pot of beer (285 mls = 4.9%) = A small glass of wine (120ml = 11%) = A glass of port (60mls = 18%) = A nip of spirit (30mls = 40%).

A schooner of full strength (heavy) beer contains approximately one and a half standard drinks. A bottle (750mls) of full strength (heavy) beer contains approximately 3 standard drinks. An average light beer contains approximately half the strength of the above amount.

(9) Please list below any medication (including inhalers or patches) you are currently taking or have been prescribed by your doctor in the last 3 months:

PART TWO: Demographics

The following is a series of questions about you and your life.

(10) Your sex (circle number of your answer)

1. Male
2. Female

(11) Your present age: _____ years.

(12) Do you speak a language other than English at home?

1. No
2. Yes

If **YES**, which language do you speak?

(13) What is the highest level of education you have reached? (Circle one number only)

1. No formal education
2. Some primary school
3. Completed primary school
4. Some secondary school
5. Completed secondary school
6. Diploma or partial degree
7. Completed University degree
8. Doctoral or masters degree

(14) What type of employment best describes your situation? (Circle one number only)

1. Employed full time
2. Employed part time
3. Unemployed
4. Home duties
5. Student
6. Retired
7. Permanently unable to work due to illness
8. Other, please specify:

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(15) Please describe your usual occupation (if retired, describe the usual occupation before retirement):

Title: _____

Kind of work you do: _____

Kind of company of business: _____

(16) If you are unemployed, how long has it been since you were last employed?

1. less than one month
2. 1 to 3 months
3. 3-6 months
4. 6-12 months
5. 1-2 years
6. more than 2 years

(17) What was your approximate net family income from all sources, before taxes, in 1998 (circle number):

1. Less than \$5,000
2. \$5,000 to \$9,999
3. \$10,000 to \$14,999
4. \$15,000 to \$19,999
5. \$20,000 to \$24, 999
6. \$25,000 to \$29,999
7. \$30,000 to \$39,999
8. \$40,000 to \$49,999
9. \$50,000 to \$59,999
10. More than \$60,000

(18) Your present marital status: (Circle one number only)

1. Never married
2. Married
3. Divorced or separated
4. De facto
5. Widowed

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7. I get sleepy after reading for 15 minutes.

1 2 3 4 5 6 7 8 9
Always Never

8. I doze off when relaxed.

1 2 3 4 5 6 7 8 9
Always Never

9. I fall asleep when riding as a passenger.

1 2 3 4 5 6 7 8 9
Always Never

APPENDIX D: Epworth Sleepiness Scale

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently try to work out how they would have affected you. Use the following scale to choose the *most appropriate number* for each situation:

- 0 = would *never* doze
- 1 = *slight* chance of dozing
- 2 = *moderate* chance of dozing
- 3 = *high* chance of dozing

Situation	Chance of dozing
a. Sitting and reading	_____
b. Watching TV	_____
c. Sitting, inactive in a public place (e.g. a theatre or a meeting)	_____
d. As a passenger in a car for an hour without a break	_____
e. Lying down to rest in the afternoon when circumstances permit	_____
f. Sitting and talking to someone	_____
g. Sitting quietly after a lunch without alcohol	_____
h. In a car, while stopped for a few minutes in the traffic	_____

APPENDIX E: Sleep Apnoea Quality of Life Index

Participant Identification no.

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Date: ____/____/____

Initials:

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Survey number: _____

Calgary SAQLI (Interviewer)

This questionnaire has been designed to find out how you have been doing and feeling over the **last 4 weeks**. You will be questioned about the impact that **sleep apnea and/or snoring** may have had on your daily activities, your emotional functioning, and your social interactions, and about any symptoms they might have caused.

A. Daily Functioning

I. Most important daily activity

In regard to performing your **most important, usual daily activity (e.g. work, school, childcare, housework, etc.)** - over the **past 4 weeks**:

1. How much have you had to force yourself to do this activity? [yellow card]
2. How much of the time have you had to push yourself to remain alert while performing this activity? [yellow card]
3. How often have you adjusted your schedule to avoid this activity because you felt that you would be unable to remain alert while doing it? [yellow card]
4. How often do you use all of your energy to accomplish only this activity? [yellow card]

II. Secondary activities

In regard to **activities other than your most important daily activity** - over the **past 4 weeks**:

5. How much difficulty have you had finding the energy to exercise and/or do activities that you find relaxing (leisure activities)? [green card]
6. How much difficulty have you had finding the time for activities that you find relaxing? [green card]
7. How much difficulty have you had with your ability to do exercise and/or activities that you find relaxing? [green card]
8. How much difficulty have you had getting chores done around the place where you live? [green card]

III. General functioning

Over the past 4 weeks:

9. How much difficulty have you had with trying to remember things? [green card]
10. How much difficulty have you had with trying to concentrate? [green card]
11. How much of a problem have you had with having to fight to stay awake? [red card]

B. Social Interactions

The following questions pertain to how your **relationship** with your partner, other household members, relatives, and/or close friends have been over the previous **four weeks**. If you have not interacted with a partner etc. in the past 4 weeks, please try to work out how your relationship might have been with these people.

1. How upset have you been about being told that your snoring was bothersome or irritating? [green card]
2. How upset have you been about having to (or possibly having to) sleep in separate bedrooms from your partner? [green card]
3. How upset have you been as a result of frequent conflicts or arguments? [green card]
4. How aware have you been of not wanting to talk to other people? [green card]
5. How much concern have you had about the need to make special sleeping arrangements if you were travelling and/or staying with someone? [green card]
6. How guilty have you felt about your relationship with family members or close personal friends? [green card]
7. How often have you looked for excuses for being tired? [yellow card]
8. How often have you experienced wanting to be left alone?
9. How often have you felt like not wanting to do things together with your partner, children, and/or friends? [yellow card]
10. How much of a problem have you felt there is with your relationship to the person who is closest to you? [red card]
11. How much of a problem have you had from not being involved in family activities? [red card]
12. How much of a problem have you had with inadequate and/or infrequent sexual intimacy? [red card]
13. How much of a problem have you had with a lack of interest in being around other people? [red card]

C. Emotional Functioning

With respect to how you have been **feeling inside** over the last **4 weeks**:

1. How often have you been feeling depressed, down, and/or hopeless? [yellow card]
2. How often have you been feeling anxious or fearful about what was wrong? [yellow card]
3. How often have you been feeling frustrated? [yellow card]
4. How often have you been feeling irritable and/or moody? [yellow card]
5. How often have you been feeling impatient? [yellow card]
6. How often have you been feeling that you are being unreasonable? [yellow card]
7. How often have you been getting easily upset? [yellow card]
8. How often have you experienced a tendency to become angry? [yellow card]
9. How often have you been feeling like you were unable to cope with everyday issues? [yellow card]
10. How concerned have you been about your weight? [green card]
11. How concerned have you been about heart problems (heart attacks or heart failure) and/or premature death? [green card]

D. Symptoms

Below is a list of symptoms that some people with **sleep apnea and/or who snore** may experience. As each symptom is read please indicate whether it has been a problem or not (answer yes or no). Circle those symptoms that you have experienced over the **past 4 weeks**. Once the list is finished please write down additional symptoms in the blank spaces you may have had that are not included in the list below. Next select the five most important symptoms you have experienced. For each of the five symptoms please identify how much of a **problem** it has been. [red card]

- | | |
|--|---|
| 1. Decreased energy | 14. Difficulty staying awake while reading |
| 2. Excessive fatigue | 15. Difficulty staying awake while trying to carry on a conversation |
| 3. Feeling that ordinary activities require an extra effort | 16. Difficulty staying awake while trying to watch something (concert, movie, TV) |
| 4. Falling asleep at inappropriate times or places | 17. Fighting the urge to fall asleep while driving |
| 5. Falling asleep if not stimulated or active | 18. A reluctance or inability to drive for > 1 hour |
| 6. Difficulty with a dry or sore mouth/throat upon awakening | 19. Concern regarding close calls while driving due to your inability to remain alert |
| 7. Waking up often (more than twice) during the night | 20. Concern regarding yours or others safety when you're operating a motor vehicle or machinery |
| 8. Difficulty returning to sleep if you wake up in the night | 21. _____ |
| 9. Concern about the times you stop breathing at night | 22. _____ |
| 10. Waking up at night feeling like you were choking | |
| 11. Waking up in the morning with a headache | |
| 12. Waking up more than once per night to urinate | |
| 13. A feeling that your sleep is restless | |

Symptoms Selected

1. _____
2. _____
3. _____
4. _____
5. _____

E. Treatment Related Symptoms

[If the patient has not had some type of therapy for sleep apnea and/or snoring leave this section blank]

Below is a list of symptoms that some people who have been treated for **sleep apnea and/or snoring** may experience. As each symptom is read please indicate whether it has been a problem or not (answer yes or no). Circle those symptoms that you have experienced over the **past 4 weeks**. Once the list is finished please write down additional symptoms in the blank spaces you may have had that are not included in the list below. Next select the five most important symptoms you have experienced. For each of the five symptoms please identify how much of a **problem** it has been. [red card]

- | | |
|---|---|
| 1. Runny nose | 17. Pain or aching in your jaw joint or jaw muscles |
| 2. Stuffed or congested or blocked nose | 18. Feeling self conscious |
| 3. Excessive dryness of the nose or throat passages especially upon awakening | 19. Aching in your teeth that lasts at least an hour |
| 4. Soreness in the nose or throat passages | 20. Discomfort, aching, or tenderness of your gums |
| 5. Headaches | 21. Hardship in being able to pay for the treatment |
| 6. Eye irritation | 22. A sense of suffocation |
| 7. Ear pain | 23. Excessive salivation |
| 8. Waking up frequently during the night | 24. Difficulty chewing in the morning |
| 9. Difficulty returning to sleep if you awaken | 25. Difficulty chewing with your back teeth that persists most of the day |
| 10. Air leakage from the nasal mask | 26. Movement of the teeth so that the upper and lower teeth no longer meet properly |
| 11. Discomfort from the nasal mask | 27. _____ |
| 12. Marks or rash on your face | 28. _____ |
| 13. Complaints from your partner about the noise of the CPAP machine | |
| 14. Having fluid/food pass into your nose when you swallow | |
| 15. A change in how your voice sounds. | |
| 16. Pain in the throat when swallowing | |

Symptoms Selected

1. _____
2. _____
3. _____
4. _____
5. _____

F. Impact

Complete this section only if you have completed section E above.

- I. Please think of the questions in sections A, B, C, and D. Having been treated for your sleep apnea and/or snoring do you believe that overall there has been an improvement in your quality of life since you started treatment? If yes how much of an impact on your quality of life has there been as reflected by the questions asked in sections A,B,C, and D.

0 _____ 10

No
Impact

Extremely
Large Impact

- II. Please think of the symptoms that developed as a result of being treated for sleep apnea and/or snoring that you highlighted in section E. How much of an impact on your quality of life have these symptoms had?

0 _____ 10

No
Impact

Extremely
Large Impact

Response Options

Yellow Card

1. All the time
2. A large amount of the time
3. A moderate to large amount of the time
4. A moderate amount of the time
5. A small to moderate amount of the time
6. A small amount of the time
7. Not at all

Green Card

1. A very large amount
2. A large amount
3. A moderate to large amount
4. A moderate amount
5. A small to moderate amount
6. A small amount
7. None

Red Card

1. A very large problem
2. A large problem
3. A moderate to large problem
4. A moderate problem
5. A small to moderate problem
6. A small problem
7. No problem

APPENDIX F: Patient satisfaction survey

Initials

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Participant identification no.

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Date: ____/____/____

This survey has been developed to help us better understand patients' experiences of and satisfaction with the treatment they received as part of the CPAP pilot program.

1. Which hospital or sleep laboratory did you attend for your overnight sleep studies?
(Circle the number of your response)

1. Austin and Repatriation Medical Centre
2. Monash Medical Centre
3. Maryvale Sleep Laboratory
4. The Alfred Hospital
5. Western Hospital
6. South Eastern Private Hospital (Noble Park)
7. Sunbury Private Hospital
8. Cabrini Hospital
9. Mercy Private Hospital
10. Vaucluse Hospital (Brunswick)
11. Mitcham Hospital
12. Other, please specify: _____

2. *Were you attended by the same doctor each time you attended the hospital outpatients or sleep clinic? (Circle the number of your answer.)*

1. Yes
2. No

For each of the statements below please tick the most appropriate box



Medical Care

The following items relate to the care you received at the hospital or sleep centre where your sleep apnoea was diagnosed.

	<u>Strongly Agree</u>	<u>Somewhat Agree</u>	<u>Somewhat Disagree</u>	<u>Strongly Disagree</u>
1. My doctor gave me a good explanation about what to expect from treatment with CPAP.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. If I had to do the whole thing all over again I would choose the same doctors.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I would have liked the doctors to have spent more time with me when I attended clinic appointments.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I would like more information about my condition (sleep apnoea).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CPAP Supplier

The following items relate to your satisfaction and experiences of the company that your CPAP machine was purchased from (e.g. pharmacy or other outlet).

	<u>Strongly Agree</u>	<u>Somewhat Agree</u>	<u>Somewhat Disagree</u>	<u>Strongly Disagree</u>
1. I knew who I should contact for advice if I was experiencing difficulty using my CPAP machine at home.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I did not find the phone call follow up provided by CPAP Suppliers helpful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I would like more information about how CPAP works.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. When I had problems with my CPAP machine, mask fitting or other technical factors I was able to obtain helpful advice easily .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Equipment and treatment

The following items relate to your satisfaction with your CPAP machine and other equipment such as your nasal or face mask.

	<u>Strongly Agree</u>	<u>Somewhat Agree</u>	<u>Somewhat Disagree</u>	<u>Strongly Disagree</u>
1. The noise my CPAP machine makes does not disturb either my partner or myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I was unhappy about the cost of attachments for the CPAP machine such as mask, head straps, tubing etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I am not concerned that I may have to use CPAP for the rest of my life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I was unhappy about the payment I had to make towards the cost of the CPAP machine.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I have experienced difficulties with my mask such as air leak, sore nose or poorly fitting mask. (at any point since starting treatment with CPAP)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. My nasal or face mask is comfortable and fits well.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall Service

The following items relate to your satisfaction with the overall service you received as part of the CPAP pilot program.

	<u>Strongly Agree</u>	<u>Somewhat Agree</u>	<u>Somewhat Disagree</u>	<u>Strongly Disagree</u>
1. The overall care I received was well organised.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I was involved in decisions about my care as much as I wanted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Overall (thinking about all aspects of your care) I am satisfied with the treatment I have received for my condition (obstructive sleep apnoea).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

APPENDIX G: Revised Timelines

February 1999:	Availability to commence project.
March 1999:	Recruit research personnel Submission of approval to collaborating centres for ethics committee approval Enrolment of collaborating centres and commencement of retrospective analysis.
April 1999 – June 1999:	Completion of retrospective analysis.
June 1999:	Commence recruitment to the prospective arm of the study.
June 1999 – August 1999:	Continued recruitment for prospective arm of the study.
July 1999 – November 1999:	Follow up period (3 months) for the prospective arm of the study.
December 1999- January 2000:	Data Entry. Completion of 12-month period of follow up of the retrospective cohort hospital utilisation post commencement of CPAP therapy. Data analysis.
February 2000:	Final report preparation and presentation.

APPENDIX H: Ethics committee approval

At the time the project was proposed approval was sought from the Royal Melbourne Hospital Research Foundation and this was granted on the 7/12/98 subject to alterations to the plain language statement and submission of surveys to be used in the project. Approval from the Royal Melbourne Hospital covers the Western Hospital however it was necessary to seek institutional approval from the other centres involved in the project. A specific ethics committee did not cover patients attending the service at the Latrobe Regional Hospital and therefore approval was sought from the Royal Melbourne Hospital Research Foundation to have these patients covered by their ethics committee. Details of submissions and approval are provided below:

Western Hospital:	Proposal submitted to the Royal Melbourne Hospital Research Foundation 7/12/98 Approval granted subject to changes 18/12/98. Alterations submitted: 8/03/99 Approved: 21/04/99
Latrobe Regional Hospital:	Patients attending the service in the Latrobe Valley Region were not covered by a specific institutional ethics committee and therefore we applied to the Royal Melbourne Research Foundation to have these patients covered by the Royal Melbourne Ethics committee. Amendment submitted: 17/03/99. Approved: 19/05/99
Alfred Hospital	Submitted: 18/03/99 Minor alterations requested: 13/04/99 Approved: 23/04/99
Monash Medical Centre:	Submitted: 19/03/99 Ethics committee meeting: 8/04/99 Requested alterations be made to the plain language statement and that a sample size calculation be provided. Statistical consultation sought for power calculations. Changes submitted: 26/04/99 Approved: 4/05/99
Austin and Repat MC:	Submitted: 5/03/99 Rejected and major alterations requested: 29/03/99 Major changes requested to patient information sheet and clarification of certain aspects of the study protocol. Resubmitted 14/04/99. Approved 27/04/99.

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