



Original Article

The management, privacy and medico-legal issues of electronic CPAP data in Australia and New Zealand



Electronic CPAP data management in Australia and New Zealand

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A B S T R A C T

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Study objective: Continuous Positive Airway Pressure (CPAP) is considered to be the gold standard treatment for obstructive sleep apnoea (OSA). CPAP monitoring systems allow tracking of patient CPAP adherence and treatment efficacy, by measuring residual sleep-disordered breathing, hours of CPAP use, and mask leak etc. The American Thoracic Society (ATS) published a position paper in 2013 highlighting issues of interpreting CPAP data such as a lack of consistency between CPAP manufacturers data algorithms, legal implications of CPAP data and implications for CPAP adherence. This paper extends on this work by investigating these issues in an Australasian context.

Method: A review of current literature on CPAP monitoring systems, privacy and security of CPAP data for major Australasian CPAP providers, and CPAP adherence was undertaken. A legal review was also commissioned for issues related to privacy and security of CPAP data.

Results: CPAP manufacturers' utilize different algorithms for respiratory event detection and clinicians need to be aware the implications for interpreting CPAP data. Australasian CPAP manufacturers have created security/privacy policies with the intent to follow relevant legislation to protect patients' CPAP data, however they do need to be constantly reviewed and updated to avoid data breaches and changes to agreements. No guarantees can be provided by the Australasian Sleep Association on CPAP manufacturers' compliance with these policies and there is the potential for some degree of liability for physicians and CPAP providers associated with CPAP data. Lastly, providing patients with feedback on their CPAP usage and OSA management appears to have positive influence CPAP adherence.

Conclusions: CPAP data provides many opportunities to increase OSA patient care and to help patients self-manage this chronic condition. However, issues relating to lack of standardization of CPAP parameters, privacy, security, and legal implications will need to be managed in this changing technologic and clinical environment.

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Introduction

Obstructive sleep apnoea (OSA) is a very common sleep disorder characterized by repeated closure or partial closure of the upper airway during sleep. Untreated OSA is associated with symptoms of tiredness and excessive daytime sleepiness as well as several

negative health outcomes, including hypertension and vascular disease, impaired cognition and mood, an increased risk of motor vehicle accidents and increased mortality. Continuous positive airway pressure (CPAP) is considered to be the gold standard treatment for OSA and evidence suggests that CPAP treatment reduces cardiovascular mortality and morbidity [1,2], daytime sleepiness [3], and the risk of motor vehicle accidents [4] in patients with OSA. Despite the advantages of CPAP treatment, adherence to CPAP is often suboptimal with approximately 50% of patients being non-adherent in the long term [5]. CPAP manufacturers have made advancements in recent years by implementing internal and

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remote monitoring systems to assess CPAP adherence and efficacy. These CPAP monitoring systems are able to record CPAP efficacy (residual sleep-disordered breathing), hours of CPAP use, and mask leak for example. However, whilst many of these measures seem intuitively useful, there are no published standards on how to use the data from monitoring systems, legal implications for physicians, CPAP providers or patients using these systems, nor have there been many studies to assess if monitoring patients' CPAP data improves adherence. The American Thoracic Society published a position paper on the issue in 2013 [6] to facilitate greater understanding by providers on how to interpret CPAP tracking system data, and to stimulate further research into CPAP monitoring systems' impact on patient adherence and how they affect OSA outcomes. Whilst this paper has done well to highlight the emerging issues and lack of research on CPAP monitoring, it has not provided guidelines on how sleep physicians should use this data, how frequently they should monitor it, or what the legal responsibilities are for the sleep physician or CPAP supplier if a patient is not optimally treated or adherent to treatment. This current position paper extends on the ATS's paper for use in Australia and New Zealand. It will discuss the current evidence for the use of CPAP monitoring data, especially in regards to privacy and medico-legal issues and the benefits of incorporating it into clinical practice, in order to develop Australia and New Zealand clinical practice standards on how best to manage CPAP data.

CPAP monitoring systems overview

CPAP monitoring systems measure a range parameters including hours of CPAP use (length of time the device is turned on and a measurable breathing signal is detected, irrespective of ramp, pressure setting or size of mask leak), residual sleep disordered breathing (event detection) and mask leak [6]. They can also record patient pressure settings, and the type of Positive Airway Pressure (PAP) the patient is receiving. The information is recorded on a computerized Secure Digital (SD) card or USB storage device, which the patient brings to their sleep physician or CPAP provider, or can also be uploaded through wireless technology to a secure PAP website. The information can then be reviewed by a CPAP therapist or sleep physician to investigate the patient's usage of CPAP (or lack thereof) and help guide how well the patient's OSA is managed.

When reviewing CPAP monitoring system data, providers need to be aware that PAP devices all use different manufacturer-specific propriety algorithms to calculate OSA parameters such as Apnoea Hypopnea Index (AHI), leak and other measures [7]. There are several limitations to this lack of standardization between PAP device algorithms, including the lack of standard definition for parameters, which has implications for interpretation of the data, the ability to compare CPAP data between different manufacturer devices and the aim of standardizing treatment management [6]. For example, a ResMed device (S9 model) scores an apnoea where the 2 s moving average root mean square ventilation, as measured by an internal flow sensor, falls below 25% of long term ventilation for 10 s [6]. This compares to Fisher and Paykel Healthcare's Infosmart™ Web software, which identifies flow patterns to score respiratory events and defines apnoea as an 80% reduction in flow relative to baseline as determined by previous breaths (see Table 1 below for Event Detection Algorithms differences between manufacturers [6]). Mask leak is also calculated differently between the different manufacturers' CPAP machines as outlined in Table 2. These discrepancies between manufacturers' parameter algorithms highlight some difficulties with interpretation of non-standardized CPAP data. They also present a challenge for incorporating CPAP data into patients' electronic medical record unless they use the

PAP providers CPAP Management Software. Taken together, these issues with discrepancies in CPAP algorithms indicate that work should be undertaken to standardize these measures to facilitate interpretation and clinical understanding of PAP data and its management.

In addition to differences in PAP parameter algorithms, the Apnoea Hypopnea Index (AHI) reported by PAP tracking systems is not the same parameter as AHI reported by polysomnography (PSG) [7]. AHI as reported by PAP devices provides averaged data for the residual AHI and residual Apnoea Index (AI) whilst a person is using CPAP, not necessarily total sleep time as in Polysomnography (PSG). PAP devices calculate AHI based only on reduction of airflow as measured by an internal flow sensor, in contrast to PSG, which uses respiratory flow patterns derived from nasal pressure and thermistor, EEG arousal, abdominal and thoracic movement and arterial oxygen desaturation. Hence, PAP reported AHI or AI is not a true measure of PSG derived AHI, which is not always understood in clinical practice or by patients. For example, Berry et al. [8] compared respiratory events as calculated by PSG or a PAP device (Remstar Auto M Series, Philips). They found that when comparing 148 studies, AHI and AI correlated well, but not Hypopnea Index (HI). They also found that the PAP data tended to overestimate AHI when PSG derived AHI was low, but underestimate the AHI when PSG derived was high. The authors concluded that there was relatively good agreement between the two measures for apnoea detection, but not as good for detecting hypopneas. This finding has been replicated [9,10], suggesting that PAP devices lack of oximetry, respiratory effort etc. make it difficult for these devices to accurately identify more subtle respiratory events and lead to some discrepancies between PSG outcomes. Based on these findings, the ATS position from a clinical perspective is that PAP derived AHI can be used when AHI is low (<10 events per hour) or high (>20 events per hour), but when residual AHI is intermediate, the PAP derived AHI and AI are difficult to interpret and should be examined clinically, taking into account the individual patient's context [6,8]. Therefore any patient with a residual AHI >10 events per hour should be clinically reviewed to identify any issues with PAP fit etc. (mask leak, incorrect pressure) or additional disorders of sleep fragmentation, such as periodic limb movements, which can cause irregularities in depth of breathing, classified as hypopneas by many proprietary algorithms. Patients who appear well treated but complain of residual OSA symptomatology, such as excessive daytime sleepiness, should also be reviewed, as CPAP data is not a substitute for clinical expertise.

Due to the different derivation of AHI from PSG versus CPAP data, the ATS position statement [8] recommends that more concise terminology is used for PAP derived AHI. The authors from this ATS position paper recommend that the terminology be changed to residual AHI_{Flow} to highlight this AHI is only based on reduction of airflow. In addition, they recommend that studies need to be conducted to determine what is a clinically meaningful AHI_{Flow} based on outcome data, as it is unknown how this measure can be reliably interpreted to identify how well a patient's OSA is actually managed. There is also a lack of research on clinical outcomes of PAP derived AHI and improvements in OSA symptomatology such as cardiovascular, cognitive and daytime functional outcomes. The ASA supports this recommendation and encourages CPAP manufacturers to integrate this new terminology into their PAP devices and also for further research to be conducted on how AHI_{Flow} is associated with clinical outcomes. Manufacturers are also encouraged to collaborate to work towards providing a standardized methodology and criteria for identifying and characterizing flow limited events.

Table 1
Event detection algorithms.

Manufacturer	Apnoea event detection	Hypopnea event detection
ResMed Unit (S9 Model)	Apnoea is defined when the 2-s moving average root mean square ventilation (based on a pneumotachograph) falls below 25% of the long-term ventilation for 10-s.	Hypopnea is defined when all the following conditions are met: 1. The 12-s moving average root mean square ventilation falls below 50% of the long-term ventilation 2. The hypopnea is not immediately followed by an apnoea 3. The hypopnea contains one or more partially obstructed breaths
Philips unit (System One model)	Apnoea is detected after a moving window of 3–4 min is established and flow decreases by more than 80% for at least 10 s.	Hypopnea is detected when moving window of 3–4 min is established and flow decreases by 40–80% for at least 10 s
DeVilbiss Healthcare IntelliPAP unit (SmartCode remote data retrieval system)	A reduction in a flow signal of >90% of the baseline for 10 s.	A reduction in a flow signal of >50% of the baseline flow for 10 s
Fisher & Paykel Healthcare Infosmart™ Web software	>80% reduction in flow relative to a baseline determined from previous breaths	>40% reduction in flow relative to a baseline determined from previous breaths

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Table 2
Continuous positive airway pressure leak measurements.

CPAP Manufacturer	How leak is measured	Large leak threshold
Philips	Intentional leak subtracted from total flow	Leak condition where the leak level exceeds a present “flow vs. pressure” curve (the averaged leak through all mask exhalation ports at various pressure)
ResMed	Unintentional leak (device flow-intentional leak) + mouth leak.	95th percentile leak (<24 L/min with nasal resistance and <36 L/min with full face interface)
Fisher & Paykel Healthcare	Total leak, including mask and exhaust flow from mask	A leak value of >60 L/min
DeVilbiss Healthcare IntelliPAP	Records high leak flow time as a percentage of the time the leak was above 95 L/min	A leak value of >95 L/min

Note: CPAP = continuous positive airway pressure.
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Summary of ASA position on CPAP tracking systems data

- Providers and clinicians should be aware of the different PAP manufacturers' algorithms for event detection and how they impact CPAP data.
- Steps should be put in place to standardize the algorithms across manufacturers
- PAP derived AHI is not the same measure as PSG derived AHI and PAP manufacturers should adopt a new name for this PAP parameter as AHI_{Flow}
- From a clinical perspective PAP derived AHI (AHI_{Flow}) is supplementary to a comprehensive clinical assessment. PAP derived AHI could be considered clinically useful if it is either very low (AHI < 10) or high (AHI > 20), however control of OSA needs to be reviewed if there is a discrepancy between symptoms and PAP data. For example, when PAP derived AHI is >10 or if patients continue to report OSA symptomatology despite low PAP derived AHI – as it is not known exactly how AHI_{Flow} correlates with clinical outcomes.
- Research needs to be considered to investigate the correlation between AHI_{Flow} and clinical OSA outcomes.

Privacy and security policies for CPAP data

The convenience and technological advancement that CPAP data provides, also presents privacy and security concerns for all who access, retain and use the data collected in relation to patients. PAP data is either stored on a portable memory card/stick and can be uploaded to a CPAP data management program (or electronic medical record at a patient's CPAP review appointment), or it can be transmitted at various intervals via a wireless modem in the PAP machine to the PAP provider's data management program or host website. The location of the stored data and the corresponding legislation that protects the data, along with how the data is protected during transmission have become important issues that need to be managed carefully. This section will highlight these security and privacy concerns for the CPAP data.

PAP companies operating in Australia and New Zealand, such as Philips, ResMed and Fisher & Paykel Healthcare, all have different approaches to PAP data management and depending on where they store their 'cloud' data, have to comply with different legislation. All of these companies operating in Australia need to comply with the 1988 Australian Privacy Act, but if the CPAP data is stored in the USA, for example, there are additional legislative issues with which the company must comply. Whilst it is common for people to be concerned with Australian data being hosted overseas, healthcare data in the USA has been especially protected under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. As part of HIPAA, the Privacy Rule (effective April 24, 2003) and Security Rule (effective April 21, 2005) were implemented. The Privacy Rule established national standards to protect individuals' medical records and other personal health information. The Security Rule specifies a series of administrative, technical, and physical security procedures to be used to assure the confidentiality, integrity, and availability of electronic health information.

This legislation benefits Australian CPAP companies hosting data in the USA in several ways, firstly by using the specific guidance related to the recommended security controls environment. The term “control environment” describes the defined actions and protections that a company should exercise when processing personal and sensitive data. By comparison an “ad-hoc environment” would not have defined controls that are followed, and important protective actions could be skipped.

The US government provided detailed guidance to companies to comply with the HIPAA Security Rule in 2008 in the form of the

NIST 800-66 Guidance. This Guide can be viewed at: <http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-66r1.pdf>.

PAP companies operating in New Zealand are required to comply with the 1993 Privacy Act of New Zealand. Guidance on how to host cloud-based data is provided by the New Zealand National Health IT Board (NHITB) advisory group, the Health Information Governance Expert Advisory Group (HIGEAG) to promote the safe sharing of personal health information. The HIGEAG policy states that all personal health information held in an identifiable form and associated with clinical or administrative data should be fully domiciled in New Zealand, unless a special exemption has been granted by the NHITB.

Investigation of the privacy and security policies of the main CPAP providers in Australasia regarding CPAP data indicates all companies have a strong interest in protecting patient's privacy and maintaining their data securely. Companies do, however, have different policies and procedures for how CPAP data is encrypted, stored and managed, and these are outlined in Table 3.

In addition to the CPAP company privacy policies, individual CPAP providers have policies in place to describe the privacy policies to patients/customers, such as "Hire or Purchase Agreements" when patients hire or buy PAP devices, and can also receive detailed paper consent when they agree to use CPAP data management programs. However, how much patients/customers understand the implications of these policies is unclear. Just as many of us automatically click "I Agree" to privacy policies and terms and conditions in websites without fully reading and comprehending the policies, it is likely that this is the case for CPAP data privacy policies and this should be discussed openly with patients to find out if they understand and agree to the policies.

Individual manufacturers have differing approaches to funding these remote monitoring services. Some are marketed as provided at no cost. Patient costs and financial liability associated with a service provider should be fully disclosed and clarified with a patient by the manufacturer and/or provider before contractual arrangements are entered into as details of these may be complex.

Creation of records

If a treating professional keeps summaries or notes of CPAP data it is still private information of a patient. Even though it is generated by a data provider and may be a summary or secondary record of primary medical data, it is still covered by the Privacy Act. The ways in which the Act may operate and apply can be subtly different to different types of treating professionals and data providers. Close consideration needs to be given to how data creation, retention and management systems comply with, or are affected by, the Privacy Act.

Cloud storage

CPAP data in general terms is capable of storage on a cloud-based platform. A feature of cloud-based platforms is that the person or entity seeking data storage does not know geographically where the information is stored. The person or entity seeking to store the information needs to ensure as reasonably as is possible that the cloud storage provider does not breach the privacy principles. A theme in the privacy principles is ensuring, from the perspective of an Australian entity, that the same or similar sets of principles with regard to the treatment of patient's private information applies where the information is stored. Whilst this provides significant logistical and practical challenges, it is an important feature of compliance.

Quality, security and access

An entity who holds the private information of others needs to take all reasonable steps to ensure that the information held is accurate and up to date as much as is possible. They need to ensure that all reasonable steps are taken to protect the information from misuse, interference or loss. Further reasonable steps need to be taken to ensure there is no unauthorized access, modification or disclosure of the private health or medical information of patients or others. Importantly, the rights largely reside with the patient. Access to the information about a person must in general terms be provided when they ask for it. There are exceptions to this principle, although they arise only in limited circumstances.

Summary of ASA position on Australia's three major PAP providers' privacy policies

- Philips, ResMed and Fisher & Paykel Healthcare have created policies with the intent to follow relevant legislation to protect patients PAP data (Privacy Policy 1988 in Australia, HIPAA, and New Zealand Privacy Policy) and have measures in place to protect patient data. However, these do need to be constantly reviewed and updated to avoid data breaches and changes to agreements. We cannot ensure that Philips, ResMed and Fisher & Paykel Healthcare comply with the law in relation to the data they collect. We do not double-check what they do and whether it complies with the law or is appropriately up to date.
- The consent process by patients on how their data is managed and the possible implications (e.g. exceptions to release of information to third parties) should be highlighted more clearly and patients encouraged to carefully read privacy policies. Patients should also have the possible implications explained to them by their PAP provider.
- Disclosure to third parties is possible under the law such as to provide information to authorities, if required by legal action or in certain circumstances identified as permitted health situations under the Act. A permitted health situation essentially relates to situations where disclosure is necessary to provide a health service to the person whose information is held. It is important for patients, providers and physicians to be aware of legal implications of disclosure and whether any of the relevant exceptions apply in the context of third party disclosures.

Legal implications of CPAP data

With advances in technology such as the ability to manage CPAP data remotely even when a patient is not physically present, comes a changing landscape of liability for physicians and PAP providers. For example, the ATS position paper [6] raised the question of what happens in the event of a motor vehicle accident if the driver is on CPAP and has CPAP tracking data available. If the patient has not been adherent to PAP treatment in the lead up to the accident then it is possible that PAP data could be used in legal proceedings. Alternatively, if PAP data is reviewed under legal proceedings and shows a high residual AHI_{flow} or large mask leak, then it is possible that the sleep physician or CPAP provider could face legal proceedings for not reviewing the patients PAP data when easily accessible. A similar issue could arise where a patient appears to be adequately managed upon last review, and so hasn't been followed up regularly even when the CPAP data was available in a PAP data management program – but not necessarily reviewed by PAP provider or physician.

This begs the question of where does the legal onus sit with sleep physicians and CPAP providers in the event of legal

Table 3

Comparison of privacy polices between the three major PAP providers operating in Australia and New Zealand.

	Philips	ResMed	Fisher and Paykel Healthcare (FPH)
Name of CPAP Data Management Program	<ul style="list-style-type: none"> • EncoreAnywhere for providers • DreamMapper (previously SleepMapper) for patients 	<ul style="list-style-type: none"> • AirView for Providers • MyAir for patients 	<ul style="list-style-type: none"> • InfoSmart for providers
Location of stored cloud data	<ul style="list-style-type: none"> • USA 	<ul style="list-style-type: none"> • USA 	<ul style="list-style-type: none"> • May be outside of Australia and New Zealand. • Australian and New Zealand data is stored in secure data center in the UK – complies with Australian Privacy Principles APP-8 and APP-11. • For New Zealand data, an exemption has been granted for FPH to store data outside of New Zealand in the UK through New Zealand's National Health IT Board (NHITB)
For personal use only			
Privacy Legislation to comply with	<ul style="list-style-type: none"> • 1988 Privacy Act in Australia • Applicable state legislation (for public health entities) • HIPAA Privacy and Security Rules in USA 	<ul style="list-style-type: none"> • 1988 Privacy Act in Australia • Applicable state legislation (for public health entities) • HIPAA Privacy and Security Rules in USA • MyAir Australia is covered by ResMed policy for users anywhere apart from North, South and Central America, Canada, Europe and Brazil, and as such is governed by laws of New South Wales, Australia. 	<ul style="list-style-type: none"> • 1988 Privacy Act of Australia • Applicable state legislation (for public health entities) • 1993 Privacy Act of New Zealand
Data Export Service Security	<ul style="list-style-type: none"> • CPAP report is encrypted during transmission • Secure transfer protocol and accessed with username and password • Independent security audit yearly • Access to data center strictly controlled • Data is encrypted at rest • Routine vulnerability scanning performed • Data retained for 7 years (minimum) • Philips employees undergo a background check and have security measures in place for departing employees • Modems remain the property of Philips at all times • Privacy Impact Assessments and Security Risk Assessments of application and application enhancements • Privacy (Corporate Binding Rules) and Security Policies • Privacy and Security training • Home Care Provider 	<ul style="list-style-type: none"> • Personal data is encrypted during transmission and also at rest • Employees have annual assessment of ResMed security and privacy controls, which are based on Privacy Law from Australia and other jurisdictions • AirView is the most audited and controlled system in ResMed at present • Quarterly and ad-hoc vulnerability scans completed using Nexpose • The source code is now assessed for security and vulnerabilities using a mixture of automated and specialist reviews 	<ul style="list-style-type: none"> • All data is encrypted in transit, and stored data is encrypted at rest • Staff are trained on their obligations when handling data to comply with relevant legislation • Only a small restricted/controlled team have access to data, and only as required to maintain the system
Who owns the data?		<ul style="list-style-type: none"> • Personal data for consumers in Australia is owned by the data subject 	<ul style="list-style-type: none"> • Ownership of data remains with the originator
Disclosure to third parties	<p>No, with exceptions</p> <ul style="list-style-type: none"> • Agreement allows for disclosure of de-identified data to Philips or 3rd parties • Unless third parties need access to perform duties in the context of providing the application to you • Or required to by law enforcement authorities • Agreement allows for Philips to change the conditions of the contract without prior notice to customers 	<p>No, with exceptions</p> <ul style="list-style-type: none"> • Only shared to the extent reasonable necessary to perform their functions and they will not be authorized to use it for any other function, unless user has consented to such disclosure • May also share personal information in the event that the business of ResMed is transferred to another entity, by way of sale, merger etc. • May be accessed by law enforcement authorities or courts if required to by law 	<p>No, with exceptions:</p> <ul style="list-style-type: none"> • Government authorities or regulatory bodies, where FPH are under legal obligation to do so • Third parties engaged by FPH to provide services in connection with the uses of personal information about client (e.g. provide CPAP information to healthcare provider, physician etc.) • As otherwise required by Law
Consent process	<ul style="list-style-type: none"> • For DreamMapper, consent is gained by creating account and agreeing to the privacy notice • If patient wants to delete data they need to contact Health Care Provider. If patient does not want to use DreamMapper anymore, they can delete the DreamMapper App and any DreamMapper data will be deleted from mobile device 	<ul style="list-style-type: none"> • By using the MyAir website and providing consent to the terms and conditions during the registration process • ResMed does honor the 'right to be forgotten' and patients can have personal data completely removed if requested. 	<ul style="list-style-type: none"> • Use of website signifies agreement to privacy policy • Healthcare providers are responsible for obtaining consent from patients before providing their personal information to InfoSmart Web

Table 3 (continued)

	Philips	ResMed	Fisher and Paykel Healthcare (FPH)
Liability for security breach	<ul style="list-style-type: none"> Philips recognize and take seriously their responsibility to protect the personal and sensitive data you entrust to Philips from loss, misuse or unauthorized access, and use a variety of security controls, technologies and organizational procedures to help protect personal and sensitive data. Philips specifies absolutely no liability of any responsibility within the fullest extent of the law. 	<ul style="list-style-type: none"> ResMed will take all reasonable measures to protect personal data and will comply with the applicable data protection law. Despite these security measures, there is no guarantee of absolute security with respect to information sent through the Internet. If ResMed is aware of a personal data breach, patient will be contacted in a timely fashion. ResMed performs Mandatory Data Breach Notification for all jurisdictions, regardless of whether that country has enacted legislation on this matter. 	<ul style="list-style-type: none"> Will take all reasonable and appropriate steps to protect secure information but FPH will not be liable in anyway for a breach of security or unintended loss or disclosure of information due to the website being linked to the internet.

Note: Information for this table was gathered from Philips, ResMed and FPH websites (see Web References following the main reference list) and personal communications with company staff.

proceedings associated with CPAP data. What is the expectation of sleep physicians and CPAP providers to monitor CPAP data long term, after the acute treatment phase has passed? There are currently no guidelines in place to manage this and due to the complexity of the issue it does require legal counsel to explore and put in place appropriate guidelines and standards for practitioners in the field to follow, to avoid the prospect of legal ramifications. There is no way to remove all prospect of liability. However, good risk management and prudent insurance practices will be essential for a practice to ensure that if a claim is made maximum protection both under the law and commercially is provided to a practice or treating professional.

Also, there could be financial legal issues involved with access to CPAP data. In the USA, Centers for Medicare and Medicaid Services (CMS) regulate rebates for CPAP machines. Patients can lose access to reimbursement for their PAP device if they are non-adherent according to the CMS guidelines (PAP usage of greater than or equal to 4 h per night on 70% of nights during a consecutive thirty day period anytime during the first 3 months of initial usage). Employers in the USA are also able to access CPAP data on employees in professions such as commercial driving, and employees can be fired if they do not adequately 'adhere' to this definition of CPAP adherence. These guidelines are not followed in Australia, but similar policies could potentially be brought in by insurance companies and employers, despite a lack of evidence for this definition of adherence and associated clinical outcomes. The evidence for this will be expanded on in the next section, but it does highlight some possible legal implications for patients that have not been explored in Australia.

Summary of ASA position on legal implications of CPAP data

- There is the potential for some degree of liability for Physicians and CPAP providers for accidents that occur if patients are on CPAP. Currently, there are no guidelines for the frequency of review of CPAP data management programs now that this information can be wirelessly updated daily. The ASA presently endorses that CPAP data should be reviewed either by the sleep clinic or CPAP provider at the regular time intervals as reported in the ASA "Best Practice Guidelines for CPAP Therapy" [11] (at 7, 30 and 60 days, then at 12 months, and yearly after that due to the chronic nature of OSA). This might be the de facto standard; until a legal review has been conducted to what extent providers should be monitoring CPAP data outside of regular review times. However, as documented earlier in this position

statement, CPAP data should not be assessed in isolation. Interpretation of CPAP data needs to be performed within the context of an overall clinical review of the patient. The ASA recommends that clinical review is of primary importance in the assessment of OSA therapy and that CPAP data is supplementary to this comprehensive clinical assessment. Once the patient is stabilized on therapy, the clinical review may be undertaken either by the sleep physician/specialist, or another medical practitioner (e.g. primary care physician) with input from the CPAP provider, with referral back to the sleep specialist as is medically necessary.

- Australian insurance companies and employers should have an interest in customer/employee adherence to PAP, however using CPAP data according the CMS definition does not have adequate research to support its definition and how it translates to clinical outcomes.

CPAP data and impact on CPAP adherence

The implementation of CPAP tracking systems provides a unique opportunity to monitor and support patients with their successful use of CPAP. Sleep physicians and CPAP therapists can now 'check in' on how adherent patients are when patients bring their data card in to their review CPAP appointment, or via wireless technology. Whilst this new technology provides opportunities to track patients between review appointments (via wireless transmission of PAP data) no guidelines have been published on how sleep physicians/providers should use patient data. In particular, there are no guidelines on how often patients should be monitored remotely and have PAP data checked; or if a patient is well 'controlled', whether they need to be monitored over time. Also, with Physicians and Providers having access to PAP data it brings up the issue of what is the duty of care to the patient to review this information. These issues will be explored throughout this section.

Overall adherence to PAP is poor, with only 50% of patients adhering to therapy long term [5]. Whilst studies investigating adherence to PAP with the help of CPAP data are limited, several recent studies are showing promising results for increasing adherence rates [12]. Fox et al. [13] utilized PAP data to conduct a telehealth intervention by responding quickly to any difficulties such as high mask leak, high residual AHI etc. and phoned patients to rectify the problem. Patients in the telemedicine/PAP data arm were found to have greater mean PAP adherence than the standard care patients after 3 months (191 min compared to 105 min). A similar study investigated adherence with wireless telemonitoring

of CPAP data (AutoSet Spirit Flow Generator Unit: ResMed) in newly diagnosed OSA patients [14]. Stepnowsky et al. [14] found after 2 months, participants who were able to view his/her CPAP usage via an interactive website had higher usage of PAP of 4.1 h per night, compared with participants on usual care of 2.8 h PAP usage per night. Lastly, Kuna et al. [15] recently published a study indicating PAP adherence is significantly improved when patients have Web access to information about their use of PAP treatment. Interestingly, they found that the addition of a financial incentive for patients to use PAP in the first week of treatment did not significantly improve PAP usage further.

Philips also released a White Paper on their 'in house' PAP data trial for patients, using a patient engagement tool called DreamMapper (formerly SleepMapper) [16]. DreamMapper not only allows patients to access their CPAP data via an app, it also uses psychological theories of behavior change to assist patients to engage with PAP treatment. DreamMapper interfaces with Philips EncoreAnywhere software that is managed by the CPAP provider or sleep physician, and provides patients with access to their adherence and therapy data, as well as an education tool. In this study, researchers investigated adherence by comparing patients in the EncoreAnywhere database who were using DreamMapper to a similar group of patients who did not use the DreamMapper App. When comparing 15,242 patient records, they found that patients in the DreamMapper group ($n = 7641$) had a higher adherence rate of 78% when compared to the Standard Care Group ($n = 7601$) adherence rate of 56% ($p < 0.0001$). Average use of PAP in the DreamMapper group was 4.5 ± 2.3 h, compared to Standard care usage of 3.1 ± 2.6 h. In addition, DreamMapper also appeared to assist "struggling users" (those who were using CPAP less than 2 h on average per night in the first two weeks) more so than did Standard Care, as 33% of DreamMapper users who were classed as "Struggling Users" went on to meet the CMS adherence guidelines (4 h per night, 70% of nights) compared to only 11% of Standard Care users. A similar White Paper was recently published by Philips with Australian data and also suggests that the use of the DreamMapper App improves adherence to CPAP [17]. Whilst Philips sponsored these studies, it does suggest that providing patients with CPAP data via an app can benefit patient adherence to PAP, even in patients who are classed as "struggling users". Taken together, these studies suggest that when patients have the opportunity to access information about their PAP usage, their adherence to treatment is positively impacted.

Whilst increasing CPAP adherence is important, the level of CPAP adherence to provide clinically significant benefit remains debatable. According to the Centers for Medicare and Medicaid Services (CMS) in the U.S., the definition of PAP adherence is PAP usage of greater than or equal to 4 h per night on 70% of nights during a consecutive thirty-day period anytime during the first 3 months of initial usage. In the USA, patients can lose access to reimbursement for their PAP device if they are not adherent according to the CMS guidelines.

Despite this well used CMS definition of adherence, research supporting this definition is limited. Marin et al. [2] investigated cardiovascular events in severe untreated OSA patients, followed for over 10 years. Results suggest that treatment with PAP for 4 h or more per night reduced the raised cardiovascular risk seen in untreated patients. However, as part of the study protocol, if the usage of CPAP was less than 4 h per night upon review, CPAP treatment was stopped after a period of time, so it is unclear if less than 4 h of CPAP treatment was at all beneficial for cardiovascular risk. Another study by Campos-Rodriguez et al. [17] suggested that cardiovascular morbidity and mortality rates vary according to CPAP use. Whilst patients who use CPAP for >6 h per night had the highest survival rate, even patients using CPAP between 1 and 6 h had

survival odds comparative to people who used CPAP for more than 6 h per night after approximately 48 months. This suggests that the higher PAP usage per night the better, however cardiovascular risk can still be improved significantly when patients use PAP for at least 1 h per night.

Other studies suggest a dose–response relationship between PAP usage and outcomes. For example, Weaver et al. [18] found that the longer PAP was used per night, the greater the improvement in both subjective and objective measures of sleepiness. However, this relationship flattened at 7 h PAP usage per night, and only 30% of patients treated with PAP had normal MSLTs after treatment, indicating that some treated patients were still sleepy. Zimmerman et al. [19] reported similar dose–response relationships when it came to verbal memory assessments, and Antic et al. [20] found that even when patients were maximally compliant with CPAP treatment as tracked by CPAP data, patients did not improve on all neurobehavioral measures such as Functional Outcomes of Sleep Questionnaire (FOSQ) and Epworth Sleepiness Scale (ESS). However, the authors did find that sleepiness scores on the ESS had greater improvement with longer use of CPAP.

Taken together, there is strong evidence that patients with OSA who adhere to CPAP treatment experience benefit across the board, in terms of cardiovascular health, neurobehavioral and cognitive functions. There does appear to be a dose–response relationship between these improvements and CPAP usage, however the optimal level of CPAP treatment has not been conclusively proven and it would appear that some patients using PAP for only a few hours per night can still experience benefit. Patients that are optimally treated may also still report as "sleepy" and may still have an abnormal MSLT, however, increasing adherence to PAP provides patients with the best chance of optimally managing the symptoms of OSA. Initial research into utilizing PAP data to increase adherence to treatment is promising and should be researched further and incorporated into clinical practice.

Summary of ASA position on CPAP data use for improving adherence

- Providing patients with feedback on their CPAP usage and OSA management appears to have positive influences on adherence to CPAP, although this does require further evidence.
- Patients should be encouraged to engage in CPAP data management programs or applications, such as DreamMapper (Philips) or MyAir (ResMed) to improve their usage of CPAP and overcome any obstacles such as mask leak.
- CPAP data should be checked by the CPAP provider in accordance with the current ASA Position on Guidelines for CPAP provision, i.e. at approximately 7, 30, 60 days and then 12 months post treatment initiation. Patients should then be reviewed every 12 months after that to check on ongoing adherence, given that long term adherence rate is approximately 50% and OSA treatment is generally required long term. Reports are to be provided or made available to the Sleep Physician/Sleep Clinic (in accordance with privacy guidelines) to provide a summary of this information including average usage or night-to-night usage, residual PAP derived AHI and Mask Leak, to facilitate Physician follow up, particularly if the patient is not optimally treated (not wearing mask for time spent asleep, large mask leak, side effects, etc.). This is especially important at the commencement of treatment. It is acknowledged that involvement of the patient's primary care provider (and potentially CPAP provider) in the follow up clinical assessment of patients stabilized on CPAP therapy is often necessary – as long as there is a mechanism for referral back to the treating specialist in the case of clinical problems.

- Patients should be encouraged to adhere to PAP treatment at all times when asleep due to the dose–response relationship for most outcomes. However, physicians and PAP providers should still be supporting patients whose adherence is >0, as some research suggests that even using PAP > 1 h per night can provide benefit to some patients.
- CPAP data should be used to help stratify access to review for those that need it most, such as those with low adherence, AHI >10, mask leaks, residual OSA symptomatology.

Summary

CPAP data has many benefits including the ability to provide objective data on patients' CPAP adherence and residual sleep disordered breathing, a way to engage patients in increasing their CPAP usage and allowing CPAP providers and physicians to intervene early if patients are having difficulties/not adhering to treatment by monitoring through wireless technology. However, this ability to monitor and record CPAP data also raises concerns with privacy issues for patient data, along with possible legal implications for physicians, PAP providers and patients in the event of accidents, if patients are not adherent or properly managed according CPAP data. With any information that is stored on the Internet, there are always threats to privacy as no information can ever be completely safe and secure. There is also always a possibility that records you hold about patients can be the subject of subpoena in legal proceedings. In this context the laws of Privacy will often be waived. This is particularly so where the person whose information is held is involved in the case. This provides the Australia and New Zealand sleep community with opportunities to do further research on CPAP data parameters and how they correlate with clinical outcomes, improving CPAP adherence with CPAP data, and also to conduct a proactive legal review on implications of CPAP data for physicians, PAP providers and patients. There are also significant opportunities to provide better management of OSA for patients by being able to identify early barriers to adherence and rectify them by monitoring data externally and providing quick feedback. In summary, CPAP data provides many opportunities to increase OSA patient care and to help patients self-manage this chronic condition. In addition, there are issues that relate to privacy, security, legal implications and the lack of standardization of PAP parameters and clinical implications that will need to be managed in this changing technologic and clinical environment.

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Conflict of interest

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The ICMJE Uniform Disclosure Form for Potential Conflicts of Interest associated with this article can be viewed by clicking on the following link: doi.org/10.1016/j.sleep.2017.03.018.

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