

Domiciliary Non-Invasive Ventilation in Adult Patients

Proposal for a
New Model of Care

ACI Respiratory Network

2010

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EXECUTIVE SUMMARY

Currently in NSW there is considerable variation in clinical practice regarding the indications, initiation and follow up of patients requiring home ventilation. Additionally, inequalities exist for patients attempting to access appropriate equipment and resources for the safe and effective management of respiratory insufficiency in the home setting. The situation is not unique to this state and a number of authors have reported this phenomenon, with differences in treatment prevalence occurring even in countries with more homogenous health care systems.

Poor record keeping and the absence of a coordinated state-wide body to collect and analyse information has made it impossible in NSW to identify prescription practices. In the absence of good epidemiological data on the prevalence of neuromuscular conditions and obesity hypoventilation syndrome, the two largest diagnostic groups for which non-invasive ventilation (NIV) is likely to be indicated, it is not possible to predict future demand. However, increasing awareness of the benefits of NIV by patients and health care professionals is likely to lead to more referrals for NIV assessment. The use of NIV in patients with chronic obstructive pulmonary disease (COPD), the prevalence of which is forecast to increase from 1.2 million to 2.6 million Australians (5.6% to 7.5% of the population) by 2050, forecasts a dramatic increase in demand for NIV services. The NSW Ministry for Healthcare System must be prepared to meet the increased demand for care of these individuals, and ensure resources are used sensibly.

To address the variation in assessment, commencement and provision of equipment for home NIV in NSW, a group of experienced clinicians involved in the clinical care of patients requiring domiciliary NIV, was empanelled under the auspice of the Greater Metropolitan Clinical Taskforce (GMCT) Respiratory Network. The Domiciliary NIV Working Group's first task was to develop best practice guidelines for domiciliary NIV in order to standardise criteria for the assessment, treatment and management of patients with chronic respiratory failure. Their second task was to develop a model of care for a state-wide domiciliary NIV service in NSW, to be submitted to NSW Ministry for Health.

To inform the development of the model of care detailed in this document considerable effort was devoted to the task of collecting and recording quantitative and qualitative information pertaining to the provision of home NIV services in NSW, other states within Australia, and similar services in other countries. In particular, a broad and inclusive face-to-face consultation process was undertaken with key clinical groups to elicit and define the main issues and elements of a new model of care.

The aim of this document is to provide recommendations to NSW Health on how to improve domiciliary NIV services for adult patients in NSW. Particular attention has been given to the requirements of patients who have difficulty accessing medical services due to their medical condition or geographical isolation.

This proposal describes a new model of care involving one 'Centralised Agency' which is responsible for the provision of:

1. all government funded domiciliary ventilation equipment
2. a state-wide database and information management system including capacity for the management of both equipment and clinical/patient-related data

Operating in conjunction with the Central Agency is a hub and spoke network of clinical services featuring:

- a) 'Specialised Hubs' with adequate resources, expertise and sufficient critical mass to assess and commence patients with complex disease on non-invasive ventilation,

- b) 'Level 2 Agencies' with resources, expertise and critical mass to commence less complex patients on NIV and share in the continued management of complex patients, and
- c) 'Level 3 Assessment' and monitoring nodes providing regular monitoring services for patients who have difficulty accessing medical services due to their medical condition or geographical isolation.

If implemented, the model of care described in this document will considerably improve domiciliary NIV services in NSW and has the potential to significantly reduce hospital admissions and length of stay for this group of patients. Additionally, it will provide a means of more accurately estimating current and future demand for home NIV services.

RECOMMENDATIONS

Recommendation 1: Basic requirements for an improved model of care for Home NIV in NSW

No.	Recommendation
1	People in NSW should receive equivalent standards of domiciliary NIV service access and quality to people in other states of Australia and other European countries with similar standards of living and health resources / expenditures.

Recommendation 2: Background

No.	Recommendation
2	The model of care for NIV in NSW should be congruent and compliant with <i>Caring Together – The Health Action Plan for NSW</i> , in which changes are geared towards using the resources that are already available to develop a culture where the patient is the focus of the system with commitment to a universal model that provides safe, equitable and high quality provision of NIV services and equipment for everyone in NSW.

3. Model of Care

Central Agency (NSW Health) / EnableNSW

Equipment Provision

No.	Recommendations
3	The Central Agency should purchase and own all equipment required for public domiciliary ventilation services in NSW. This may include, but is not limited to: bi-level ventilators (spontaneous and spontaneous-timed); volume ventilators; hybrid ventilators; and mechanical cough in-exsufflator.
4	<p>The Central Agency must provide the Specialised Hubs and Level 2 Agencies with timely delivery of equipment.</p> <p>The requested piece of equipment should be delivered directly to the patient <u>within 24 hours</u> from the time telephone approval is obtained from the Central Agency.</p> <p><i>Alternatively</i>, a minimum level of on-site equipment, suitable to specific requirements, is to be made available to each Specialised Hub and Level 2 Agency if rapid provision (within 24 hours) is not possible (See Section 7). The pool of on-site equipment would be automatically replenished with replacement stock as it is depleted</p>
5	<p>The Central Agency should be responsible for coordinating equipment repair, maintenance and replacement in a timely manner.</p> <p>Ventilator users should be given direct line access (phone number) for the Central Agency, or third party nominated by the Central Agency, to enable direct communication regarding equipment repair, maintenance and replacement.</p> <p>Depending on the patient's ventilatory requirements, malfunctioning equipment should be either repaired or replaced within 24 to 48 hours of notification. (See section 12 for additional equipment recommendations for ventilator dependent patients).</p> <p>The agency conducting the assessment should also notify the patient's principal clinical team that an equipment issue has been raised by the patient.</p>
6	If, during assessment for repair or replacement, a piece of equipment is found to be functioning properly, the agency conducting the assessment must notify the patient and principal treating clinical team of the outcome of the assessment as soon as this information becomes available and within 48 hours of a notification of equipment malfunction.
7	The Central Agency should be responsible for retrieval of equipment.

3.1 Central Agency (NSW Health) / EnableNSW (contd)
Information Management System

No.	Recommendations
8	<p>Information on public home NIV services in NSW should be managed by developing a single, comprehensive, computerised information management system.</p> <p>The system should contain two data streams:</p> <ol style="list-style-type: none"> 1. <u>Equipment-related Information</u> Including ventilator settings and prescription histories 2. <u>Clinical / Patient-related Information</u> (see Appendix B for suggested data sets) <p>Such a system should incorporate:</p> <ol style="list-style-type: none"> 1. A centralised <u>database / data repository</u> enabling data storage, database queries, analysis and reporting. 2. A <u>state-wide information collection tool</u>, in the form of user-friendly computer software accessible (via secure password login or similar) at the point of service, to all clinicians involved in the management of the patient irrespective of geographic location.
9	<p>The Central Agency should provide and maintain a stable platform for a secure, comprehensive information management system which is accessible to all centres and clinicians involved in home NIV services across NSW.</p>
10	<p>Data input into the Information Management System is mandatory and ensures initial and continued provision of equipment. Data entry is one of the core tasks of the Support Officers (see Support Officer position description, Appendix C)</p> <p>Where relevant, data entries into the Information Management System should be electronically signed to include the clinician's name, designation, location and service contact details.</p>
11	<p>Periodically, data reports should be generated for analysis and publication / website posting. Using such data comparative research and journal publication should be encouraged.</p>

3.2 Specialised Hubs

No.	Recommendation
12	<p>It is recommended that patients with complex ventilation requirements should be <u>initially assessed and commenced at a small number of specialised centres or 'hubs'</u>.</p>
13	<p>Specialised Hubs (hospitals) should be responsible for the assessment, treatment and establishment of 'complex' or 'high to medium level support' patients on domiciliary NIV from a wide spectrum of patient conditions (e.g. significant neuromuscular disease and the need for ventilatory support; or patients without coexistent neuromuscular or respiratory disease requiring long term invasive ventilation).</p> <p>Subsequent to assessment and establishment on ventilation, these patients may be monitored and reviewed closer to their places of residence by Level 2 or 3 centres, if more convenient / appropriate.</p>
14	<p>Specialised Hubs should have an annual throughput of an agreed minimum number / critical mass of new patients, and should maintain an adequate critical mass of on-going patients.</p>
15	<p>Specialised Hubs should have agreed levels of clinical expertise and be equipped with workforce resources to maintain a broad, multi-disciplinary service.</p>

No.	Recommendation
16	<p data-bbox="272 241 842 271">To qualify as a Specialised Hub an existing centre should have:</p> <ol style="list-style-type: none"> <li data-bbox="316 286 1497 371">1. Demonstrable experience in managing a spectrum of patients with respiratory failure requiring domiciliary ventilation, and an established home ventilation program, or specialist skills in managing complex disorders requiring domiciliary ventilation (e.g. neuromuscular disorders, spinal cord injury). <li data-bbox="316 387 1118 416">2. An accredited Sleep Medicine physician and Respiratory Medicine physician on site. <li data-bbox="316 432 1497 461">3. Access to on-site advanced level diagnostic and clinical testing (e.g. Full PSG, pulmonary function tests, arterial blood gases). <li data-bbox="316 477 1497 703">4. A Sleep Unit on site that can take 'complex' patients who have multiple co-morbidities or are unwell. The sleep unit should have: <ul style="list-style-type: none"> <li data-bbox="363 562 799 591">– Medical fitness assessment for sleep study <li data-bbox="363 618 644 647">– Registered Nurse on duty <li data-bbox="363 674 1123 703">– On site and close links with an Emergency / Arrest service or Respiratory Ward <li data-bbox="316 719 1497 804">5. A dedicated service which has expertise in the management of patients with acute and chronic respiratory failure. This service would include personnel with practical experience in the assessment, treatment and management of respiratory failure and secretion management in neuromuscular disorders. <li data-bbox="316 819 1497 882">6. Access to on-site specialised multidisciplinary services (e.g. Speech pathology, Physiotherapy, Palliative Care, Occupational Therapy, Respiratory, Gastroenterology, Cardiology etc.). <li data-bbox="316 898 1437 927">7. A rostering system which will ensure adequate levels of staffing taking into account expertise, experience and workload. <li data-bbox="316 943 1107 972">8. Patient's on domiciliary ventilation should have access to a 24 hour clinical service. <li data-bbox="316 987 900 1016">9. Dedicated clinics for patients with chronic respiratory failure. <li data-bbox="316 1032 1497 1095">10. Access to multidisciplinary health professionals for radiographic procedures and surgical interventions (e.g. PEG tube insertion) for high risk patients. <li data-bbox="316 1111 1497 1218">11. Established successful programmes for ventilation weaning and tracheostomy tube management, weaning and decannulation. Concern was raised that tracheostomies can fall between specialities at times (e.g. ICU / ENT / Respiratory Medicine) and that a dedicated tracheostomy service or team would assist with streamlining patient management and weaning. <li data-bbox="316 1234 1497 1296">12. Access to more sophisticated on site ventilatory and non-invasive ancillary equipment (e.g. mechanical in-exsufflator), including staff with experience and expertise in the use of this equipment. <li data-bbox="316 1312 1497 1375">13. On site dedicated clinical support personnel to organise patient appointments, collect and input data, monitor compliance, liaise with the central agency or provider companies and chase patient appointments and equipment. <li data-bbox="316 1391 1054 1420">14. Involvement in dissemination of clinical information and training programmes. <li data-bbox="316 1435 1497 1498">15. Ability to perform home or community visits, or have a specialised outreach service which has been trained in baseline clinical domiciliary NIV clinical assessment. <li data-bbox="316 1514 1059 1543">16. A commitment to improving their process through data collection and auditing. <li data-bbox="316 1559 1235 1588">17. Involvement in research and the ability to participate in innovative clinical trials or clinical practise. <li data-bbox="316 1603 948 1632">18. Efficient transport service to deliver patients to Specialised Hubs. <li data-bbox="316 1648 1497 1711">19. Knowledge base and expertise to provide consultative services to clinicians at other sites in the management and care of patients requiring NIV.

3.3 Level 2 Agencies

No.	Recommendation
17	Level 2 Agencies should be responsible for assessment, treatment and establishment of 'non-complex' or 'minimal support' patients on domiciliary NIV.
18	Level 2 Agencies should monitor, assess and treat 'high level' or 'complex' patients who have already been established on ventilation at a Specialised Hub and who are located closer geographically to the Level 2 Agency.
19	The critical patient mass for a Level 2 Agency should be defined as commencing at least 1 patient per month (i.e. 12 per year).
20	Level 2 Agencies require on site baseline services such as access to full polysomnography and personnel including a sleep physician, a respiratory physician and staff with a certain amount of expertise (e.g. nursing or allied health) to assist with assessment and management of patients on domiciliary NIV.
21	Level 2 Agencies should have access to the common database and be responsible for entry of all relevant data.

3.4 Level 3 Assessment and Monitoring Nodes

No.	Recommendation
22	<p>Level 3 Assessment and Monitoring Nodes should provide local access to routine baseline assessment, monitoring and support for patients on domiciliary ventilation.</p> <p>Examples of suitable patients include:</p> <ol style="list-style-type: none">Patients isolated geographicallyPatients who have difficulty travelling to a Level 2 Agency (or Specialised Hub) for medical reasons (e.g. patients with advanced neuromuscular disease or bariatric transport requirements) or reasons of logistics / special need (eg. equipment requirements such as electric wheelchair, hoist, mattress, oxygen cylinders).
23	Level 3 Assessment and Monitoring Nodes should be located at convenient central physical addresses and/or may be deployed as mobile community units.
24	Trained outreach teams should be involved in assessing the patient's ventilator equipment (via checklist) and secretion removal techniques, and perform basic monitoring such as oximetry and spirometry.
25	Level 3 Assessment and Monitoring nodes should have access to the common database and be responsible for entry of compliance and monitoring data.

3.5 Non-Metropolitan Community Care and Outreach Programs

No.	Recommendation
26	The transfer of patients from non-metropolitan areas to Specialised Hubs for initial assessment and management, including their return home, should be adequately funded.
27	Specific training should be made available for local rural community care programs such that they can be involved in the routine assessment of the patient's ventilator equipment (via checklist), symptom/side effects related to NIV and secretion removal techniques, and perform basic monitoring such as oximetry, spirometry and arterial blood gases.
28	Support should be made available for clinicians from Specialised Hubs to travel to rural areas to conduct periodic 'respiratory support' clinics. Input into these clinics by experienced staff from the Specialist Hubs may be drawn up along geographical lines or based on historic ties and relationships.
29	Additional financial input or resources should be made available to support Specialised Hubs as they take on extra responsibilities (e.g. outreach services). A natural funding source for such programs may be the recipient Rural Area Health Service; that is, funding may be transferred from the Area receiving the benefit of additional clinical support / outreach services to the Metropolitan Area providing those services.

3.6 'Other Hospitals'

No.	Recommendation
30	'Other Hospitals' should have access to a standardised referral system to transfer patients to a Level 2 Agency or Specialised Hub depending on complexity of the ventilatory requirements of their patient.

1.1.1.1

3.7 Resources for Proposed Model

No.	Recommendation
31	A dedicated NIV Support Officer should be located on-site at each Specialised Hub.

4. Referral System / Patterns

No.	Recommendation
32	A standardised referral system should be developed. Referral forms should be clear and concise.
33	To improve equity of access and prioritisation, patients requiring NIV assessment and treatment should be administered on a centralised waiting list.
34	A central role of the Support Officer at the Specialised Hubs should be to coordinate referral information and relay this information through appropriate clinical personnel.

5. Inter-Agency Relationships

No.	Recommendation
35	Specialised Hubs should be required to maintain open lines of communication with other major (and minor) centres and develop systems facilitating the effective referral of complex patients as required. Additionally, all centres involved in the specialist provision of chronic NIV services should be required to participate in state-wide clinical education and training programs to share information, experience and skills (see section 17 Education and Training).
36	'Low level' or 'non-complex' patients should be referred to either Level 2 Agencies or Specialised Hubs for initial assessment and commencement of domiciliary ventilation. The choice of service will be dependent on factors such as proximity to patient's residence and severity of the patient's condition.
37	Level 2 Agencies can monitor, assess and treat 'high level' or 'complex' patients which have already been established on ventilation at a Specialised Hub. Level 2 Agencies will, however, retain the ability to refer established 'high level' or 'complex' patients to their Specialised Hub for further management if required / indicated.
38	Regardless of where the patient is initially commenced, it should be made clear who is responsible for the continued management of the patient (i.e. clinician or clinical service and location). This information should be recorded in the Information Management System.
39	It is recommended that hospitals that do not routinely assess and treat patients for domiciliary NIV should participate in education and training sessions to ensure they maintain a continued awareness of chronic respiratory failure and know when and who to refer such cases to.

6. Clinical Link with Central Agency

No.	Recommendation
40	On a rotational basis from each of the Specialised Hubs, experienced clinicians should be involved in monitoring the overall quality and quantity of applications submitted to the Central Agency. Monitoring reports should be made available to improve evidence based care and optimise the efficient use of available clinical and equipment resources.

7. Ready Access to Home NIV Equipment

No.	Recommendation
41	<p>The Central Agency should guarantee delivery of equipment to Specialised Hubs and Level 2 Agencies throughout NSW within 24 hours of application approval.</p> <p><i>Alternatively, if the Central Agency is not able to guarantee such delivery –</i></p> <p>Baseline levels of equipment stock should be held at Specialised Hubs and Level 2 Agencies.</p> <p>Less frequently used machines (e.g. Volume ventilators or ventilators approved for life support) should be held in a small quantity at the Central Agency and couriered to the appropriate site upon approval.</p>

8. Process for Obtaining Equipment

No.	Recommendation
42	<p>The following process for obtaining government funded domiciliary NIV equipment in NSW is recommended:</p> <ol style="list-style-type: none">i) If, based on standardised clinical and eligibility guidelines, a patient appears to satisfy requirements and is deemed potentially eligible for publicly funded equipment, the Central Agency should give tentative approval for the provision of equipment for an initial, short-term (usually 1 - 2 months) compliance period. Tentative approval should be obtainable via telephone discussion between a senior clinician (or recognised local support officer) and Central Agency staff. Equipment should be delivered to the patient within 24 hours of such approval. <p>[The patient is responsible for the purchase of ventilator tubing and masks].</p> <ol style="list-style-type: none">ii) The prescribing clinician (through the local support officer) would then use standardised forms on the online information management system to lodge a formal application for long term equipment provision.iii) The prescribing clinician would use the online information management system to document standard patient clinical information and equipment prescription information.iv) On receipt of the loan equipment the prescribing clinician would commence the patient on NIV. Equipment settings would be recorded in the online information management system.v) Review appointments are made, based on standardised guidelines, and recorded in the information management system.vi) A review of the patient's clinical condition, equipment needs and machine compliance is conducted at the first review appointment. Data form review is entered into the information management system.vii) If the patient demonstrates adequate compliance, and approval for long term ventilation is given by the Central Agency, the patient continues to use their current loan machine. <p>[Should the patient require a less sophisticated machine, a more appropriate machine is ordered and provided. All details are recorded in the information management system.]</p>

9. Elimination of Self-Funded Equipment Hire During Initial Compliance Period

No.	Recommendation
43	Patients who are eligible for government funded domiciliary NIV equipment should not have to pay to hire their own equipment to

demonstrate initial compliance.

10. Ventilator Set-Up

No.	Recommendation
44	Equipment should be set up by clinicians who have an understanding of the patient's condition and the script requirements (e.g. by Specialised Hubs and Level 2 agencies). Having a small amount of on site equipment stock will ensure that the patient is acclimatised and set-up with the correct ventilator settings.
45	Changes to non-invasive ventilator settings and / or machines outside the Specialised Hubs and Level 2 agencies should only be performed by experienced clinicians and by non-clinicians who have been accredited to do so and where quality control checks are routinely performed.

11. Special Ventilation Equipment

No.	Recommendation
46	<p>A process should be available to facilitate the application for a specific (non-regular) make or model of ventilator if/when:</p> <ul style="list-style-type: none">i) an effective trial period of the standard issue ventilator has been attempted (i.e. following correct set-up, adequate compliance for sufficient duration and appropriate settings) <p>and</p> <ul style="list-style-type: none">ii) there is objective demonstration that an alternate make / model is significantly superior in the treatment of the patients nocturnal or diurnal hypoventilation <p>and</p> <ul style="list-style-type: none">iii) the machine requested is on the Central Agency's pre-approved list (reviewed on a regular basis)

12. Ventilator-Dependent Patients

No.	Recommendation
47	Secondary back-up ventilators (TGA approved for life-support) and back-up power supplies should be provided for ventilator dependent patients. Back-up machines should be located at the patient's home.

13. Continued Provision of Equipment

No.	Recommendation
48	<p>Continued provision of government issued NIV equipment is based on fulfilling the following criteria:</p> <ul style="list-style-type: none">a. Compliance (> 4 hours per 24 hour period over a consecutive 4 week period).b. Minimum number of clinical reviews (actual numbers of reviews are at clinicians' discretion i.e. earlier or more frequent if required)<ul style="list-style-type: none">• Initial review (within 3 months after commencement)• Subsequent reviews (6 or 12 months depending on clinical stability or requirements)c. Clinician and NIV Support Officer to continue to input required data on Clinical Information System.

14. Reasonable Period of Acclimatisation

No.	Recommendation
49	Clinicians should have the ability to recommend to the Central Agency a more reasonable period of acclimatisation for the purpose of compliance for patients where it is medically justifiable.

15. Removal of Equipment Due to Poor Compliance

No.	Recommendation
50	<p>The responsibilities of the patient in accepting government funded NIV device should be clearly explained from the outset of treatment. Patients should demonstrate an understanding of the relevant information and agree to accept conditions through signed documentation.</p> <p>Specifically, patients should be made aware that they will forfeit their qualification for publicly funded equipment assistance, following which equipment will be withdrawn, if:</p> <p>i) they can not demonstrate that they are using their prescribed device for the required minimum number of hours (> 4 hours) per night,</p> <p>and</p> <p>ii) over a subsequent period of several months they fail to demonstrate compliance improvement.</p>
51	Ventilators provided should have the capacity to download information, including daily hours of usage.
52	<p>If compliance falls below 4 hours per night for greater than one month and cannot be explained by a hospital admission or other reasonable event, the following sequence is recommended:</p> <ol style="list-style-type: none">1. Patient is made aware of their poor compliance and reminded of the implications of poor compliance2. A letter is sent to the patients primary physician / clinician to inform them of the patient's poor compliance3. A telephone call is made by the patient's clinical team to see<ol style="list-style-type: none">a. If the problem may be addressed over the phone, <p>If the problem can not be addressed over the phone,</p> <ol style="list-style-type: none">b. An appointment (outpatient or community where appropriate) is organised to assess the patient and problem solve where required. <ol style="list-style-type: none">4. A follow-up phone call is made two weeks later and compliance checked again 1 month after the initial attempt to address the problem. <p>If compliance has not improved to a satisfactory level after efforts by the clinical staff to troubleshoot problems, the clinical team via the Support Officer is obliged to inform the Central Agency. The Central Agency will then be responsible for the retrieval of government funded equipment. Patients who are not compliant according to Central Agency standards (i.e. unable to fulfil the criteria of using it for > 4 hours per 24 hour period) but wish to continue having a ventilator on their premises will be given information on where to hire or purchase their own equipment.</p>

16. Provision of Mechanical In-Exsufflators

No.	Recommendation
53	Mechanical in-exsufflators should be provided for patients with expiratory muscle weakness, adequate bulbar control and peak cough flow rates < 270 L/min.
54	Patients/carers need to be adequately trained in the use of mechanical in-exsufflators, and need to use them on a regular daily basis.

17. Education and Training

No.	Recommendation
55	Specialist consultation, monitoring and training should be available equally for all involved parties.
56	Specialised Hubs should develop dedicated training programs and, on a rotational basis, should provide training programs to clinicians from metropolitan and rural areas.
57	To assist with education, training and dissemination of information, clinicians from the Specialised Hubs should be required to meet every 6 months to: <ul style="list-style-type: none">▪ Discuss clinical or operational issues▪ Discuss clinical cases▪ Exchange knowledge (Level 2 Agencies and other clinicians may meet, contribute or join these sessions)

18. Expansion of Telemedicine

No.	Recommendation
58	Promote and use videoconferencing facilities to improve monitoring and assessment of patients on domiciliary NIV in clinically or geographically isolated areas.
59	Explore the technologies of remote real-time ventilator and oximetry monitoring. Information from ventilators and oximeters could be streamed directly via a modem to an operator at a Specialised Hub where ventilator settings could be assessed and altered remotely. Such capability would be particularly useful in remote locations or where it is not feasible for patients to travel for assessment.

1. INTRODUCTION

The aim of this document is to provide recommendations to NSW Health on how to improve domiciliary NIV services for adult patients in NSW.

This proposal describes a new model of care involving one 'Centralised Agency' which is responsible for the provision of:

1. all government funded domiciliary ventilation equipment
2. a state-wide database and information management system including capacity for the management of both equipment and clinical/patient-related data

Operating in conjunction with the Central Agency is a hub and spoke network of clinical services featuring:

- a) 'Specialised Hubs' with adequate resources, expertise and sufficient critical mass to assess and commence patients with complex disease on non-invasive ventilation,
- b) 'Level 2 Agencies' with resources, expertise and critical mass to commence less complex patients on NIV and share in the continued management of complex patients, and
- c) 'Level 3 Assessment' and monitoring nodes providing regular monitoring services for patients who have difficulty accessing medical services due to their medical condition or geographical isolation.

The Working Group agreed that paediatric respiratory disease management - and thus the provision of home NIV services to children - is characterised by substantial variability at the individual patient level. Whilst it is recognised that there are aspects of clinical care which overlap between adult and paediatric clients this model of care, and the medical guidelines developed in conjunction with this document, do not address the management of paediatric patients.

Further, this document does not address the provision of Continuous Positive Airways Pressure (CPAP) devices for simple, non-hypercapnic Obstructive Sleep Apnoea (OSA). The Working Group agreed that provision of CPAP services for OSA should be addressed separately. However, the inclusion of a trial of CPAP for disorders presenting initially with hypercapnia (eg: patients with obesity hypoventilation syndrome) is a clinically appropriate approach once the underlying respiratory disorder is stabilised, and is therefore included within the scope of the model described.

With the above points in mind, however, we see no reason why the process of equipment provision to adults, as outlined in this model, should not assist with the delivery of similar equipment to paediatric patients or the delivery of CPAP devices to adult patients with OSA.

If implemented, the model of care described in this document will considerably improve domiciliary NIV services in NSW and has the potential to significantly reduce hospital

admissions and length of stay for this group of patients. Additionally, it will provide a means of more accurately estimating current and future demand for home NIV services.

1.1. NON-INVASIVE VENTILATION

Over the past two decades, non-invasive ventilation (NIV) has emerged as a feasible and effective method of managing hypercapnic respiratory failure. Originally introduced as a method of reversing hypercapnia (high blood carbon dioxide levels) in patients with chronic respiratory failure, the technique is now widely used in hospitalised patients with acute respiratory failure. The simplicity, low cost and acceptability of NIV has led to this approach being widely adopted by the respiratory community and accepted by patients to the extent that NIV is now considered first line therapy in the management of chronic respiratory failure. Importantly, it is now recognised clinically that ventilatory support during sleep is all that is required to achieve sustained daytime improvements for most patients.

1.1.1. What is non-invasive ventilation?

Non Invasive Ventilation (NIV) refers to the delivery of mechanical ventilation using a face and or nasal mask, rather than an invasive tube (e.g. tracheostomy). For examples of patients using NIV, see Figure 1.



Figure 1: Patients using non-invasive ventilation

A) 22 year old with Duchenne Muscular Dystrophy on 24 hour non-invasive ventilation (From ⁽¹⁾)

B) Patient with congenital muscular dystrophy using nasal non-invasive ventilation (From ⁽²⁾)

1.1.2 Why is non-invasive ventilation required?

There are many conditions which can cause a patient to under-breathe to the point where their oxygen levels fall and carbon dioxide levels rise, causing respiratory failure. This can be the result of respiratory muscle weakness, alterations in the chemical control of the breathing centres or abnormalities of the chest wall and lungs. General examples of disorders include patients with neuromuscular disorders (such as Duchene Muscular Dystrophy, Spinal Muscular Atrophy, Motor Neurone Disease), spinal cord injury, chest wall deformities, lung disease (such as cystic fibrosis or chronic obstructive pulmonary disease (COPD)), obesity hypoventilation syndrome, congenital breathing abnormalities and breathing problems resulting from catastrophic illness (such as brainstem tumours or trauma).

To ameliorate the patient's under-breathing the most common and cost effective way is to treat the patient with an external mechanical breathing machine (ventilator), either through an invasive route (e.g. tube placed in their windpipe) or non-invasive route (e.g. mask placed firmly over the patient's nose and/or mouth). Although long term invasive ventilation is the only solution in certain circumstances, where ventilation can be safely managed non-invasively, this should be encouraged as it is preferred over invasive ventilation for safety, reducing infections and airway trauma, convenience, comfort, speech, swallowing, sleep, appearance and cost ^(3, 4). Non-invasive ventilation (NIV), the provision of ventilatory assistance without an invasive airway, has assumed an important role in the therapy of respiratory failure in both acute and chronic settings ⁽⁵⁾.

1.1.3 Benefits of providing NIV

The benefits of providing domiciliary ventilatory support include:

- Reversal of nocturnal and daytime respiratory failure
- Reversal or improvement in sleep fragmentation
- Reduction in daytime sleepiness
- Improvements in physiological parameters
- Improvements in quality of life
- Reduction in hospital admissions

1.1.4 How many hours a day is NIV required?

There is a wide continuum of how many hours a day a patient is required to use NIV to circumvent respiratory failure and ill effects of reduced breathing effort. It can range from ventilation use only when asleep (when effective breathing is most vulnerable) to patients with little or no spontaneous breathing ability who need to be supported by a ventilator on a continuous or near continuous basis to avoid death by asphyxiation.

1.1.5 What resources are required to provide a patient with NIV?

Patients may present for assessment for NIV either with chronic respiratory failure, acute on chronic respiratory failure or signs or symptoms related to sleep disordered breathing. Currently, the majority of NIV assessment and commencement of treatment occurs as an

inpatient. However, in less severe and less complex patient conditions NIV may be initiated as an outpatient.

For the majority of conditions, diagnostic and treatment sleep studies are required to establish the need and efficacy of NIV treatment. In addition to this the patient requires access to lung function testing, arterial blood gases, measures of carbon dioxide, and access to the appropriate personnel with adequate clinical experience in NIV for continued monitoring and support. Appropriate personnel and services usually includes: a team experienced in the use of NIV in acute and chronic situations; sleep and respiratory physicians; access to allied health services such as physiotherapists who have been specifically trained in sputum clearance in neuromuscular disorders, speech pathology for swallow assessment and dietetics for nutritional support; and access to sub-specialties such as neurology, gastroenterology and palliative care, for close consultation and multidisciplinary care.

Equipment requirements for NIV at a minimum include a ventilator, ventilator tubing and an interface (mask to go over the nose and/or mouth). Depending on the patient's ventilatory requirements, the ventilator can range from a spontaneous bi-level pressure ventilator (patient triggered ventilator), to a spontaneous-timed bi-level pressure ventilator (for patients who cannot always trigger the ventilator) through to a volume or volume/pressure ventilator (Hybrid ventilator) which are reserved for patients who are ventilator dependent or where pressure ventilation has failed to improve their respiratory failure. Patients who cannot be without their ventilator for short periods of time require additional equipment such as a back-up ventilator and a back-up battery supply. Patients with significant coughing weakness should be taught and given equipment to assist them with removal of their lung secretions in order to minimise the risk of developing pneumonia, which can lead to protracted admissions and death.

1.2 COST-EFFECTIVENESS OF PROVIDING DOMICILIARY NIV

NIV provides a reduction in overall costs and hospital admissions for COPD patients treated for acute respiratory acidosis ^(6, 7) and for patients with chronic respiratory failure treated with domiciliary NIV ⁽⁸⁻¹²⁾. The lack of a state-wide NIV database in NSW makes it impossible to project actual cost savings to NSW Health that may be seen if eligible patients are commenced on NIV and provided with appropriate equipment in a timely manner.

1.2.1 Acute COPD

Patients with COPD pose a significant burden to healthcare providers with frequent exacerbations which may require a hospital admission ⁽⁸⁾. A meta-analysis of randomised controlled trials has demonstrated that NIV is a highly cost effective treatment that both reduces total costs and improves mortality in patients admitted to hospital with an acute exacerbation of COPD and respiratory acidosis ⁽¹³⁾. The main cost savings in this context is through in preventing the use of more expensive intensive care facilities, avoiding the development of ventilator-associated pneumonia and reducing length of stay. Other studies have also demonstrated that the use of NIV in acute respiratory failure in COPD is cost

saving ⁽⁷⁾ or is neither more expensive nor time consuming in comparison to conventional medical treatment ^(14, 15).

1.2.2 Chronic COPD

NIV has been used in stable chronic COPD with evidence suggesting a reduction in hospital admissions, general practitioner care and cost savings ^(8, 9, 16). A 2003 cost and consequences analysis of domiciliary NIV in a highly selected group of 13 patients with recurrent acidotic exacerbations of COPD who tolerated and responded well to NIV was performed based on a one year before and one year after commencement of domiciliary NIV case note audit ⁽⁸⁾. The provision of a home NIV service resulted in a mean saving of £8,254 per patient per year and total days in hospital significantly fell from a mean of 78 to 25. Admissions also significantly fell from a mean of 5 to 2. While not reaching significance, ICU days fell from 25 to 4 and outpatient visits fell from 5 to 4. This study demonstrates for these 13 patients, there was a net saving of £107,298 by the acute hospital, even after taking into account the cost of the non-invasive ventilator, consumables, mask, humidifier, staff training and staff time. A longer prospective study in domiciliary ventilation showed that hospitalisation rates decreased in the COPD group for up to 2 years, although after 3 years the difference was no longer significant ⁽¹⁰⁾.

1.2.3 Restrictive diseases

A shift towards less expensive bi-level pressure ventilators and a decrease in hospitalisation after initiating domiciliary NIV have had positive impacts on the cost effectiveness of NIV in patients with chronic respiratory failure and restrictive respiratory diseases ⁽¹⁰⁻¹²⁾. One cohort of patients which included neuromuscular diseases, post tuberculosis and kyphoscoliosis showed that after initiating NIV, when compared with the year before NIV, hospitalisation rates decreased for up to 5 years after commencement ⁽¹⁰⁾. Subjects with obesity hypoventilation in this same study showed a reduction in hospitalisation rates for 3 years following domiciliary NIV commencement ⁽¹⁰⁾.

In thoracic wall diseases the annual rate of hospitalisation significantly decreased in one study from 1.52 hospitalisations per year before ventilation to 0.89 after ventilation, and in neuromuscular diseases hospitalisations significantly decreased from 1.22 per year before ventilation to 0.44 per year after ventilation ⁽¹²⁾. The numbers needed to treat calculations indicated that treatment would be needed for two thoracic wall disease patients and one neuromuscular disease patient to prevent one hospitalisation per year per disease group.

Neuromuscular disease

In paediatric patients with severe neuromuscular disease, hospitalisation rates and substantial cost savings have been found when comparing the year after commencing NIV to the year preceding NIV commencement ⁽¹¹⁾. In the year after commencing NIV, hospitalisation decreased by 73% from a mean of 41.7 days per year to 10.5 days per year and mean annual number of hospitalisations decreased to 0.7 per year from 3.8 per year. The time spent in intensive care decreased from 10.2 to 2.3 days ($p=0.06$) and mean annual direct cost of health care per patient decreased from \$55,129 to \$14,914 ⁽¹¹⁾.

Kyphoscoliosis

Leger and colleagues ⁽⁹⁾ extrapolated savings associated with commencing patients with kyphoscoliosis on domiciliary ventilation based on the significant decrease in hospitalisation in kyphoscoliosis from 34 ± 31 days during the year before NIV to 6 ± 6 during the first year of NIV. Based on their 56 patients, with an average hospital day costing \$750 and factoring \$500 a month for equipment rental and monitoring, they calculated a saving of \$840,000 (from the initial non-treated estimate of \$1,428,000) within the first year of NIV treatment.

1.3 CURRENT NIV EQUIPMENT AND SERVICE PROVISION IN NSW

The provision of NIV equipment and services in NSW is inadequate and fragmented. NSW Health has recently undergone significant reform of its disability support services through a formation of a unit called EnableNSW, under the auspice of Health Support, NSW Health. EnableNSW was established in 2009 to integrate and manage the state wide administrative function of support programs. The Home Respiratory Program was one of the Enable NSW programs designed to rebalance some of the inequities and inconsistencies in the previous provision of respiratory equipment through the ENABLENSW/HRP scheme, by developing a centralised and standardised program. While this restructuring provided an important opportunity to address significant shortcomings in the previous system, there continues to be considerable variation in waiting times and equipment funding based on postcode. Furthermore, the overall funding for home respiratory equipment has grossly under met the clinical demand. As a consequence the majority of eligible clients were not provided with their medically necessary equipment for months to years after diagnosis, resulting in unnecessary hospital readmissions, increased health resource utilisation, and in the worst case scenario, early and preventable death.

In NSW, there is often a lack of appreciation / acknowledgment by funding bodies of the special needs and circumstances of many patients who require domiciliary ventilation. NIV is a medical therapy that improves quality of life and is life sustaining. Delays in equipment provision has ranged from months to years in NSW and can cause avoidable morbidity and financial and emotional burdens on patients and carers.

Referral lines for access to NIV services in NSW are also fragmented and patients with complex ventilatory needs do not always receive the high level of assessment and treatment they require. Once admitted, assessed and commenced on treatment there are further difficulties in financing patients with high level support needs (e.g. newly discharged patients with tracheostomy/ventilator dependency; patients with slowly progressive disorders) where increasing ventilatory support is needed. Funding for back up ventilators and alternative power supplies is often not available, or may take months to access.

In NSW there is also a lack of integration between home ventilation programs and other community support service and there is difficulty of following up patients who live out of area. Most programs are hospital based with no funding for community visits / home monitoring.

There is currently no unified database for collection of government owned NIV equipment and patient clinical information, in order to monitor current requirements or plan for future services. NIV data is generally captured on an ad hoc basis and is primarily collected by clinicians at some hospitals to monitor their chronic ventilatory service.

1.3.1 Estimated number of new patients commenced on NIV in NSW

Based on suggestions by other authors that the incidence of new patients commenced on domiciliary NIV each year is 10 per 500,000 inhabitants ⁽¹⁷⁾, the following number of patients would theoretically be commenced on NIV in each of the previous Local Health Districts for the years 2006 and 2011 ⁽¹⁸⁾ (see Table 1).

Table 1: Minimum estimated number of new patients commenced on Domiciliary NIV across the previous Area Health Services for 2006 and 2011.

Area Health Service	2006		2011	
	Population ⁽¹⁸⁾	No. of estimated new patients established	Projected population ⁽¹⁸⁾	No. of estimated new patients established
NSCCAHS	1,104,624	22 / year	1,158,068	23 / year
SESAHS	1,173,593	23 / year	1,237,286	25 / year
SSWAHS	1,342,316	27 / year	1,447,390	29 / year
SWAHS	1,097,139	22 / year	1,178,394	24 / year
GSAHS [§]	473,578	9 / year	492,985	10 / year
GWAHS [§]	300,528	6 / year	301,560	6 / year
HNE [§]	844,765	17 / year	880,812	18 / year
NCAHS [§]	479,544	10 / year	511,146	10 / year

[§] Rural Area Health Services

Notes:

1. Actual rates of yearly commencement of NIV in NSW are unknown
2. Rates of commencement are likely to be an underestimation as there has been substantial rises in the proportion of patients being treated with NIV for OHS and COPD ^(10, 19).
3. Local Health Districts treat patients from other health districts, especially from rural areas.
4. As there is no baseline data, it is unknown if there are large disparities in the incidence of patients being commenced on NIV between different areas in NSW.

- Based on the above minimum estimations, there appears to be approximately “n > 23” patients per metropolitan area health service requiring initiation of NIV per year.
- Rural area health districts have a lower estimated numbers of patients requiring commencement on NIV.

1.3.2 1.3.2 Number of patients requiring continued NIV management in NSW

Prevalence rates for Domiciliary NIV usage in Australia or NSW have not been documented. While rates of 5 to 10 / 100,000 have been suggested ⁽¹⁷⁾, there have been wide variations reported between other countries and even between different geographical locations within each country. For example, in Sweden the overall prevalence in 2002 was 10.5 / 100,000, however, some areas had a prevalence of 4 / 100,000, whereas other areas had a prevalence of 22 / 100,000. The Eurovent survey performed in 2002 showed a large variability in prevalence rates for the European member countries with a range of 0.1 to 17 / 100,000 (overall average 6.6 / 100,000) ⁽²⁰⁾. The Victorian respiratory support service (VRSS) ⁽²¹⁾ reported prevalence rates at approximately 10/100,000 which were acknowledged as being broadly comparable to rates from a number of Northern European countries surveyed in the Eurovent study ⁽²⁰⁾, where there are similar patterns of ventilator use and clinical support for degenerative neuromuscular disorders.

There has been growing use of domiciliary NIV for COPD and obesity related hypoventilation, causing an increase in the prevalence of Domiciliary NIV. A recent survey (2006 to 2007) of NIV in Valencia, Spain showed that the most common disorders using NIV in their district were COPD (31%) and OHS (30%) and that domiciliary NIV was used in 29 / 100,000 individuals ⁽²²⁾.

As the exact prevalence of domiciliary NIV usage in NSW is unknown, a conservative prevalence of 10/100,000, which is congruent with VRSS estimations, has been chosen to estimate the minimum number of patients in a domiciliary ventilation programme for each of the previous Local Health Districts (See Table 2).

Table 2: Minimum estimated number of potential patients in a domiciliary ventilation programme across the various Area health Services for 2006 and 2011.

Area Health Service	2006		2011	
	Population ⁽¹⁸⁾	No. of estimated patients in a home ventilation programme	Projected population ⁽¹⁸⁾	No. of estimated patients in a home ventilation programme
NSCCAHS	1,104,624	110	1,158,068	116
SESAHS	1,173,593	117	1,237,286	124
SSWAHS	1,342,316	134	1,447,390	145
SWAHS	1,097,139	110	1,178,394	118
GSAHS [§]	473,578	47	492,985	49
GWAHS [§]	300,528	30	301,560	30
HNE [§]	844,765	84	880,812	88
NCAHS [§]	479,544	48	511,146	51

[§] Rural Local Health Districts

Notes:

1. Actual rates of prevalence of Domiciliary NIV in NSW are unknown.
2. Unknown spread of diagnostic conditions being treated with NIV throughout NSW.
3. Prevalence rates are likely to be an underestimation as there have been substantial rises in the proportion of patients being treated with NIV for OHS and COPD ^(10, 19) and regional differences in assessment, management and equipment provision are not accounted for.
4. As there is no baseline data, it is unknown if there are large disparities in the prevalence of patients being commenced on NIV between different areas.

- Based on the above minimum estimations, there appears to be feasibility of there being a critical mass of having a total “n > 100” patients in their chronic NIV service per metropolitan area health service. Actual prevalence rates are likely to be higher and are required for more accurate prediction.
- Rural health services may be able to achieve adequate numbers for a domiciliary ventilation programme by treating ‘complex’ patients which are referred from adjoining Local Health Districts which are geographically convenient.

1.4 NIV SERVICES IN NON-METROPOLITAN NSW

While the issues faced with the provision of NIV equipment and access to specialised services are state-wide, these issues are significantly amplified for rural patients and clinicians. Many rural patients experience difficulties accessing specialist services, assessment facilities and equipment. Of particular concern is the provision of specialised

services to complex patients at the commencement of their treatment. Patients with complex diseases requiring non-invasive ventilation need, at the initiation of their treatment, access to specialised assessment facilities - including access to a sleep laboratory - and access to a multi-disciplinary team of specialist clinicians.

Section 3.1.2 outlines consensus-based requirements for specialised services. Such services are currently limited to a handful of principal teaching hospitals in metropolitan NSW. Currently, therefore, the majority of patients from rural NSW requiring assessment and initiation of chronic ventilatory support are referred to metropolitan centres. The model of care presented in this document has, as a principal consideration, the goal of improving access to home NIV services for rural patients.

1.5 NIV SERVICES IN OTHER AUSTRALIAN STATES AND EUROPE

There is considerable variation in how NIV equipment and services are provided both in Australia and overseas. The following section provides basic descriptions of how NIV is currently provided and recommendations for how the provision of NIV could be and/or has been improved in Victoria, Queensland and Europe. The aim of this section is to put the current NSW system of NIV provision in perspective to other models of care.

1.5.1 Victorian Respiratory Support Service

The Victorian Respiratory Support Service (VRSS) has been operating since 1996 and provides a range of clinical, nursing and allied health services along the continuum of acute and sub-acute care for people with chronic ventilatory failure. The service originated from a consolidation of several Victorian respiratory support services in the mid 1990's, including the polio-related services at Fairfield Hospital. The VRSS is essentially a centralised service, operating from an inner metropolitan tertiary health service (sponsored by Austin Health) with a small number of outreach staff who provide service (within available resources) to VRSS patients who live in Victoria ⁽²¹⁾.

Over the years there has been an increase in the number of patients in the service with 291 patients in 1999, 380 patients in 2001 and 434 patients in 2004 ⁽²¹⁾. It is difficult to make conclusions about diagnostic group trends with VRSS data for this period as changes have been made in the way the data was collected.

The VRSS commences approximately 80 new patients a year on ventilation, with an annual net gain of 50 additional patients ⁽²¹⁾. Data from 2003/2004 "new patients" indicates that ⁽²¹⁾:

- 72% are metropolitan residents and 28% were from rural or regional areas.
- 29% required a lower level of service (e.g. obesity hypoventilation and some with chronic lung disease) and 71% required a higher level of service (e.g. neuromuscular disease, musculoskeletal disease, spinal cord injury etc.).
- 25% are commenced on simplest forms of ventilation (spontaneous bi-level ventilator) and 75% use timed ventilators, with a quarter of these on volume cycled ventilators.

In 2006 the total number of patients receiving ventilatory support was reported as 450. The form and direction of the VRSS has evolved in response to the changing composition of the patients they treat ⁽²¹⁾. In recent years, patients with degenerative neuromuscular disorders have emerged as the predominant group of new specialised service users ⁽²¹⁾. The VRSS estimates its overall prevalence rate of ventilator users to be 10/100,000 ⁽²¹⁾.

A review of the VRSS was performed in April 2006 to develop recommendations to the Executive Director, Metropolitan Health and Aged Care Division, Department of Human Services, Victoria on the future role and priorities of the VRSS. The main conclusions from the review included (page 37, ⁽²¹⁾):

- While centralisation facilitates control of service standards and resource allocation, it can also create blockages in transferring patients to the VRSS from other acute hospitals.
- A number of patients exist with less complex needs which may not need access to highly specialised services to assess and support their ventilator equipment needs.
- Ventilator supply has been managed on a somewhat ad hoc basis with no long-term planning for overall asset maintenance and replacement.
- Review of VRSS performance was complicated by a lack of consistent, comprehensive and longitudinal data on relevant performance indicators.

Some of the main recommendations gleaned from this review included (page 38, ⁽²¹⁾):

- Establishing comprehensive data collection and structures for systematic evaluation of service provision.
- Developing guidelines to inform assessment of eligibility for state-funded ventilators.
- Developing a business management strategy for a ventilator supply scheme.
- Investigating the possibility of a single purchasing agency for all ventilators.
- Adopting a model which formalises the existing VRSS and extends the service to incorporate of primary and secondary agencies (See Appendix A).

The proposed extended model involves the 'Primary Agency' continuing to focus on service provision for highly complex and high risk patients. Additionally, it is suggested that one or two 'Level 2 Agencies' are located within other major health providers which meet certain critical mass / competency standards. Elements of these important recommendations and this proposed model ⁽²¹⁾ have been used to assist with the formulation of a model of care for NSW, taking into account the differences in geographical spread of inhabitants and services.

1.5.2 Queensland Health

In Queensland a centralised, state wide system for provision of home NIV for patients with sleep disordered breathing was developed and has been successfully operating since 1994. The QLD CPAP Program originally operated out of the Medical Aids Subsidy Scheme (MASS), the equivalent of the NSW ENABLENSW. Due to the rapid increase in the number of patients accessing the scheme and recognition of the specialised clinical input required for

equipment procurement tenders and patient eligibility assessment, the Program was separated from the MASS and provided with its own Program Administrator.

A steering committee was convened consisting of the Clinical Directors of the Sleep/Respiratory Units of the tertiary hospitals in Brisbane, Townsville and Cairns, together with scientific and nursing representatives from each of these hospitals. The steering committee is responsible for the ongoing development of clinical guidelines for patient eligibility to the program, selection of NIV equipment for purchase under bulk tender arrangements, budget submissions and data projections based on data provided by each 'Prescriber Hospital'.

Eligibility to the program is based on both financial and standardised clinical data/severity criteria and continued eligibility requires acceptable compliance with therapy (for NIV patients this is assessed at clinical review at least annually). All applications are sent to a central location for approval and approvals are made within one to several days. Patients requiring NIV are issued with equipment immediately at no cost to the patient with compliance checks being performed in 1 to 2 months.

Equipment is issued from one of the six prescriber hospitals and all prescriber hospitals hold a pool of NIV (and CPAP) equipment. Equipment repairs/servicing can be arranged through any of the Prescriber Hospitals and the Program Administrator and machine supplier are notified via a standard repair form and the patient is issued with a loan machine from the Prescriber Hospital equipment pool. In the event of patient death or discontinued use, equipment is returned to the Prescriber hospital and the Program Administrator notified to allow re-issue of equipment.

Prescriber hospitals are required to keep a database of all patients issued with Queensland Health machines. Patient compliance records are also kept. This data is submitted at regular committee meetings to track program spending and to provide future budget estimates. The Program Administrator also holds a combined database of all patients/equipment issued under the program (collected at time of application).

1.5.3 Europe

The social healthcare systems in many European countries provide for the use of NIV in patients with chronic respiratory failure, but few countries have clear guidelines as to when NIV should be initiated and in which patient groups ⁽²³⁾. Arrangements for funding and reimbursement are poorly developed and often there is no formal infrastructure ⁽²³⁾. One standout exception to this is the home ventilation program in France, which has been strongly advocated by researchers ^(24, 25) as providing a template for an integrated system for chronic disease management. The effectiveness of the French model for chronic ventilator support has been attributed to its basis in regional and local services, supported by a hub of specialised assessment and treatment services. The network of services is effectively maintained through a nationally unified capacity for data collection to drive and support service evaluation and research ^(24, 25).

In order to assess the patterns of use of home mechanical ventilation for patients with chronic respiratory failure across Europe, a detailed questionnaire of centre details, domiciliary ventilator user characteristics and equipment choices were sent to 483 carefully identified centres across 16 European countries (Eurovent survey) ⁽²⁰⁾. Responses from 329 centres which represented 21,526 ventilator users were obtained and revealed wide variation in rates of ventilation and differing clinical approaches to the use of ventilation across the various disorders. The estimated prevalence rate of domiciliary mechanical ventilation was 6.6/100,000 people and the prevalence rates for the individual countries are listed in Table 3. The variation in prevalence was partially related to the median year of starting NIV services and other studies have showed that prevalence rates within particular countries have increased with time, especially with regards to ventilator users who are obese or have chronic lung disease ^(10, 19).

Table 3: Estimated prevalence of ventilator users in 16 European Countries (2001 to 2002)

	Estimated Prevalence per 100,000 (2001 to 2002)
Austria	3.8
Belgium	5.0
Denmark	9.6
Finland	8.7
France	17.0
Germany	6.5
Greece	0.6
Ireland	3.4
Italy	3.9
Netherlands	5.6
Norway	7.8
Poland	0.1
Portugal	9.3
Spain	6.3
Sweden	10.0
United Kingdom	4.1
ALL COUNTRIES	6.6

The findings from the Eurovent survey have been proposed to facilitate national and European planning for mechanical ventilation in the future ⁽²⁰⁾. By adopting Europe-wide registers of centres and users, standardising guidelines and performing further epidemiological research, appropriate development of domiciliary ventilation services and equality of NIV provision for members of the European Union could be achieved ⁽²⁰⁾.

Recommendation 1

People in NSW should receive equivalent standards of domiciliary NIV service access and quality to people in other states of Australia and other European countries with similar standards of living and health resources / expenditures.

2. BACKGROUND

2.1 INFORMATION COLLECTION

To inform the development of the model of care detailed in this document considerable effort was devoted to the task of collecting and recording quantitative and qualitative information pertaining to the provision of home NIV services in NSW, other states within Australia and similar services in other countries.

2.1.1 Data

Quantitative data on the nature and extent of home NIV services in NSW is limited. Currently there is no data available for the number of ventilator machines provided by ENABLENSW / Home Respiratory Program (HRP), nor of the diagnostic categories for which these machines are provided. Analysis of uncollated and non-standardised paper records at individual / HRP offices was beyond the scope and resources of this project.

Some data was obtained from Royal Prince Alfred Hospital (RPAH), the SHORES program (Westmead Hospital), St. George Hospital and John Hunter Hospital. However, the range of collected information was variable and much of the data was estimated and incomplete. Determining potential state-wide need for ventilator equipment via extrapolation from these data sets is therefore difficult. It is also difficult to estimate prevalence of domiciliary NIV, as the various sites receive patients from multiple and overlapping Local Health Districts making it impossible to ascertain an accurate population denominator.

2.1.2 Consensus Expert Opinion via Consultation

The ACI (previously GMCT) working group addressing this issue engaged in a face-to-face consultation process to define the main issues faced by NSW with the provision of NIV and discuss elements of a proposed model. Invitations by telephone and email were made to all of the centres responsible for the majority of provision of domiciliary NIV in NSW. Invitations were also extended to other hospitals in NSW in an attempt to sample a cross section of the general domiciliary NIV experience in NSW. Rural input was targeted by presenting the model to the GMCT Rural Respiratory Working Group and seeking their feedback and input into the proposed model. In addition, metropolitan hospitals were able to provide feedback on unique issues faced by rural patients, many of whom are currently commenced on domiciliary NIV at metropolitan facilities. Clinicians at these hospitals see patients from all over the state and were able to report the disparities between equipment and service provision between metropolitan and rural patients.

Initial attempts to contact the relevant heads of department and clinicians occurred 4 weeks prior to the 6 week block assigned for the site visits (June to July 2009). In total 11 sites were interviewed, 1 site was not able to commit due to time constraints, 2 sites were unable to participate due to staff leave and no response was obtained from 3 other sites.

ACI (previously GMCT) has developed a productive working relationship with ENABLE NSW who are responsible for the administration of the NSW Health Disability support programs including the equipment for the Home Respiratory Program.

2.2 CURRENT PROVISION OF NIV IN NSW - MAIN ISSUES

The main issues raised from the information gathering and consultation process are listed in Table 4. Issues to be addressed by the new EnableNSW structure and guidelines are highlighted.

TABLE 4: Current system of NIV provision in NSW and the issues faced

	OBSERVATION	ISSUES
1	Decentralised model	- Surplus idle equipment is not utilised – wastes resources. To be addressed by new EnableNSW structure and guidelines.
2a	Equipment provision Apply to individual programmes - HRP / ENABLENSW (based on postcode).	- No issue if each programme has access to sufficient funding to ensure equality of service provision. However, due to the decentralised nature of the current system there is no communication between the various programmes regarding equipment provision, or surpluses or deficits in funding. To be addressed by new EnableNSW structure and guidelines.
2b	Equipment provision Variable / non-standardised criteria for equipment provisions between the different areas / programmes	- Non-standardised criteria promotes inequality with regards to equipment provision. Equipment provision should be based on standardised NSW criteria. To be addressed by new EnableNSW structure and guidelines.
2c	Equipment provision Criteria for NIV provision in some HRP/ENABLENSW lodgement centres require revision	- Changes in evidence based assessment, treatment and monitoring of patients requiring NIV continues to evolve and progress. Up to date standardised criteria for the various diagnostic groups are required. This is to improve patient clinical management and flow, and decrease the performance of tests requested on administrative and not clinical grounds. An example of this is the provision of NIV for patients with MND, where diagnostic sleep studies and proof of failure on CPAP sleep studies (although requested by certain lodgement centres) are not required and would be viewed as a waste of valuable resources and time. To be addressed by new EnableNSW structure and guidelines.
2d	Equipment provision Patients can be placed on waiting lists with unspecified timeframes	- Patients need to fund their own equipment in the interim. Monthly equipment hire is very expensive for the majority of patients with respiratory failure with limited incomes or who rely on government assistance. Unspecified timeframes cause inequality in service provision and create significant financial planning stresses in these patients. - Some patients need to actively decide to cease treatment if they can no longer afford the machine rental.

	OBSERVATION	ISSUES
2e	<p>Equipment provision</p> <p>Waiting lists for equipment provision are highly variable between areas</p>	<p>- All other aspects being equal, eligible patients can be waiting for ventilator equipment provision based on their postcode and not clinical need. To be addressed by new EnableNSW structure and guidelines.</p>
2f	<p>Equipment provision</p> <p>No / limited prioritisation of equipment provision for high needs patients between lodgement centres</p>	<p>- No/limited movement of resources from lodgement centres which have low patient-to-ventilator resource ratios or balanced ratios to lodgement centres with high patient-to-ventilator resource ratios. This can leave patients with a very high need for ventilatory support without a ventilator in one area; whilst patients with a much lower need for ventilatory support may receive a ventilator in another area.</p>
2g	<p>Equipment provision</p> <p>Issues arise when patients move from one area to another re: continuation of equipment provision</p>	<p>- Re-application for equipment is required when a patient moves from one programme area to another. This can be very stressful for the patient especially if they are unsure if there will be an extended gap in equipment provision or if additional or alternate criteria need to be filled (for example further testing such as additional sleep studies).</p> <p>- Lack of a central system to track the location of ventilator equipment results in ventilators becoming lost in the system and never retrieved when patients move and become “uncontactable” to a particular programme.</p>
2h	<p>Equipment provision</p> <p>Means testing</p>	<p>- Questionable relevance of means testing for life-sustaining medical equipment and variation in eligibility.</p>
2i	<p>Equipment provision</p> <p>Requires disability or aged pension</p>	<p>- Fosters an environment which can discourage patients from contributing to society through paid employment.</p> <p>- May not be suitable for young adults transitioning from paediatric to adult services or people with aims of completing tertiary education and joining the workforce.</p>
2j	<p>Equipment provision</p> <p>Some areas provide masks and tubing in addition to the ventilator</p>	<p>- Needs to be standardised to ensure equity of service provision. To be addressed by new EnableNSW structure and guidelines.</p>
2k	<p>Equipment provision</p> <p>Some areas require an annual co-payment</p>	<p>- Needs to be standardised to ensure equity of service provision. To be addressed by new EnableNSW structure and guidelines.</p>
3	<p>No standardised referral system</p>	<p>- Timing of referrals for assessment for suitability for NIV can be variable. This can lead to significant delays for commencing NIV treatment in some patients.</p>
4	<p>System is not integrated</p>	<p>- Patients can be lost in the system, without regular clinical follow up or review of equipment needs.</p>

	OBSERVATION	ISSUES
5	No shared database or central information system	<ul style="list-style-type: none"> - No public state-wide NIV baseline information available. - Unable to determine accurately current care needs. - Unable to identify trends or future needs. - Unable to plan for annual costs associated with ventilator provision (e.g. ventilator purchases, ventilator servicing, ventilator repairs, consumables, other equipment, asset replacement strategies etc.). - Unable to ascertain areas of greater need. - Unable to plan for optimal location for outreach / telemedicine services / education.
6	Review or follow-up of the patient is not standardised	<ul style="list-style-type: none"> - To ensure continued, equitable and accurate provision of equipment, patients should be monitored or assessed at specified intervals. - Patient follow-up should be standardised.
7	Review of the patient's equipment requirements is not standardised	<ul style="list-style-type: none"> - Issues arise when a patient may be downgraded from one ventilator mode to another, yet the equipment is not appropriately changed and the equipment provider is not notified. <p>E.g. The patient with obesity hypoventilation syndrome being treated with bi-level pressure ventilation who is suitable for a trial of CPAP, but is not trialled on this much cheaper and simplistic form of positive pressure. This results in a misallocation of resources.</p>
8	Patients funding equipment hire to demonstrate adequate compliance in the initial trial period	<ul style="list-style-type: none"> - Hire of ventilators can be very expensive (including bond and monthly fees) especially when adding the cost of the mask, tubing and other equipment needs. This can lead to: <ul style="list-style-type: none"> - Delay in discharge (increasing the cost of hospitalisation). - Inability to continue with therapy leading to readmission, potentially to costly acute care environments.
9	Not all patients with complex needs (e.g. patients with neuromuscular disorders) receive access to specialised care including specialised personnel, testing and multidisciplinary management	<ul style="list-style-type: none"> - Patients with complex needs may not have access to appropriate reviews, treatment options and referral to services.
10	Limited access to ventilation services in country or regional areas	<ul style="list-style-type: none"> - Patients in regional areas may need to travel great distances for review. Patients unable to easily travel may have delays in their assessment and management.
11	Limited use / access to telemedicine in patients with chronic respiratory failure.	<ul style="list-style-type: none"> - This technology could be used to greatly enhance the monitoring and care of patients who are logistically immobile or living in remote country areas.
12	Limited or ad hoc training of community staff with NIV	<ul style="list-style-type: none"> - Community or other health care facilities may be apprehensive in accepting and caring for patients with NIV (for chronic respiratory failure).

	OBSERVATION	ISSUES
13	<p>Difficulty in accessing back-up ventilators for patients who are dependent on ventilation.</p> <p>(e.g.: >18 hours a day; or cannot support spontaneous ventilation > 4 consecutive hours; or geographically isolated patients which use ventilation >16 hours a day and where a back-up machine cannot be supplied within 4 hours).</p>	<p>- Patients who are ventilator dependent need access to equipment which is designed for “life support” and access to a back-up ventilator. This is to minimise the risk of inadvertent death of the ventilator dependent patient due to equipment failure and to improve patient safety.</p>
14	<p>Nil ENABLENSW/HRP access to cough in-exsufflators for patients with expiratory muscle weakness with PCF<270 L/min</p>	<p>- Patients with expiratory muscle weakness unable to generate peak cough flows > 270 L/min are at risk of not being able to clear secretions during times of respiratory infection. This can lead to sputum retention, persistent micro-atelectasis and pneumonia, which if left untreated, may result in worsening respiratory failure and ultimately death. Mechanical cough in-exsufflators are able to significantly improve peak cough flows in patients with expiratory muscle weakness without severe bulbar involvement and when used in the domiciliary setting can reduce hospital re-admission. <i>Cough In-exsufflators not available on EnableNSW equipment prescription list.</i></p>
15	<p>Lack of Quality control checks of equipment set-up as initially prescribed</p>	<p>- Lack of education and training of third party setting up the ventilator</p> <p>- Most up to date ventilator script not always readily available</p> <p>- Difficulty in easily and rapidly checking actual ventilator settings by specialised centres when patients are geographically isolated or isolated from expert monitoring</p> <p>These factors can result in patients not receiving NIV as initially prescribed, with incomplete or inadequate management of their condition.</p>
16	<p>Unclear service point for emergency replacement of malfunctioning equipment.</p>	<p>- At times ventilator users are unsure who to contact in the event of equipment malfunction.</p> <p>- Some lodgement centres can only be contacted on a part-time basis.</p> <p>- At times ventilator users are unsure who to contact outside of the lodgement centre operating hours.</p> <p>- At times ventilator users present to their local Emergency department for ventilation if there is going to be an extended delay in the replacement of their machine and where it is clinically warranted.</p>

2.3 GOVERNMENT RESPONSES TO THE SPECIAL COMMISSION OF INQUIRY INTO ACUTE CARE SERVICES IN NSW PUBLIC HOSPITALS

Government-supported recommendations pertinent to improving the access to and quality of domiciliary NIV service and equipment provision are presented below under the following tables:

- Concentration of highly specialised services and critical mass (Table 5)
- Referral pattern and funding to follow the patient (Table 6)
- Education (including ensuring protected time each week and rural access) (Table 7)
- National E-health (Centralised Information System) (Table 8)
- Transport – non urgent state-wide efficient transport service (Table 9)
- Equipment - Central register and Asset renewal (Table 10)

Table 5: Concentration of highly specialised services and critical mass

No	SUB	RECOMMENDATION	STAGE	GOVERNMENT RESPONSE
117	a	In my view, there needs to be a complete state-wide review undertaken by NSW Health which involves: (a) the identification of a set of criteria, which relate to at least, patient safety, necessary workforce skills, the volume and quality of services regarded as an appropriate critical mass for the services provided across NSW in public hospitals;	One	Supported. Planning for a statewide review will begin immediately and include community and workforce consultation. Supported by existing health service plans the review will analyse population size and distribution, ageing, level of disease, changing models of care and lifestyle to agree on services that are needed and can be provided safely. Highly Specialised Services will be considered on a statewide level. The issue of patient safety will be paramount and considered in light of both the availability of an appropriately qualified workforce and the provision of appropriate facilities.
117	b	(b) a determination of whether each hospital, having regard to its location, the available workforce determined on a long term basis, the size of the population which it services, the alternative locations within an appropriate distance (measured by time or distance) and the age and state of repair of the facilities and equipment, is (or can become) a location for the delivery of safe patient care;	One	Supported. Refer response to recommendation 117 (a)
117	c	(c) a clear delineation of the role of each hospital – what it can and can't do;	One	Supported. The role and function of hospitals in NSW are already well articulated according to the NSW Health role delineation documentation. This will be reviewed as part of the statewide review (Refer also response to R117a).
117	d	(d) clear communication of the role of a local hospital to its community, and community understanding of the limitations of the local hospital;	Two	Supported. Refer response to recommendation 117 (a)
117	e	(e) re-allocation of specialist medical services to hospitals in NSW best placed to deliver those services; and	Two	Supported. Refer response to recommendation 117 (a)

Table 6: Referral pattern and funding should follow the patient

No	SU B	RECOMMENDATION	STAG E	GOVERNMENT RESPONSE
132	0	Referral patterns should be made by clinicians on the basis of finding the appropriate clinical setting for the patient's treatment. If there is more than one setting, then the treatment ought to be undertaken at the nearest appropriate facility. If that is within area health service boundaries, then that should be used where possible. If not possible, then one out of the area health service boundary should be accessed. Funding should follow the patient.	Two	Supported. Further consultation and review will occur over the next twelve months to assess the impact of this recommendation on patient care; access to services; cost and availability of medical staff with consideration as part of the statewide review of hospital roles and networks (Refer also response to R117).

Table 7: Education (including ensuring protected time each week and rural access)

No	SU B	RECOMMENDATION	STAG E	GOVERNMENT RESPONSE
12	c	(c) Developing education facilities and programs which ensure that clinicians working in rural and remote areas of NSW are provided with adequate education and training.	Two	Supported. Already rural clinical schools provide a strong focus for education and training of rural doctors, nurses and allied staff. NSW Healthwill review education and training support for rural clinicians as part of the review of existing education and training investment which is planned as part of stage two (Refer also response to R36.1a).
31	0	NSW Healthshould review, develop if required and implement such policies as will clearly specify the roles and responsibilities of the Institute of Clinical Education and Training and the roles and responsibilities of Local Health Districts and relevant statutory health corporations in the delivery of training and education relevant to health services.	Two	Supported. NSW Healthwill review current policies in relation to the delivery of training and education and ensure that roles and responsibilities are clear. Consultation indicates that further consideration be given to the recommendation on establishment of the Institute of Clinical Education and Training. Further consultation and review of existing education and training investment is planned as part of stage two (Refer also response to R36.1a).
32	0	NSW Healthshould ensure that all hospital directors and supervisors of training for prevocational doctors are provided with protected time each week to carry out their duties in relation to training and formal teaching within the hospital. This time should be protected as part of the terms of employment and through the employment performance management process.	One	Supported. Dedicated Directors of Prevocational Education and Training are currently funded in the 53 hospitals where new doctors in their first and second years are allowed to be placed. NSW Healthwill ensure that the time of these Directors to support training of first and second year new doctors is identified as part of their performance agreement.

Table 8: National E-Health Transition Authority (Centralised Information System)

No	SU B	RECOMMENDATION	STAG E	GOVERNMENT RESPONSE
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50	0	<p>NSW Health should cooperate with and support the National E-Health Transition Authority including in particular developing appropriate policies to and platforms which govern the manner of and the circumstances sufficient to permit general practitioners, specialists, allied health professionals and community health clinicians, who are located outside the hospital, to gain access to relevant parts of, and information from, the electronic medical record generated within NSW public hospitals.</p>	One	<p>Supported. The NSW Government has supported the introduction of centralised electronic health records and is pursuing the development of these in conjunction with the e-health strategy being considered by the Council of Australian Governments.</p>
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Table 9: Transport – non urgent state-wide efficient transport service

No	SU B	RECOMMENDATION	STAG E	GOVERNMENT RESPONSE
117	f	(f) the consideration of the availability of an efficient transport and retrieval system state-wide to transport patients to the hospital best placed to provide the medical service required, and return the patient to their original locations.	One	Supported. Consultation indicates that further consideration be given to this recommendation which will occur as part of stage two. In the interim an independent study of an efficient Non Emergency Patient Transport System (NEPTS) is progressing. Various organisations provide the current service network across NSW, often duplicating services. Understanding this complexity and opportunities for change is the first objective of this study (Refer also response to R123a-c).
123	a,b & c	NSW Health to ensure that there is provided, separately from the emergency transport service of NSW Ambulance, a non urgent transport service which is responsible for: (a) The return transport of rural patients from metropolitan or rural referral hospitals to either their hospital of origin or their home depending upon their clinical condition; (b) The transport of metropolitan patients between hospitals or from hospitals to aged care facilities; and (c) Any other transport required to enable timely investigation and treatment of patients where their clinical condition necessitates access to specialised transport.	One	Supported. NSW Health has already begun to examine the availability of dialysis services and transport solutions for disadvantaged patients; started a review of Non-Emergency Patient Transport provided by the Ambulance Service of NSW; and begun work with the national Patient Assisted Travel Scheme (PATS) Taskforce to draft agreed principles for providing patient transport. The Isolated Patients Travel and Accommodation Assistance Scheme (IPTAAS) currently provides for return of well patients following transfer home and a review of other non emergency transport is underway. Further consultation and review on this will occur as part of stage two (Refer also response to R14b).

Table 10: Equipment - Central register and Asset renewal

No	SU B	RECOMMENDATION	STAG E	GOVERNMENT RESPONSE
129	a-e	Within 24 months, NSW Health should establish a central State-wide equipment asset register recording details of fixed assets with an acquisition value greater than \$10,000 and attractive assets greater than \$1,000. Details recorded in the register should, as a minimum, include: (a) the purchase price; (b) the date of acquisition; (c) the estimated life expectancy (usability) or contract expiry date; (d) the half-life usability assessment date; and (e) the location of the asset.	Three	Supported. NSW Health will establish a more comprehensive registration and reporting system for assets and include leased equipment. NSW Health has already introduced the Health Asset Management and Maintenance System (HealthAMMS) in three Local Health Districts, which is an enabling technology tool specifically to assist health services in the effective management and maintenance of their facilities and biomedical equipment. A strategy has also been completed for the rollout the HealthAMMS application to other Local Health Districts.
130	0	NSW Health should ensure that each hospital performs equipment functionality assessments every 6 months to assess and predict the need for equipment replacement.	Three	Supported. NSW Health will ensure reporting on equipment consistent with current requirements under the Australian Standards; Building Code of Australia; Therapeutic Goods Administration Accreditation and Manufacturer's warranties and maintenance contracts.

Recommendation 2

The model of care for NIV in NSW should be congruent and compliant with *Caring Together – The Health Action Plan for NSW*, in which changes are geared towards using the resources that are already available to develop a culture where the patient is the focus of the system with commitment to a universal model that provides safe, equitable and high quality provision of NIV services and equipment for everyone in NSW.

3. MODEL OF CARE

This proposal describes a new model of care which aims to improve the provision of public domiciliary non-invasive ventilation (NIV) to adult patients in NSW.

The model involves one Centralised Agency which is responsible for the provision of:

1. All government funded domiciliary ventilation equipment
2. A state-wide database and information management system

Operating in conjunction with the Central Agency is a hub and spoke network of clinical services featuring:

- a) Specialised Hubs which have the adequate resources, critical mass and expertise to commence complex patients on NIV,
- b) Level 2 Agencies which have the resources, expertise and sufficient critical mass to commence less complex patients on NIV and share in the continued management of complex patients, and
- c) Level 3 Assessment and monitoring nodes designed to enhance and ensure regular monitoring of patients who have difficulty in accessing medical services due to their medical condition or geographical isolation.

3.1 CENTRAL AGENCY (NSW HEALTH) / ENABLENSW

Graphical representation of the Central Agency in schematic diagram:
[See diagram page 42]



The Central Agency belongs to NSW Health and logically would be run by EnableNSW. The two main responsibilities include **equipment provision** and **managing a state-wide information management system**.

3.1.1 Equipment Provision

In order to maximise economies of scale all NSW government funded equipment should be pre-approved and purchased by one Central Agency. Mass purchasing results in significantly discounted machine prices, and improved warranty and service arrangements.

Recommendation 3

The Central Agency should purchase and own all equipment required for public domiciliary ventilation services in NSW. This may include, but is not limited to: bi-level ventilators (spontaneous and spontaneous-timed); volume ventilators; hybrid ventilators; and mechanical cough in-exsufflators.

A lack of ready access to non-invasive ventilation equipment has obvious ramifications in terms of patient flow in hospitals. Delay in equipment provision can significantly delay a patient's discharge from hospital and create bed blockage issues and a backlog of patients requiring access to specialised NIV assessment and treatment services. Ready access to equipment would improve patient flow and improve the overall efficiency of the system by minimising bed blockage.

Recommendation 4

The Central Agency must provide the Specialised Hubs and Level 2 Agencies with timely delivery of equipment.

The requested piece of equipment should be delivered directly to the patient within 24 hours from the time telephone approval is obtained from the Central Agency.

Alternatively, a minimum level of on-site equipment, suitable to specific requirements, is to be made available to each Specialised Hub and Level 2 Agency if rapid provision (within 24 hours) is not possible (See *Section 7*). The pool of on-site equipment would be automatically replenished with replacement stock as it is depleted

The clinician consultation process revealed that at times ventilator users are unsure who to contact in the event of equipment malfunction and that there were unclear service points for emergency replacement of malfunctioning equipment. Delays in equipment replacement can result in some patients presenting to their local hospital for mechanical ventilation until equipment issues are rectified, an expensive and avoidable drain on acute care environments and resources.

Recommendation 5

The Central Agency should be responsible for coordinating equipment repair, maintenance and replacement in a timely manner.

Ventilator users should be given direct line access (phone number) for the Central Agency, or third party nominated by the Central Agency, to enable direct communication regarding equipment repair, maintenance and replacement.

Depending on the patient's ventilatory requirements, malfunctioning equipment should be either repaired or replaced within 24 to 48 hours of notification. (See *section 12 for additional equipment recommendations for ventilator dependent patients*).

The agency conducting the assessment should also notify the patient's principal clinical team that an equipment issue has been raised by the patient.

It is not uncommon for patients to mistake a deterioration in their condition for a malfunction of their machine ⁽²⁶⁾. In this event if, during assessment for repair or replacement, a piece of equipment is found to be functioning properly, the agency conducting the assessment has a duty of care to notify the patient and principal treating clinical team of the outcome of the assessment so that a clinical assessment of the patient may be conducted.

Recommendation 6

If, during assessment for repair or replacement, a piece of equipment is found to be functioning properly, the agency conducting the assessment must notify the patient and principal treating clinical team of the outcome of the assessment as soon as this information becomes available and within 48 hours of a notification of equipment malfunction.

Currently it is not always clear who is responsible for the retrieval of equipment when it is no longer required and family members or carers may incorrectly assume that the equipment is owned by the patient and not actively try to return it. The current lack of coordinated databases at some ENABLENSW / HRP programs makes it difficult to ascertain which equipment is no longer in use. Timely equipment retrieval is important to maintain the circulation pool and avoid machine replacement costs as the general costs of the majority of ventilators range from \$3000 to \$7000.

Recommendation 7

The Central Agency should be responsible for retrieval of equipment.

3.1.1 Information Management System

Current practice does not include collection of clinical or equipment data. This lack of information makes it impossible to determine the real need or cost of NIV equipment and public NIV services in NSW. By collecting clinical and equipment data, expenditure can be matched to clinical need, thereby limiting equipment surpluses and resource waste, and maximising overall system efficiency.

Recommendation 8

Information on public home NIV services in NSW should be managed by developing a single, comprehensive, computerised information management system.

The system should contain two data streams:

1. Equipment-related Information
Including ventilator settings and prescription histories
2. Clinical / Patient-related Information (see Appendix B for suggested data sets)

Such a system should incorporate:

1. A centralised database / data repository enabling data storage, database queries, analysis and reporting.
2. A state-wide information collection tool, in the form of user-friendly computer software accessible (via secure password login or similar) at the point of service, to all clinicians involved in the management of the patient irrespective of geographic location.

A system of this nature, integrating clinical and equipment data, assists with patient management and provision of equipment and confers considerable potential to improve service quality and efficiency and inform future service planning and on-going service delivery reform.

Baseline clinical/patient data and equipment settings will be entered into the system by clinicians so that it can be accessed by other clinicians and the Central Agency.

Equipment details should be entered by the Central Agency to assist with equipment delivery, tracking, maintenance, repair and return etc.

3.1.2 Benefits of a comprehensive, integrated information management system:

- a. Integration of equipment and clinical information including records of patient assessments, reviews and equipment settings, will assist with service integration, coordinated patient care, and substantial service efficiencies including a potential reductions in patient admissions to hospital.
- b. policing of appropriate machine use / patient compliance,
- c. tracking of equipment location,
- d. analysis of state-wide NIV service data to inform service planning and reform; for example, assessments may be conducted to determine annual patient throughput (type and number), costs associated with ventilator provision (e.g. ventilator purchases, ventilator servicing, ventilator repairs, consumables, other equipment, asset replacement strategies etc), and may assist to predict future service demand. Such information could be gleaned for each diagnostic patient group and for each Area Health Service.

Recommendation 9

The Central Agency should provide and maintain a stable platform for a secure, comprehensive information management system which is accessible to all centres and clinicians involved in home NIV services across NSW.

Recommendation 10

Data input into the Information Management System is mandatory and ensures initial and continued provision of equipment. Data entry is one of the core tasks of the Support Officers (see Support Officer position description, Appendix C)

Where relevant, data entries into the Information Management System should be electronically signed to include the clinician's name, designation, location and service contact details.

Recommendation 11

Periodically, data reports should be generated for analysis and publication / website posting. Using such data comparative research and journal publication should be encouraged.

3.2 SPECIALISED HUBS

Graphical representation of a Specialised Hub in schematic diagram:

[See diagram page 42]



The information gathering and consultation process revealed that not all patients with complex needs (e.g. patients with neuromuscular disorders) are able to access the appropriate level of specialised care required to adequately manage their condition. Due to insufficient access to appropriate testing and assessment facilities, and multi-disciplinary clinical personnel, it is likely that these patients will not receive appropriate review, treatment or referral.

Additionally, there is consensus amongst key clinicians in NSW that centres of excellence require an annual critical mass of new patients being assessed for and commenced on ventilation in addition to a minimum number of existing patients requiring on-going chronic ventilation services. While not formally studied, critical mass recommendations for the annual number of patients to be established on NIV range from a minimum of 12 ⁽²³⁾ to 20 new patients per hospital per year ⁽²⁷⁾. It has also been suggested that centres should achieve a critical mass of at least 100 ongoing NIV patients per year in order to sustain a safe and effective chronic NIV service ⁽¹⁷⁾.

Information obtained from the site visits revealed a wide variation in the suggested critical mass deemed to be suitable to be viewed as a Specialised Hub ranging from 12 to 60 (mean =29.75, median = 22) new patients per year.

3.2.1 Numbers of Specialised Hubs in NSW

The notion of concentrating the number of Specialised Hubs in NSW is generally supported by key clinicians in NSW. Proposed benefits of concentrating the number of Specialised Hubs include:

- Concentration of skills and expertise generally affords higher quality services
- Higher critical patient mass promotes clinical competency through more frequent clinical education.
- Systems serving sufficient patient throughput are often able to achieve economies of scale.
- Greater access to onsite services such as diagnostic testing and multidisciplinary teams
- Access to larger dedicated multidisciplinary clinics for patients with chronic respiratory failure

- Increased capacity for development of multidisciplinary outreach teams

Recommendation 12

It is recommended that patients with complex ventilation requirements should be initially assessed and commenced at a small number of specialised centres or 'hubs'.

3.2.2 Functions of Specialised Hubs in NSW

Recommendation 13

Specialised Hubs (hospitals) should be responsible for the assessment, treatment and establishment of 'complex' or 'high to medium level support' patients on domiciliary NIV from a wide spectrum of patient conditions (e.g. significant neuromuscular disease and the need for ventilatory support; or patients without coexistent neuromuscular or respiratory disease requiring long term invasive ventilation).

Subsequent to assessment and establishment on ventilation, these patients may be monitored and reviewed closer to their places of residence by Level 2 or 3 centres, if more convenient / appropriate.

Recommendation 14

Specialised Hubs should have an annual throughput of an agreed minimum number / critical mass of new patients, and should maintain an adequate critical mass of on-going patients.

Recommendation 15

Specialised Hubs should have agreed levels of clinical expertise and be equipped with workforce resources to maintain a broad, multi-disciplinary service.

3.2.3 Criteria for a Specialised Hub

In addition to a critical patient mass, other requirements for a Specialised Hub that were recommended from the literature ⁽¹⁷⁾ and consultation process are listed below:

Recommendation 16

To qualify as a Specialised Hub an existing centre should have:

- Demonstrable experience in managing a spectrum of patients with respiratory failure requiring domiciliary ventilation, and an established home ventilation program, or specialist skills in managing complex disorders requiring domiciliary ventilation (e.g. neuromuscular disorders, spinal cord injury).
- An accredited Sleep Medicine physician and Respiratory Medicine physician on site.
- Access to on-site advanced level diagnostic and clinical testing (e.g. Full PSG, pulmonary function tests, arterial blood gases).
- A Sleep Unit on site that can take 'complex' patients who have multiple co-morbidities or are unwell. The sleep unit should have:
 - Registered Nurse on duty
 - Medical fitness assessment for sleep study
 - On site and close links with an Emergency / Arrest service or Respiratory Ward
- A dedicated service which has expertise in the management of patients with acute and chronic respiratory failure. This service would include personnel with practical experience in the assessment, treatment and management of respiratory failure and secretion management in neuromuscular disorders.
- Access to on-site specialised multidisciplinary services (e.g. Speech pathology, Physiotherapy, Palliative Care, Occupational Therapy, Respiratory, Gastroenterology, Cardiology etc.).
- A rostering system which will ensure adequate levels of staffing taking into account expertise, experience and workload.
- Patient's on domiciliary ventilation should have access to a 24 hour clinical service.
- Dedicated clinics for patients with chronic respiratory failure.
- Access to multidisciplinary health professionals for radiographic procedures and surgical interventions (e.g. PEG tube insertion) for high risk patients.
- Established successful programmes for ventilation weaning and tracheostomy tube management, weaning and decannulation.
- Access to more sophisticated on site ventilatory and non-invasive ancillary equipment (e.g. mechanical in-exsufflator), including staff with experience and expertise in the use of this equipment.
- On site dedicated clinical support personnel to organise patient appointments, collect and input data, monitor compliance, liaise with the central agency or provider companies and chase patient appointments and equipment.
- Involvement in dissemination of clinical information and training programmes.
- Ability to perform home or community visits, or have a specialised outreach service which

3.3 LEVEL 2 AGENCIES

Graphical representation of Level 2 Agency in schematic diagram:

[See diagram page 42]

Level
2
Agency

The Level 2 Agency is hospital based and is responsible for assessment, treatment and establishment of 'non-complex' or 'minimal support' patients on domiciliary NIV (e.g. NIV support for patients without significant neuromuscular disease or respiratory disease). Level 2 Agencies require a reasonable critical mass of patients and a certain amount of baseline services and onsite personnel.

Level 2 Agencies will also monitor, assess and treat 'high level' or 'complex' patients who have already been established on ventilation at a Specialised Hub and who are located geographically closer to the Level 2 Agency.

Level 2 Agencies will retain the ability to refer established 'high level' or 'complex' patients to their Specialised Hub for further management if required / indicated.

Over time as total patient numbers increase, services in Level 2 Agencies may expand to meet the requirements of a Specialised Hub. Data analysis will elucidate appropriate locations in which to expand these services.

Recommendation 17

Level 2 Agencies should be responsible for assessment, treatment and establishment of 'non-complex' or 'minimal support' patients on domiciliary NIV.

Recommendation 18

Level 2 Agencies should monitor, assess and treat 'high level' or 'complex' patients who have already been established on ventilation at a Specialised Hub and who are located closer geographically to the Level 2 Agency.

Recommendation 19

The critical patient mass for a Level 2 Agency should be defined as commencing at least 1 patient per month (i.e. 12 per year) ⁽²³⁾.

Recommendation 20

Level 2 Agencies require on site baseline services such as access to full polysomnography and personnel including a sleep physician, a respiratory physician and staff with a certain amount of expertise (e.g. nursing or allied health) to assist with assessment and management of patients on domiciliary NIV.

Recommendation 21

Level 2 Agencies should have access to the common database and be responsible for entry of all relevant data.

3.4 LEVEL 3 ASSESSMENT AND MONITORING NODES

Graphical representation of a Level 3 Assessment and Monitoring Node in schematic diagram:

[See diagram page 42]



NSW is geographically large and has a wide distribution of population densities. There are many home NIV patients, particularly in rural areas, who have difficulty accessing routine support, assessments and reviews. Often these patients rely solely on reviews by their sleep / respiratory physicians or sleep study reviews which, for practical purposes, may not be frequent enough to detect early clinical deterioration, monitor patient compliance and perform adequate ventilator equipment checks. To address this issue the establishment of Level 3 Assessment and Monitoring Nodes is recommended.

Recommendation 22

Level 3 Assessment and Monitoring Nodes should provide local access to routine baseline assessment, monitoring and support for patients on domiciliary ventilation.

Examples of suitable patients include:

- a. Patients isolated geographically
- b. Patients who have difficulty travelling to a Level 2 Agency (or Specialised Hub) for medical reasons (e.g. patients with advanced neuromuscular disease or bariatric transport requirements) or reasons of logistics / special need (eg: equipment requirements such as electric wheelchair, hoist, mattress, oxygen cylinders).

Recommendation 23

Level 3 Assessment and Monitoring Nodes should be located at convenient central physical addresses and/or may be deployed as mobile community units.

Recommendation 24

Trained outreach teams should be involved in assessing the patient's ventilator equipment (via checklist) and secretion removal techniques, and perform basic monitoring such as oximetry and spirometry.

Recommendation 25

Level 3 Assessment and Monitoring nodes should have access to the common database and be responsible for entry of compliance and monitoring data.

3.5 NON-METROPOLITAN COMMUNITY CARE AND OUTREACH PROGRAMS

Limited resources and wide geographical spread of individuals requiring non-invasive ventilation in rural and regional areas substantially dilutes patient access to appropriate treatment and follow-up.

Recommendation 26

The transfer of patients from non-metropolitan areas to Specialised Hubs for initial assessment and management, including their return home, should be adequately funded.

Routine monitoring of patients through community care programs such as home nursing or established pulmonary rehabilitation programs is required. Simple monitoring such as oxygen saturation, spirometry, a record of symptoms and side effects related to NIV and arterial blood gases may be undertaken. This information can be entered into the Information Management System and/or given to the patient's NIV management team to document that follow up is occurring and to identify any early change in the patient's condition. Such programs will help to reduce hospital admissions and therefore, be a cost saving measure.

In addition, telemedicine technology should be supported to assist patient care in rural areas.

Recommendation 27

Specific training should be made available for local rural community care programs such that they can be involved in the routine assessment of the patient's ventilator equipment (via checklist), symptom/side effects related to NIV and secretion removal techniques, and perform basic monitoring such as oximetry, spirometry and arterial blood gases.

Opportunities exist for rural areas to identify locations for periodic 'respiratory support' or outreach clinics within their region. These clinics may operate once or twice per year and would serve patients who have been identified as potential candidates for domiciliary ventilation or those already on home ventilation. Input from experienced clinicians from Specialised Hubs would enable patients to be followed up much closer to home. This is particularly important for those patients with mobility problems. In addition, these clinics will provide opportunities for local staff to be trained in monitoring and management of basic aspects of NIV.

Recommendation 28

Support should be made available for clinicians from Specialised Hubs to travel to rural areas to conduct periodic 'respiratory support' clinics. Input into these clinics by experienced staff

from the Specialist Hubs may be drawn up along geographical lines or based on historic ties and relationships.

Recommendation 29

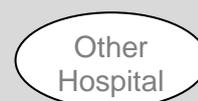
Additional financial input or resources should be made available to support Specialised Hubs as they take on extra responsibilities (e.g. outreach services).

A natural funding source for such programs may be the recipient Rural Area Health Service; that is, funding may be transferred from the Area receiving the benefit of additional clinical support / outreach services to the Metropolitan Area providing those services.

3.6 'OTHER HOSPITALS'

Graphical representation of an 'Other Hospital' in schematic diagram:

[See diagram page 42]



'Other Hospital' refers to hospitals in an area health service or geographical region which are neither a Specialised Hub nor Level 2 Agency. The important role that these hospitals play is to identify patients who may require further assessment for domiciliary NIV and refer them on to the appropriate facilities.

Recommendation 30

'Other Hospitals' should have access to a standardised referral system to transfer patients to a Level 2 Agency or Specialised Hub depending on complexity of the ventilatory requirements of their patient.

3.7 RESOURCES FOR PROPOSED MODEL

The proposed model uses currently available resources to improve the efficiency, quality and equity of equipment provision. It does not make recommendations for additional workforce resources.

However, local equipment support staff are required, and it is proposed that the current HRP positions would fulfil this modified role resulting in a cost neutral scenario. It should be recognised that actual workloads may vary between sites and over time. The number of staff required for this role would therefore need to accurately reflect workload.

3.7.1 Local support personnel – NIV Support Officers

Local NIV Support Officers provide a link between the Specialised Hub and the Central Agency and are critical to the effectiveness and sustainability of local services. The roles and responsibilities of local support officers (detailed in the draft job description, Appendix C) include:

- Making on-site appointments for reviews and sending reminders to patients.
- Entering patient clinical information and equipment tracking information into the Information Management System (i.e. maintain the sites contribution to the centralised database).
- Performance of routine tasks to free up clinician time (e.g. downloading machine compliance, changing filters etc).

The NIV Support Officer would need to be located on-site at the Specialised Hubs providing advantages of a single enquiry reference point or one person to contact per hub. Only in this way can patients and equipment effectively be tracked, reviewed, updated and removed when appropriate.

Continued provision of government-funded NIV equipment is dependent on routine clinical reviews of the patient and compliance checks. Local Support Officers will assist to monitor this requirement.

It has been recommended that the classification of this job description is not as an administration officer but at a level and classification which reflects the unique, vital and ongoing role required for the efficient provision of NIV.

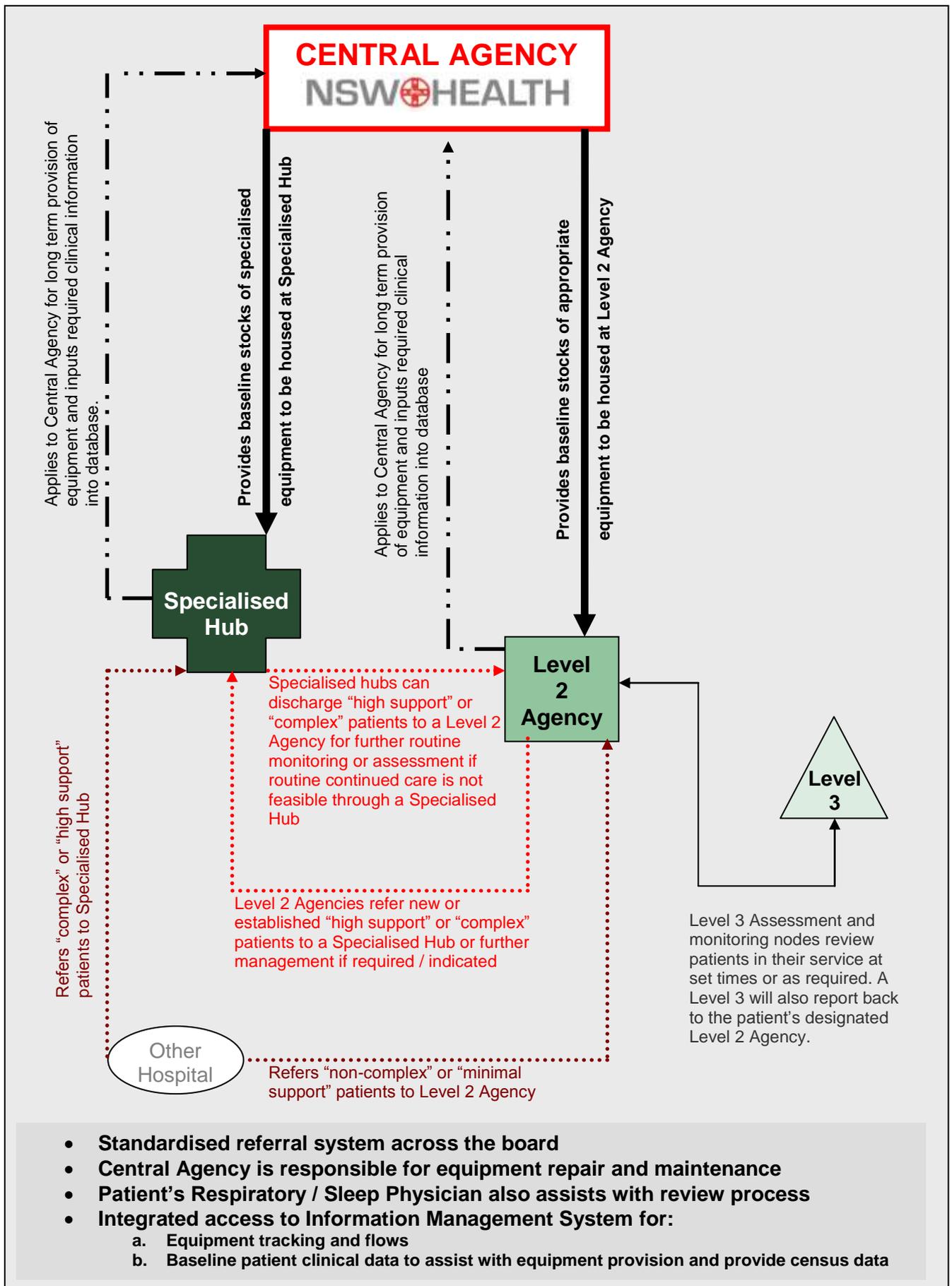
Recommendation 31

A dedicated NIV Support Officer should be located on-site at each Specialised Hub.

Ultimately, service demand and the related requirement for rigorous resource allocation, will be dependent on the collection of accurate clinical and equipment-related data. However, due to the lack of current data and service fragmentation it is not possible to accurately estimate the current or predicted on-going cost of home NIV services in NSW. Nevertheless, significant cost savings may be achieved with the following components of the model:

1. Benefits of centralisation with regards to equipment provision:
 - Mass purchase and tender processes will provide reductions in the cost of machines
 - Having one inventory for assets
 - Prompt recirculation of viable equipment to the system in the event of poor compliance, when the equipment is no longer required, or in the event of death
 - Reduction in the number of machines / equipment 'lost' in the community
2. Enhanced timeliness of assessment and provision of NIV services and equipment can significantly reduce length of stay in hospital, hospital readmission rates and overall treatment costs to Local Health Districts.
3. Limiting specialised services to a small number of Specialised Hubs will assist in improving and streamlining the assessment and treatment of patients with complex ventilatory needs, thereby enhancing safety and quality of care, and potentially reducing length of hospital stay.

3.8 SCHEMATIC OF PROPOSED NIV MODEL OF CARE



4. REFERRAL SYSTEM / PATTERNS

The consultation process highlighted that inequitable access to services was related to issues with the current fragmented and *ad hoc* referral systems for assessing and commencing patients for domiciliary NIV at the various hospitals. There was a strong perception that the majority of referrals are based on historical relationships between clinicians at the various centres and a lack of knowledge exists about the varying referral lines or services that are available across the state.

Discussion revealed that resources in existing centres are stretched and hospitals may not have sufficient capacity to accept additional patient loads, particularly patients with complex care needs.

Further, there is a lack of coordination and prioritisation of cases between services. Whilst the majority of patients may not be deemed as requiring critical transfer, rapid access to enhanced clinical assessment and treatment is important. If the importance of rapid transfer is not acknowledged in a timely manner the potential exists for the patient's condition to deteriorate to the point that the situation becomes critical.

Recommendation 32

A standardised referral system should be developed. Referral forms should be clear and concise.

Recommendation 33

To improve equity of access and prioritisation, patients requiring NIV assessment and treatment should be administered on a centralised waiting list.

Recommendation 34

A central role of the Support Officer at the Specialised Hubs should be to coordinate referral information and relay this information through appropriate clinical personnel.

5. INTER-AGENCY RELATIONSHIPS

Consultations with clinicians highlighted that clear relationships and responsibilities of the various clinical services are required to improve quality and access of care, such as clearer referral lines and follow-up responsibilities.

The important relationships and responsibilities between the clinical services of the model are described below:

SPECIALISED HUBS:

Relationship with other Specialised Hubs

1. Refer to another Specialised Hub which has particular expertise in the management and treatment of a specific condition.
2. Assessment can take the form of members from one Specialised Hub visiting the referring Specialised Hub to ascertain if the patient needs to be transferred.
3. Share experiences and skills to standardise care through biannual clinical meetings of clinical representatives of the Hubs to discuss specific and general patient management issues.

Relationship to Level 2 Agencies

1. Inform the Level 2 Agency about the discharge of any patient who is referred back into the community including discharge plans and/or requirements.
2. Adequate education, training and support for Level 2 Agencies, to ensure that they have the basic skills to safely use non-invasive respiratory aides, assess 'complex' patients and know when they need to refer them to a Specialised Hub.
3. If needed, provide personnel to work with local staff in reviewing patients on NIV at periodic local "review" clinics.

Relationship to Level 3 Assessment and Monitoring nodes

1. The Specialised Hub is responsible for providing continuing education and training to the Level 3 Assessment nodes.
2. Where needed, provide personnel to work with local staff in reviewing patients on NIV at periodic local "review" clinics.

Relationship with "Other Hospital"

1. "Other Hospitals" refer patients to Specialised Hubs for assessment and management for Domiciliary Ventilation. If the patient is 'non-complex' and can be assessed and treated at a Level 2 agency which is closer to the "Other Hospital", then they are referred to the Level 2 Agency instead.

LEVEL 2 AGENCIES:

Relationship with Specialised Hubs

1. Level 2 Agencies refer 'high level' or 'complex' patients to Specialised Hubs for initial assessment and commencement of domiciliary ventilation.
2. Level 2 Agencies can monitor, assess and treat 'high level' or 'complex' patients which have already been established on ventilation at a Specialised Hub. Level 2 Agencies will, however, refer established 'high level' or 'complex' patients to their Specialised Hub for further management if required / indicated.
3. Level 2 Agencies are responsible for patients referred into their care from Specialised Hubs.

Relationship to Level 3 Assessment and Monitoring nodes

1. When required, a Level 2 Agency will assign a Level 3 assessment and monitoring node to a patient.
2. Level 2 Agency is responsible for the Level 3 Assessment and Monitoring Node reviewing geographically isolated patients and collecting the relevant data.

Relationship with "Other Hospital"

1. "Other Hospitals" refer non-complex patients to Level 2 Agencies for assessment and management for Domiciliary Ventilation.

LEVEL 3 ASSESSMENT AND MONITORING NODES

The Level 3 Assessment and Monitoring Node is responsible for reporting their clinical findings to their local Level 2 Agency and Respiratory / Sleep Physician, where clinical action becomes the responsibility of the Level 2 Agency or Respiratory / Sleep Physician (whoever is nominated).

Recommendation 35

Specialised Hubs should be required to maintain open lines of communication with other major (and minor) centres and develop systems facilitating the effective referral of complex patients as required.

Additionally, all centres involved in the specialist provision of chronic NIV services should be required to participate in state-wide clinical education and training programs to share information, experience and skills (see section 17 Education and Training).

Recommendation 36

'Low level' or 'non-complex' patients should be referred to either Level 2 Agencies or Specialised Hubs for initial assessment and commencement of domiciliary ventilation. The choice of service will be dependent on factors such as proximity to patient's residence and severity of the patient's condition.

Recommendation 37

Level 2 Agencies can monitor, assess and treat 'high level' or 'complex' patients which have already been established on ventilation at a Specialised Hub. Level 2 Agencies will, however, retain the ability to refer established 'high level' or 'complex' patients to their Specialised Hub for further management if required / indicated.

Recommendation 38

Regardless of where the patient is initially commenced, it should be made clear who is responsible for the continued management of the patient (i.e. clinician or clinical service and location). This information should be recorded in the Information Management System.

Recommendation 39

It is recommended that hospitals that do not routinely assess and treat patients for domiciliary NIV should participate in education and training sessions to ensure they maintain a continued awareness of chronic respiratory failure and know when and who to refer such cases to.

6. CLINICAL LINK WITH CENTRAL AGENCY

During the consultation process there was strong consensus that it would be beneficial for one experienced clinician to oversee the quality and quantity of applications submitted to the Central Agency. It was felt that this responsibility should not be left to Central Agency administrative staff.

The identification of such a clinician would strengthen the system by:

- Prioritising equipment provision across the board.
- Highlighting sites whose applications significantly deviate from best clinical practice and assisting with specific recommendations for education programs.
- Monitoring the type of equipment used and the appropriateness of NIV in particular patient populations to prevent an inappropriate drain on resources, e.g. use of spontaneous bi-level ventilation versus CPAP in Obesity Hypoventilation Syndrome; use of NIV in chronic COPD who have not been carefully selected.
- Decreasing the number of applications rejected inappropriately where the scenario is unique, but based on best expert practise, is medically appropriate and justifiable.

This role could be selected on a rotational basis from a pool of experienced clinicians who have affiliations with the Specialised Hubs.

Recommendation 40

On a rotational basis from each of the Specialised Hubs, experienced clinicians should be involved in monitoring the overall quality and quantity of applications submitted to the Central Agency. Monitoring reports should be made available to improve evidence based care and optimise the efficient use of available clinical and equipment resources.

7. READY ACCESS TO HOME NIV EQUIPMENT

The efficient and timely provision of NIV equipment from the Central Agency to the Specialised Hub or Level 2 Agency is critical to avoid bed blockage, ensure that the ventilator is set-up correctly and that the patient and their family are trained in its use. If state-wide provision of equipment can be guaranteed from the Central Agency within 24 hours from application, then the need for individual loan pools at the respective Hubs or Agencies would be obviated. However, if the Central Agency is not able to guarantee this service, baseline levels of equipment stock should be held at Specialised Hubs and Level 2 Agencies.

Specialised Hubs:

- As Specialised Hubs will be assessing and managing greater numbers of both 'complex' and 'non-complex' patients, they should have instant access to a wider range of ventilator modes and specifications (in comparison to Level 2 Agencies).
- Equipment housed at Specialised Hubs will generally consist of spontaneous bi-level pressure machines, spontaneous-timed bi-level pressure machines, CPAP machines, and one mechanical in-exsufflator.

Level 2 Agency:

- As Level 2 Agencies will be assessing 'non-complex' patients for non-invasive ventilation, they should not require instant access to loan ventilators with more sophisticated ventilator modes or specifications.
- Baseline loan equipment housed at Level 2 Agencies will generally consist of spontaneous bi-level pressure machines and CPAP machines.
- Level 2 Agencies which have geographically isolated spontaneous-timed ventilator users in their vicinity should have access to a spare spontaneous-timed bi-level ventilator which can be utilised when usual replacement of equipment is delayed due to issues with regional travel. The Central Agency remains responsible for coordinating this exchange of equipment.

Suggested type and volume of equipment to be housed at each Specialised Hub and Level 2 Agency

	Specialised Hub	Level 2
Spontaneous-timed bi-level	2	-
Spontaneous bi-level	3	2
CPAP*	4	3
Adaptive-servo ventilation	1	1
Mechanical cough in-exsufflator	1	-

* These CPAP machines are for the sole purpose of trialling a patient on CPAP to ascertain if a spontaneous bi-level machine is no longer required. They are not be used for treating simple non-hypercapnic OSA as these patients will apply for a CPAP machine separately.

Recommendation 41

The Central Agency should guarantee delivery of equipment to Specialised Hubs and Level 2 Agencies throughout NSW within 24 hours of application approval.

Alternatively, if the Central Agency is not able to guarantee such delivery –

Baseline levels of equipment stock should be held at Specialised Hubs and Level 2 Agencies.

Less frequently used machines (e.g. Volume ventilators or ventilators approved for life support) should be held in a small quantity at the Central Agency and couriered to the appropriate site upon approval.

8. PROCESS FOR OBTAINING EQUIPMENT

Currently, the criteria for equipment provision for domiciliary NIV in NSW are variable. A single, standardised set of criteria is required to remove inequalities in equipment provision.

For standardised clinical guidelines, refer to “Domiciliary Non-Invasive Ventilation in Adult Patients – a consensus statement for the Domiciliary NIV Working Group, ACI”.

Recommendation 42

The following process for obtaining government funded domiciliary NIV equipment in NSW is recommended:

- i) If, based on standardised clinical and eligibility guidelines, a patient appears to satisfy requirements and is deemed potentially eligible for publicly funded equipment, the Central Agency should give tentative approval for the provision of equipment for an initial, short-term (usually 1 - 2 months) compliance period. Tentative approval should be obtainable via telephone discussion between a senior clinician (or recognised local support officer) and Central Agency staff. Equipment should be delivered to the patient within 24 hours of such approval.

[The patient is responsible for the purchase of ventilator tubing and masks].

- ii) The prescribing clinician (through the local support officer) would then use standardised forms on the online information management system to lodge a formal application for long term equipment provision.
- iii) The prescribing clinician would use the online information management system to document standard patient clinical information and equipment prescription information.
- iv) On receipt of the loan equipment the prescribing clinician would commence the patient on NIV. Equipment settings would be recorded in the online information management system.
- v) Review appointments are made, based on standardised guidelines, and recorded in the information management system.
- vi) A review of the patient’s clinical condition, equipment needs and machine compliance is conducted at the first review appointment. Data form review is entered into the information management system.
- vii) If the patient demonstrates adequate compliance, and approval for long term ventilation is given by the Central Agency, the patient continues to use their current loan machine.

[Should the patient require a less sophisticated machine, a more appropriate machine is ordered and provided. All details are recorded in the information management system.]

9. ELIMINATION OF SELF-FUNDED EQUIPMENT HIRE DURING INITIAL COMPLIANCE PERIOD

Currently at many sites, patients fund their own NIV equipment for the period from when they leave hospital to prove they are compliant with therapy prior to being able to apply for government equipment. While proving compliance is extremely important to the long term provision of NIV, many patients cannot afford to hire their own equipment to demonstrate initial compliance. A typical example is hire of a machine which may cost \$300 a month, with a \$700 deposit and interface equipment which may cost up to \$350. The majority of NIV patients are on a disability or aged pension and do not have a credit card or access to sufficient loan facilities.

When patients are unable to obtain their own equipment due to financial reasons, they are left with two scenarios. In the first scenario the patient is discharged home “off treatment” after the significant resources have been utilised to assess and commence treatment in hospital. Future avoidable usage of resources may also occur when these patients who remain off treatment relapse into acute or chronic respiratory failure and are often readmitted to expensive acute care environments for treatment. In the second scenario the patient remains in hospital until appropriate resources are located to provide continued NIV treatment. This scenario may result in significant bed blockage and at times the cost of the additional length of stay can exceed the purchase cost of the equipment required.

Eliminating the self-funded trial has been supported elsewhere in Australia e.g. In Queensland Health’s State-wide CPAP program, patients requiring NIV are exempt from the patient funded home trial due to the high rental cost and potential seriousness of their medical condition (<http://www.health.qld.gov.au/cpap/asp/eligibility.asp>).

Recommendation 43

Patients who are eligible for government funded domiciliary NIV equipment should not have to pay to hire their own equipment to demonstrate initial compliance.

10. SET-UP OF VENTILATOR

All of the sites which routinely set-up patients on NIV on a regular basis commented strongly on how poorly, and at times dangerously, ventilators are set up by third parties including rental agencies.

Common examples include:

- An old script is used to set-up the ventilator.
- Misunderstanding of the varying functions between machines potentially leading to incorrect ventilator set-up.
- Machines are not appropriately locked and the settings are accidentally changed.

Serious and Life threatening examples include:

- Patients given a previous patient's machine with no alteration to ventilator settings.
- Patients given an incorrect positive pressure device or where the device is set in the wrong mode (e.g. given CPAP or Spontaneous bi-level instead of Spontaneous-Timed).
- Inappropriate settings are inputted due to limited training of staff and limited understanding of the importance and functions of the various settings.

Recommendation 44

Equipment should be set up by clinicians who have an understanding of the patient's condition and the script requirements (e.g. by Specialised Hubs and Level 2 agencies). Having a small amount of on site equipment stock will ensure that the patient is acclimatised and set-up with the correct ventilator settings.

Recommendation 45

Changes to non-invasive ventilator settings and / or machines outside the Specialised Hubs and Level 2 agencies should only be performed by experienced clinicians and by non-clinicians who have been accredited to do so and where quality control checks are routinely performed.

11. SPECIAL VENTILATION EQUIPMENT

The purchase of one type of ventilator suitable for the majority of candidates will achieve economies of scale. However, in certain circumstances, patients have special clinical needs and will require a specific model or make of ventilator.

Recommendation 46

A process should be available to facilitate the application for a special (non-regular) make or model of ventilator if/when:

iii) an effective trial period of the standard issue ventilator has been attempted (i.e. following correct set-up, adequate compliance for sufficient duration and appropriate settings)

and

iv) there is objective demonstration that an alternate make / model is significantly superior in the treatment of the patients nocturnal or diurnal hypoventilation

and

v) the machine requested is on the Central Agency's pre-approved list (reviewed on a regular basis)

Changes of ventilator type should be performed under the supervision of an experienced clinician. This recommendation is especially important for:

- Patients with neuromuscular weakness or chest wall disorders where altered and reduced respiratory mechanics may produce significant variation in triggering and cycling patterns between machines.
- Patients with central alveolar hypoventilation, to ensure that back-up breaths remain at an adequate duration.
- Patients with anxiety over alterations to their ventilator or who are sensitive to any change in ventilator settings.

12. VENTILATOR DEPENDENT PATIENTS

The continuum of non-invasive ventilation ranges from use during sleeping hours only to individuals who use it on a continuous basis to support life. Patients who use their ventilator on a continuous or near continuous basis are deemed ventilator dependent and are at risk of death if their ventilator fails.

A ventilator dependent individual is defined as:

- a. ≥ 18 hours ventilator use per 24 hour period
- b. ≤ 4 hours continuous ventilator free time

- c. \geq 16 hours ventilator use per 24 hour period who live in an isolated area where a machine cannot be provided within 4 hours

These patients require back-up ventilators.

Recommendation 47

Secondary back-up ventilators (TGA approved for life-support) and back-up power supplies should be provided for ventilator dependent patients. Back-up machines should be located at the patient's home.

3.5 13. CONTINUED PROVISION OF EQUIPMENT

To ensure continued, equitable and accurate provision of NIV equipment, compliance needs to be routinely checked and patients monitored or assessed at regular intervals. This would also assist in reducing the number of patients 'lost to follow-up', an issue that is particularly important for patients who live in isolated or rural areas. In order to monitor and track NIV service and equipment requirements, and plan for future NIV needs, a small amount of data (including compliance and clinical review data) will need to be collected to ensure continued provision of government funded equipment.

Recommendation 48

Continued provision of government issued NIV equipment is based on fulfilling the following criteria:

- a. Compliance ($>$ 4 hours per 24 hour period over a consecutive four week period).
- b. Minimum number of clinical reviews (actual numbers of reviews are at clinicians' discretion i.e. earlier or more frequent if required)
 - Initial review (within 3 months after commencement)
 - Subsequent reviews (6 or 12 months depending on clinical stability or requirements)
- c. Clinician and NIV Support Officer to continue to input required data on Clinical Information System.

14. REASONABLE PERIOD OF ACCLIMATISATION

Some patients, while willing to use and accept NIV treatment, have difficulty in initially acclimatising to therapy. Examples may include patients with neuromuscular disorders or patients with concomitant psychiatric issues. In order to prevent equipment being removed from such patients due to poor compliance in the initial period, clinicians should be able to recommend a more reasonable period of acclimatisation for the purpose of compliance for specific patients.

Recommendation 49

Clinicians should have the ability to recommend to the Central Agency a more reasonable period of acclimatisation for the purpose of compliance for patients where it is medically justifiable.

15. REMOVAL OF EQUIPMENT DUE TO POOR COMPLIANCE

It has been shown in patients with neuromuscular disorders or chest wall deformity that there is a significant relationship between hours of NIV use (compliance) and treatment effectiveness in the treatment of nocturnal respiratory failure (evident by a decrease in carbon dioxide dissolved in the blood and a decrease in the Epworth Sleepiness Scale)⁽²⁸⁾. There appears to be a threshold effect where there is little consistent change in these measures until NIV has been used for at least 4 hours per night⁽²⁸⁾. Obese patients with high carbon dioxide levels and obstructive sleep apnoea, who use therapy for more than 4.5 hours per day experience significant improvements in the amount of carbon dioxide eliminated from their blood and significant improvements in blood oxygen levels, compared with less-adherent patients⁽²⁹⁾. In selected patients with COPD, studies that have ensured adequate pressures and adequate compliance have shown beneficial effects on physiological measures and health-related outcomes⁽³⁰⁾.

Due to lack the of efficacy of NIV if used for less than 4 hours per night, it would be an inappropriate use of government allocated resources to provide equipment for patients who are unable to use it for at least 4 hours per 24 hour period. Patients are to be made aware of this condition from the outset, understanding that removal and reallocation of equipment will occur if usage falls below this threshold if, despite intervention by clinical staff, compliance cannot be improved over a period of several months.

Recommendation 50

The responsibilities of the patient in accepting government funded NIV device should be clearly explained from the outset of treatment. Patients should demonstrate an understanding of the relevant information and agree to accept conditions through signed documentation.

Specifically, patients should be made aware that they will forfeit their qualification for publicly funded equipment assistance, following which equipment will be withdrawn, if:

i) they can not demonstrate that they are using their prescribed device for the required minimum number of hours (> 4 hours) per night,

and

ii) over a subsequent period of several months they fail to demonstrate compliance improvement.

Recommendation 51

Ventilators provided should have the capacity to download information, including daily hours of usage.

Patients should be informed that the NIV device remains property of the Central Agency and the device must be returned to the Central Agency when it is no longer indicated.

Recommendation 52

If compliance falls below 4 hours per night for greater than one month and cannot be explained by a hospital admission or other reasonable event, the following sequence is recommended:

1. Patient is made aware of their poor compliance and reminded of the implications of poor compliance
2. A letter is sent to the patients primary physician / clinician to inform them of the patients poor compliance
3. A telephone call is made by the patient's clinical team to see
 - a. If the problem may be addressed over the phone,
If the problem can not be addressed over the phone,
 - b. An appointment (outpatient or community where appropriate) is organised to assess the patient and problem solve where required.
4. A follow-up phone call is made two weeks later and compliance checked again 1 month after the initial attempt to address the problem.
5. If compliance has not improved to a satisfactory level after efforts by the clinical staff to troubleshoot problems, the clinical team via the Support Officer is obliged to inform the Central Agency. The Central Agency will then be responsible for the retrieval of government funded equipment. Patients who are not compliant according to Central Agency standards (i.e. unable to fulfil the criteria of using it for > 4 hours per 24 hour period) but wish to continue having a ventilator on their premises will be given information on where to hire or purchase their own equipment.

16. PROVISION OF MECHANICAL IN-EXSUFFLATORS

Patients with expiratory muscle weakness unable to generate peak cough flows > 270 L/min are at risk of not being able to clear secretions during times of respiratory infection. This can lead to sputum retention and pneumonia, which if left untreated, can result in worsening respiratory failure and ultimately death. Mechanical cough in-exsufflators are machines (separate to the patient's ventilator) which can significantly improve cough flows in patients with expiratory muscle weakness without severe bulbar involvement, and reduce hospital re-admission when used in the domiciliary setting ⁽³¹⁾. However, they need to be used on a regular basis for effect.

Recommendation 53

Mechanical in-exsufflators should be provided for patients with expiratory muscle weakness, adequate bulbar control and peak cough flow rates < 270 L/min.

Recommendation 54

Patients/carers need to be adequately trained in the use of mechanical in-exsufflators, and need to use them on a regular daily basis.

17. EDUCATION AND TRAINING

During the consultation process it became clear that clinicians are seeking to develop stronger education and training links between hospitals. Centres with the greatest expertise in the area of providing domiciliary NIV should develop specific training programmes to assist with the dissemination of clinical information. It is extremely important for all clinicians throughout NSW to gain equal access to this training and education in order to improve the quality of assessment, management and referral of patients requiring domiciliary NIV, with provisions made to ensure access for rural clinicians.

Education/training may occur through:

- Face to face in-services with hands-on practical experience
- Education packages
 - Documents
 - Video
 - Webcast
- Videoconference
- Telephone assistance
- Companies who obtain tenders may assist with training clinicians how to use their respective ventilators
- Experienced staff from Specialist Hubs assisting regional areas to run periodic “review” clinics

Recommendation 55

Specialist consultation, monitoring and training should be available equally for all involved parties.

Recommendation 56

Specialised Hubs should develop dedicated training programs and, on a rotational basis, should provide training programs to clinicians from metropolitan and rural areas.

Recommendation 57

To assist with education, training and dissemination of information, clinicians from the Specialised Hubs should be required to meet every 6 months to:

- Discuss clinical or operational issues
- Discuss clinical cases
- Exchange knowledge

(Level 2 Agencies and other clinicians may meet, contribute or join these sessions)

18. EXPANSION OF TELEMEDICINE

Using videoconferencing and sending real-time ventilator and oximetry information online (via modems) will improve patient monitoring and assessment of patients on domiciliary NIV in rural or isolated areas. While there is some infrastructure currently in place to support videoconferencing, it has not generally been used for this purpose.

Recommendation 58

Promote and use videoconferencing facilities to improve monitoring and assessment of patients on domiciliary NIV in clinically or geographically isolated areas.

Recommendation 59

Explore the technologies of remote real-time ventilator and oximetry monitoring. Information from ventilators and oximeters could be streamed directly via a modem to an operator at a Specialised Hub where ventilator settings could be assessed and altered remotely. Such capability would be particularly useful in remote locations or where it is not feasible for patients to travel for assessment.

19. BASELINE ESTIMATES OF EQUIPMENT

NOTE: Due to the current lack of data regarding NIV equipment provision in NSW, the following section is based on estimates and may under represent the actual equipment requirements for NSW. Estimates presented below should be used as a guide until accurate data is collected.

19.1 Baseline estimates for new applicants per year

Currently there is no centralised database that can access the total number of ventilator machines provided by EnableNSW/ HRP per year, therefore, exact requirements are unknown. Based on conversations with public hospitals in NSW that provide NIV for adult patients, it has been estimated that approximately 130 to 150 patients are commenced on domiciliary NIV per year. This figure is in line with European literature which suggests that 10 patients are commenced per year in a typical area of 500,000, ⁽¹⁷⁾ (In NSW with a population of 6,816,087 in 2006, this would equate to 136 patients). It is likely that the vast majority would be eligible for equipment via pension concession. This number is likely to grow over the coming years, with the expansion of obesity related requirements for NIV ^(10, 19).

As we were unable to obtain individual or cumulative data from the EnableNSW/ HRP programs, specific data was requested from Royal Prince Alfred Hospital (RPAH), SHORES program (Westmead Hospital), St George Hospital and John Hunter Hospital for trending purposes:

1. In one year, the average number of applications for spontaneous bi-level machines

2. In one year, the average number of applications for spontaneous/timed bi-level machines
3. In one year, the average number of applications for volume ventilators
4. Approximate population that these numbers apply to
5. Average number of patients who cease using NIV annually (for any reason including death, non-compliance, transference from Spontaneous bi-level to CPAP etc)

There was a wide variation in the information collected and maintained amongst the sites. In addition to this, it is difficult to estimate prevalence as the various sites receive patients from multiple and overlapping Local Health Districts making it impossible to ascertain an accurate denominator. The following paragraphs summarise the data received.

RPAH data: Shows stability in the number of patients commenced on domiciliary NIV per year from 2006 to 2008 (2006 = 37 patients; 2007 = 39 patients and 2008 = 38 patients). In 2008, of 38 patients commenced on NIV, 71% were commenced on spontaneous mode and 29% were commenced on spontaneous-timed bi-level ventilation. Over the year, 16 % ceased requiring a bi-level device (e.g. non-compliance / death / other treatment). 15% of spontaneous bi-level users were moved to CPAP and 9% of spontaneous-timed users were moved to spontaneous bi-level.

John Hunter Hospital data: The NIV devices commenced per calendar year in the Greater Newcastle cluster (Hunter New England Area Health Service) are summarised below:

Year	Total	VCV / AVAPS	S/T	S
2005	33	1 (3.0%)	4 (12.1%)	28 (84.8%)
2006	17	1 (5.9%)	1 (5.9%)	15 (88.2%)
2007	20	0 (0%)	2 (10.0%)	18 (90.0%)
2008	14	0 (0%)	2 (14.3%)	12 (85.7%)
TOTAL (Average %)	84	2 (2.4%)	9 (10.1%)	73 (86.9%)

VCV = Volume control ventilation AVAPS™ = average volume assured pressure support
 S/T = Spontaneous/Timed S = Spontaneous

SHORES (Western Sydney Support for Home Oxygen and Respiratory Equipment Service) / Westmead Hospital data: Approximately 22 new requirements for bi-level machines and 1 volume ventilator per year. In total there are approximately 67 patients requiring government funded equipment (47 on SHORES list, 8 on rentals and 12 on loan machines yet to apply to SHORES). Proportions of spontaneous versus spontaneous-timed were not reported.

St. George Hospital data: An overview of the Northern, Central and Southern Networks for oxygen, CPAP and NIV provision in SEIAHS was obtained. The numbers of CPAP and NIV machines were combined and the total numbers of machines being maintained by each network were reported. A total of 170 CPAP / NIV machines were reported from the Central Network. NIV consisted of 27% of these ongoing applications (45.9 NIV machines in Central

Network). It was not reported how many of these machines were spontaneous-timed, however, an estimate of 40% was given.

RPAH data was considered in making recommendations regarding equipment provision as it was the most comprehensive and appeared to sit in the middle of the wide range of collected information, much of which was estimated and incomplete.

Based on a minimum of 140 new patients per year, the following number of machines would be required as a baseline for government assisted provision per year (*Assuming 71% are spontaneous machines and that machine provision ceases in 16% cases overall*).

	Total = 140 patients	Subtract 16 % due to patients ceasing using the device	Estimated baseline net new applicants per year
Spontaneous (71%)	99.4	- 15.9	83.5
Spontaneous - timed (29%)	40.6	- 6.5	34.1
Total			117.6

19.2 Asset renewal program

Estimates in 19.1 do not include the ongoing replacement of ventilator equipment that has passed its working life. As there is no database available, the number of patients on government supplied ventilation and the turn around time for machines to re-enter the loan pool for specific conditions in NSW are not known.

Using estimates based on the Victorian Respiratory Support Service ⁽²¹⁾ and data from European countries with similar patterns of ventilator use for degenerative neuromuscular conditions ⁽²⁰⁾, the prevalence of ventilator use in NSW has been estimated at a baseline of 10/100,000. Based on the 2006 NSW population figures (6,816,087), the total number of ventilator users can therefore be estimated at 681.6. An extra 112.8 $((681.6-117.6) \times 1/5)$ ventilators would need to be supplied per year for asset replacement based on a 5 year working life span of equipment, assuming that the spread of equipment provision has been even and removing the 117.6 new applicants per year. This would equate to an extra 80.1 spontaneous machines and 32.7 spontaneous-timed machines.

3.6.1.1 19.3 Estimates of total numbers bi-level equipment required per year

The estimates of total numbers of bi-level equipment required per year are listed below:

	New applicants per year	Asset renewal program	Estimated baseline total per year[#]
Spontaneous (ratio = 71%)	83.5	+ 80.1	163.6
Spontaneous – timed (ratio = 29%)	34.1	+ 32.7	66.8

[#]It is important to note that this does not include more sophisticated ventilators (e.g. volume / hybrid / life support), secondary back-up ventilators or respiratory devices such mechanical cough-inexsufflators. EnableNSW may provide data on how many of these devices are requested each year in NSW.

20. CONCLUSION

This proposal addresses the variation in clinical practice regarding the indications, initiation and follow up of patients requiring home ventilation and the inequities of access to, and outcome from, services for patients requiring home NIV in NSW.

Particular attention has been given to the requirements of patients who have difficulty accessing medical services due to their medical condition or geographical isolation.

The ACI Respiratory Network submits 59 recommendations as components of a new model of care involving at its core a Centralised Agency responsible for the provision of all government funded domiciliary ventilation equipment and a comprehensive information management system. Operating in conjunction with the Central Agency is a hub and spoke network of clinical services featuring Specialised Hubs, Level 2 Agencies and Level 3 Assessment and monitoring nodes.

If implemented, the model of care described in this document will considerably improve domiciliary NIV services in NSW and has the potential to significantly reduce hospital admissions and length of stay for this group of patients. Additionally, it will provide a means of more accurately estimating current and future demand for home NIV services.

GLOSSARY

Critical mass in this context refers to the volume of patients required to present for domiciliary NIV services at a particular site to ensure that the site has the adequate skills to appropriately assess and effectively manage patients on NIV, and maintain/retain competence.

While not formally studied some baseline recommendations have been proposed:

- A critical mass requires a minimum of one case of establishment of ventilation for chronic needs per month over previous 12 month period to be recorded ⁽²³⁾.
- A minimum of 20 patients per year as a minimum number ⁽²⁷⁾.

Level of complexity in this context refers to the level of support a patient requires with regards to mechanical ventilation, multi-disciplinary care and other medical co-morbidities. An example of 'complex' or 'high to medium level of support' patients requiring domiciliary ventilation may include significant neuromuscular disease and the need for ventilatory support, or patients without coexistent neuromuscular or respiratory disease requiring long term invasive ventilation. Alternatively, an example of 'non-complex' or 'minimal support' may include NIV support for patients without significant neuromuscular disease or respiratory disease.

Spectrum in this context refers to the variety of disorders which are assessed and managed on domiciliary ventilation.

Specialisation in this context is where a centre demonstrates specialist skills in managing particular complex disorders requiring domiciliary ventilation. While the prevalence of the particular disorder may not be high enough to reach a theoretical critical mass, a centre may be a specialised centre if, in comparison to other centres, it has experience with particular disorders requiring domiciliary ventilation.

APPENDIX A: Recommended Model of Care for Victorian Chronic Ventilation Services - Review of the VRSS

(page 35-36, ⁽²¹⁾)

Review of the Victorian Respiratory Support Service

<p>Model 4 Formalisation and Extension of Existing VRSS Model/Service consisting of primary and secondary agencies</p> <p>A single primary specialist agency (the VRSS), with core roles as follows:</p> <ul style="list-style-type: none">➤ clinical focus on high complexity/high risk clients;➤ continuation and extension of role of consultation and outreach services to respiratory specialists in other health services to establish individual clients on ventilation locally as jointly determined, with referral back to the local service provider for joint follow-up after ventilation has been established;➤ operation of specialist outpatient clinics;➤ overall responsibility for ventilator provision contract, including "loan" arrangements to secondary centre(s), purchase of ventilators for all age groups (that is, including paediatric needs), provision of 24-hour back-up to adult service users;➤ as the primary specialist centre, additional responsibilities for<ul style="list-style-type: none">○ the development and implementation of innovative strategies to provide outreach services to rural areas, building on existing capacity in health sector.○ 'specialist centre' activities in clinical practice development and development of acute health/community sector linkages, particularly in relation to neuromuscular and chest wall disorders and ventilator-dependent spinal injuries.○ development and implementation of quality enhancement strategies, such as consumer surveys, regular workshops with key consumer agencies.○ establishment of a register and other appropriate data collection strategies to assist analysis of operation and identification of emerging trends.○ conduct of an appropriate research program.○ provision of an annual report. <p>One or more level 2 agencies</p> <ul style="list-style-type: none">➤ located within other major health providers which meet certain critical mass/competency standards (e.g. record of minimum of 1 case of establishment of ventilation for chronic needs per month over previous 12 month period). These centres would also require a sleep laboratory capable of performing complex sleep studies such as ventilation implementation studies, as well as appropriately skilled medical, nursing and allied health staff.➤ These agencies would have clinical focus on facilitation (through ventilator provision) of discharge for clients with anticipated CVP due to respiratory issues, and also have<ul style="list-style-type: none">○ capacity for basic 24-hour emergency contact, and○ capacity to provide ongoing outpatient support with ventilator-dependent clients.
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Feasibility:

Aspects of this model are already operating informally in Victoria, with capacity for formalisation and extension

Strengths

- Builds upon existing specialist capacity and achievements to date, particularly in relation to use of ventilatory support in neuromuscular conditions.
- Recognises and formalises a network role of the specialist agency in consultation and support for secondary agency(s) in interim implementation of ventilation.
- By enabling discharge on interim arrangements, enables faster throughput within acceptable risk limits.
- Establishes clear role expectation of specialist agency in relation to data collection, and program research and development.
- Enables incremental systems change within considered volume/risk limits. Is realistic in terms of very limited numbers of potential providers in this specialised area.

Weaknesses

- Does not substantially enhance overall service system capacity.

APPENDIX B: Proposed Data Sets for Information Management System

The Information Management System is concerned with two streams of data collection:

1. Equipment tracking and flows
2. Baseline patient clinical data

STREAM 1: EQUIPMENT TRACKING AND FLOWS

- 1.1 Each piece of equipment has a unique identifying code.
- 1.2 The equipment is tracked and logged on the Information Management System according to its location (i.e. Central Agency Store; Specialised Hub location, Level 2 Agency location or patient's residence).
- 1.3 Equipment stocks at the Specialised Hubs or Level 2 Agencies are automatically monitored by the tracking system and are replenished when stocks reach a critical level.
- 1.4 Flows of equipment repairs are tracked on the Information Management System.
- 1.5 Flows of equipment replacements are tracked on the Information Management System.
- 1.6 A log of the patient's ventilator settings and most recent chronic ventilator settings are recorded on the system.
- 1.7 Automatic reminders can be sent from the Central Agency to the patient.
- 1.8 Ability to report issues regarding quality control (e.g. incorrect ventilator settings).

STREAM 2: BASELINE PATIENT CLINICAL DATA SET

2.1 Patient details and demographics

- a. Name
- b. Date of birth
- c. Gender
- d. Medicare number
- e. Address
- f. Contact phone number
- g. Next of Kin
- h. Carer details
- i. Primary language spoken at home

2.2 Clinical Relationships

- a. L.M.O.
- b. Patient's primary or local Respiratory / Sleep Physician
- c. Respiratory / Sleep Physician at Specialised Hub or Level 2 Agency
- d. Location where ventilation was commenced / acclimatised
- e. Level 3 Assessment and monitoring node (as appropriate)
- f. Relationships with particular respiratory failure services or clinic
- g. Where and by whom subsequent reviews after initial assessment will be conducted

2.3 Person to contact / responsible for making medical decisions. (This person may also have up to date advanced care directive information, know where to get information or, if they are the patient's enduring guardian, may be able to assist with decision making).

2.4 Diagnostic group and disorder

2.5 Forms completed for long term provision of equipment with disorder specific justification for provision

2.6 Justification of mode or type of ventilator required

- a. Sophistication of ventilator required: Requirements for the ventilator to be approved for "life support" or "continuous use"
- b. Bi-level pressure ventilator versus volume or hybrid ventilator
- c. If bi-level ventilator: spontaneous versus spontaneous timed
- d. Back-up ventilator for patients deemed as "ventilator dependent patients"
- e. Mechanical in-exsufflation equipment (Documentation of mechanical cough in-exsufflation provision if peak cough flows < 270 L/min)

2.7 CLINICAL DATA - based on specific disorder categories, where appropriate:

2.71 Clinical data – BASELINE

- a. ABGS, with FiO₂ specified
 - i. Pre-treatment
- b. SpO₂
- c. Lung function
 - i. Spirometry
 - ii. Lung volumes
 - iii. MIP / MEP / SNP
 - iv. Peak cough flow (unassisted and assisted) – where appropriate
- d. Height and weight (for body mass index)
- e. Relevant PSG oximetry
- f. Studies with oximetry and CO₂ monitoring demonstrating hypoventilation
- g. Signs and symptoms of sleep disordered breathing
- h. Date of NIV commencement
- i. Number of hospital admissions in the year proceeding NIV commencement
- j. Number of chest infections in the year prior to commencing non invasive ventilation and other respiratory aids
- k. Disease specific justification
- l. Quality of Life questionnaires
 - i. Pre-treatment
- m. Baseline ventilator settings
- n. Interface used
- o. Mobility
 - i. Independent, assistance required or dependent
 - ii. Walking aid requirements
 - iii. Wheelchair dependency
 - iv. Ventilator / supplemental oxygen requirements

2.7.2 Clinical data – INITIAL REVIEW

- a. ABGS, with FiO₂ specified
 - i. Post-treatment
- b. SpO₂
- c. Relevant PSG information
- d. Compliance information
- e. Quality of Life questionnaires
 - i. Post-treatment
- f. Adjusted ventilator settings
- g. Alterations to patient function
- h. Problem list (check list and free text of what the problem is and how it was solved or reason why it was not solved)
 - i. No issues
 - ii. Mask problem
 - iii. Face breakdown
 - iv. Leak issues
 - v. Humidification issues
 - vi. Ventilator issues

2.7.3 Clinical data – SUBSEQUENT REVIEWS / ASSESSMENT

- a. SpO₂
- b. ABGS, with FiO₂ specified (as required)
 - i. Serial measures
 - ii. Post significant change in treatment
- c. Simple lung function measures
 - i. FEV₁ / FVC
 - ii. VC
 - iii. MIP / MEP / SNP (for neuromuscular disorders if available)
 - iv. PCF (for patients with expiratory muscle weakness)
- d. Compliance information
- e. Confirm or update ventilator settings
- f. Alterations in patient function
- g. Problem list (check list and free text of what the problem is and how it was solved or reason why it was not solved)
 - i. No issues
 - ii. Mask problem
 - iii. Face breakdown

- iv. Leak issues
 - v. Humidification issues
 - vi. Ventilator issues
- h. Disorder specific prompts for referral to other multidisciplinary services

2.8 Compliance data –needs to be recorded at predefined intervals to ensure continues provision of equipment

2.9 Ventilator setting script history (ongoing)

2.10 Record of telephone calls where patient contacts the Central Agency or third party for technical problems / equipment malfunction

- a. Initial call
 - i. Date / time
 - ii. Problem
 - 1. Equipment required (tubing, filters, mask spares)
 - 2. Technical issue (including alarming, not reaching pressure, noisy)
 - 3. Ventilator not working
 - 4. Issues with replacement / new ventilator
 - 5. Incorrect ventilator settings
 - 6. Battery not working
 - 7. Request for service
 - 8. Internal malfunction error message
 - iii. Person dealing with the problem
 - iv. Patient given plan of action with time frame
- b. Action required (Drop down box for heading, then free text)
 - i. Equipment required (tubing, filters, mask spares)
 - ii. Replacement ventilator required
 - iii. Further patient education required (circuit assembly and ventilator usage)
 - iv. Correction of ventilator settings
 - v. No technical fault identified – requires clinical review
- c. Action taken (Drop down box for heading, then free text)
 - i. Ventilator replaced, same model
 - ii. Ventilator replaced, alternate model
 - iii. Mask / tubing / accessories replaced by patient
 - iv. Incorrect ventilator settings corrected
 - v. Received further education and support
- d. Result of action (Drop down box for heading, then free text)
 - i. Problem solved

- ii. Problem cannot be solved by technical team - requires clinical review
- e. Follow-up required (Drop down box for heading, then free text).
(Including, if required, clinical follow up to ensure problems have been solved)

2.11 Documentation of commencement of training manual insufflation techniques and cough assistance techniques in patients with inspiratory and expiratory muscle weakness.

2.12 Discontinuation (reason and date)

- a. Clinical improvement
- b. Patient intolerance / Poor compliance
- c. Death

APPENDIX C: NIV Support Officer - Job Description (Outline)

Why are Local NIV Support Officers required?

Local NIV Support Officers are critical to effective and sustainable local service provision. The Support Officer will provide a necessary link between the Specialised Hub and the Central Agency and will substantially reduce the administrative workload of respiratory clinicians. Continued government-funded NIV provision is dependent on routine clinical reviews of the patient, including prescription compliance checks. The NIV Support Officer would be responsible for making on-site appointments for reviews and sending reminders to patients. They would also be responsible for entering patient / clinical information and all equipment tracking information into the Information Management System (i.e. maintain the sites contribution to the centralised database). The NIV Support Officers will also perform routine tasks which can free up clinician time even further (e.g. downloading machine compliance, changing filters etc).

The support personnel would be located on-site at the Specialised Hubs providing advantages of a single enquiry reference point or one person to contact per Hub. Only this way can patients and equipment effectively be tracked, reviewed, updated and removed when appropriate.

Without this dedicated position the work would be unreasonably shared between unfunded clinical and administrative personnel.

Position:

Responsible to: Each NIV Support Officer is responsible to:

1. Respiratory Directors at each Hub / Network
2. EnableNSW

Operational service time: 0800 to 1630 hours Monday to Friday
Number of Full Time Equivalent (FTE) will be proportional to workload

Roles:

- NIV Clinical Officer to be allocated and affiliated with their respective Respiratory department in each Hub.
- Administer NIV equipment needs and respiratory equipment related to the patient's NIV assessment and management.
- Enter NIV patient demographic information into the Information Management System.
- Enter NIV patient baseline clinical information into the Information Management System.
- Check (download where appropriate) and record machine compliance.
- Check and replace filters or organise for the patient to do this.

- Provide information and educate patients on cleaning their equipment.
- Organise review appointments to dedicated clinics to ensure continued provision of equipment.
- As requested by clinical team, book in clinical studies including: arterial blood gases, lung function tests and sleep studies.
- Enter patient equipment information (unique identifying code) into Information Management System to ensure that equipment can be tracked, reviewed, updated and removed when appropriate.
- Obtain a copy of the patient's pension card.
- Organise transport for appropriate patients when requested by clinical team.
- Be a single enquiry reference point for the affiliated Hub.
- If the patient is transferred to another Hub or Agency, ensure that the relevant information is also transferred.
- Liaise with Enable NSW if equipment stocks are at critical levels and are unlikely to be replenished in time under the automated system.
- Make appointments with other multi-disciplinary teams.
- Send reminders to patients to ensure they are aware of their upcoming appointments and their responsibilities for continued equipment provision.
- Organise equipment replacement and repairs (via EnableNSW) where appropriate.



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