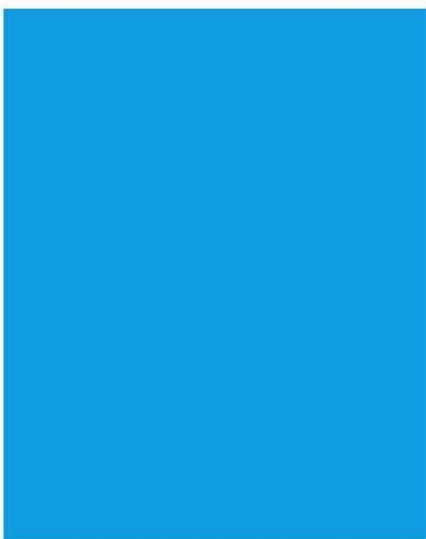


**Clinical Commissioning
Policy: Phrenic Nerve Pacing
Following Spinal Cord Injury**

April 2013

Reference : NHSCB/D13/P/a



NHS Commissioning Board

Clinical Commissioning Policy: Phrenic Nerve Pacing Following Spinal Cord Injury

First published: April 2013

**Prepared by the NHS Commissioning Board Clinical Reference Group for
Spinal Cord Injury**

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First published April 2013

Published by the NHS Commissioning Board, in electronic format only.

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Policy Statement

The NHS Commissioning Board (NHS CB) will commission phrenic nerve pacing following spinal cord injury in accordance with the criteria outlined in this document.

In creating this policy the NHS CB has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

The NHS CB has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

Plain Language Summary

Mechanical ventilation has been the standard treatment for respiratory device-dependent spinal cord injury patients but mechanical ventilation can also impair the ability to cough and can limit speech. The phrenic nerve, which originates in the cervical spine, is the nerve that controls diaphragmatic movements. The diaphragm is responsible for the majority of the movement of air during normal breathing.

The term 'phrenic nerve stimulator' applies to systems whereby an electrode(s) is surgically implanted around the phrenic nerve(s), which are stimulated by a radio-frequency receiver usually implanted in the chest wall. Intact phrenic nerves and functioning diaphragm muscles are essential for this intervention.

The aim of this policy is to describe the situations under which the NHS CB will fund the implantation of phrenic nerve implants following spinal cord injury due to traumatic and non-traumatic spinal cord injury.

Information on the outcome of treatments for these patients will be collected and considered when this policy is reviewed.

1. Introduction

The incidence of cervical spinal cord injury (SCI) is about 1 per 60,000 people per year. This is about 1,000 cervical SCIs each year in England. Approximately 20% of these occur between the levels of C1 and C4² with the majority of SCIs caused in road traffic incidents.

Up to 4% of cases of SCI require long-term artificial respiratory device to support breathing.³

An injury to the spinal nerves or cord (between C0 and C4) causes quadriplegia and can impair breathing resulting in the need for a lifelong ventilation support.

Quadriplegia reduces life expectancy, affecting motor and sensory function and quality of life. The degree of functional impairment and independence achievable depends, in part, on the severity of the injury and location of the spinal cord lesion.

Mechanical ventilation has been the standard treatment for respiratory device-dependent SCI patients. Air is forced into the lungs under positive pressure to enable lung function, but mechanical ventilation can also impair the ability to cough and can limit speech. Comorbidity can include respiratory infections due to an impaired ability to cough. Regular suction of secretions helps to avoid these complications, but is itself a potentially intrusive and disruptive process for patients. As a consequence of these complications, ventilated patients have reduced independence and increased mortality compared with patients with similar injuries who are not ventilator-dependent.¹

The phrenic nerve, which originates in the cervical spine from the C3, 4 and 5 roots, is the nerve that controls diaphragmatic movements. The diaphragm is responsible for the majority of the movement of air during normal breathing.

Some patients with damage to the cervical spine will have an intact phrenic nerve. Implanted phrenic nerve stimulation applies regular electrical pulses direct to the nerve. This causes the diaphragm to contract, resulting in the intake of air, akin to natural breathing. Intact phrenic nerves and functioning diaphragm muscles are essential for this intervention.

Two main types of procedures are possible for stimulating the diaphragm following SCI. Intramuscular diaphragm stimulation using an abdominal laparoscopic approach has been the subject of recent interventional procedure guidance issued by NICE.⁹ The benefits of this device for long-term use following SCI are questionable. The second procedure is phrenic nerve stimulation, which involves direct stimulation of the nerve. The implanted phrenic nerve stimulator deploys a low amplitude current to the phrenic nerve to achieve diaphragm muscle contraction, as opposed to the direct diaphragm stimulator. Stimulators are inserted via either a cervical or thoracic approach. Phrenic nerve stimulation with direct stimulation of the phrenic nerve is the focus of this policy.

2. Definitions

The term 'phrenic nerve stimulator' applies to systems whereby an electrode(s) is surgically implanted around the phrenic nerve(s), leading to a radio-frequency receiver usually implanted in the chest wall. An external transmitter then sends radio frequency signals to the device by an antenna which is worn over the receiver.

There are two commercially available systems, one manufactured by Atrotech OY (Finland), and a second system manufactured by Avery Biomedical Devices (USA). The electrodes are implanted once and in long term use (over 20 years in some cases) have proven robust. The external transmitter is battery powered and routinely robust, requiring replacement every 5-10 years. The cables connecting the external transmitter to the antenna are silicone coated but can be damaged by careless handling. They are readily available and a relatively low cost replacement item.

The surgical procedure for implantation of the radio-frequency receiver involves bilateral anterior thoracotomy through the 2nd or 3rd rib approach, through a small (5 – 6 cm) skin incision. The electrodes are placed around the phrenic nerves and stabilised. The electrode in turn is connected to a passive receiver and implanted subcutaneously under the skin. This is performed bilaterally and completes the procedure with rapid post-operative recovery.

3. Aim and objectives

The aim of this policy is to describe the situations under which the NHS Commissioning Board will fund the implantation of phrenic nerve implants following SCI due to traumatic and non-traumatic SCI.

This policy only considers use of phrenic nerve stimulation for patients with high cervical spine injury (traumatic and non-traumatic). Other patients whom may potentially benefit from this intervention (for example those with central sleep apnoea, diaphragm paralysis from amyotrophic lateral sclerosis, brainstem encephalitis or congenital central hypoventilation) are not considered by this policy.

4. Criteria for commissioning

Selection of cases

Patients meeting the following criteria will be funded for phrenic nerve stimulation:

Chronic ventilator-dependent patients with traumatic or non-traumatic SCI:

Who have been offered the opportunity to discuss the clinical and psychological impact of the two possible outcomes of assessment and their responses to receiving a positive or negative screening outcome. This should be undertaken by suitable trained Consultants in SCI, respiratory management after SCI, and a SCI clinical psychologist.

AND

Who have an intact functioning phrenic nerve, as confirmed by electromyographic (EMG) response of the diaphragm to nerve stimulation,

AND

Who have discussed with the implanting consultant the known risks and benefits associated with surgery and implantation and given their consent for surgery.

AND

Who are under the care of the commissioned implanting centre.

Exclusions

Patients with bulbar palsy with impaired swallowing mechanism.
Patients for whom the treating SCI centre and/or the implanting SCI centre have assessed and identified one or more of the following conditions;

Poor lung compliance

Impaired swallow

Extreme bariatric conditions

Severe enduring mental health issues

AND

Where the implanting centre considers such a condition would limit the ability of the patient to gain benefit from phrenic nerve stimulation.

Starting and stopping criteria.

Not applicable. In the unlikely scenario of a patient requesting return to life-long ventilation, the device is simply turned off. The implanted components would remain in place and are inert.

5. Patient pathway

All ventilator dependent people with SCI (C0-C4) with intact phrenic nuclei should be considered for this procedure, regardless of age or gender.

'Basic Screening' would include preparation of the patient and electromyographic (EMG) screening, and may be undertaken at the treating SCI centre.

'Full screening' would entail SCI Consultant (medical, respiratory and psychological) review of referred cases, EMG response confirmed, videofluoroscopy, magnetic stimulation, ultrasonics, and a final agreement reached for implantation. 'Full screening' would require admission to the implanting centre for a maximum of 3 full days with discharge on the 4th day (back to the current treating centre or home, as appropriate).

Where treating SCI centres opt not to undertake 'Basic screening', the 'Basic and Full screening' would be undertaken within the implanting centre within the same time scale of 3 full days.

Positively screened patients will receive detailed discussion of all aspects of the surgical and pacing procedures,

Positive cases would be scheduled for surgery within 90 days. An in-patient stay (surgery, post-surgical recovery and phrenic conditioning) typically takes 12 weeks. Patient, family and carers/nurses will be expected to attend the implanting centre undertake training in the on-going use of the pacing controller (7 days) At the end of pacer surgery and conditioning the person will return to their treating centre/home. For those returning to a SCI centre, a guarantee of bed availability on completion of the procedure will be required. Annual review of the system is undertaken for the first three years after surgery, requiring readmission on each occasion for a maximum of 2 days. The implanting centre will provide further support through telephone, outreach and/or further out-patient review as required.

Protocol

On admission after injury (All regional SCI centres)

Completion of standard American Spinal Injury Association (ASIA) assessment; identification of C0-C4 cases. (National SCI pathway indicates final identification and allocation to ASIA grading occurs at 28 days post-injury).

National SCI weaning protocol undertaken (Appendix 4).

Chronic ventilation cases identified (normally at 3 months post-injury) and possibility of phrenic nerve implantation considered by treating SCI consultant.

Treating SCI centre* or implanting centre

Initial discussion with patient (and family) regarding the possibility of pacing – initial clinical and psychological preparation of patient for positive and negative screening outcome.

Functioning of the phrenic nerve, confirmed by testing for an electromyographic (EMG) response of the diaphragm and confirmatory x-ray screening of the diaphragm during nerve stimulation. Such cases should be referred to the implanting Centre. Negative cases at 3 month's screen should be re-screened at 6 months. Positive EMG response cases referred to implanting centre.

Ambiguous cases referred to implanting centre for further assessment.

*Treating centres may wish to undertake this 'baseline assessment' or prefer the implanting centre to undertake this, in addition to their extended assessment and treatment.

Implanting centre

SCI Consultant (medical, respiratory and psychological) review of referred cases.
Preparation for final screening.

EMG response confirmed.

Videofluoroscopy

Magnetic stimulation

Ultrasonics

Final agreement reached for implantation

Surgical strategy and device to be implanted discussed and agreed.

Surgery and post-surgical management.

Pacer conditioning.

Patient / family / carer training.

Ongoing post-discharge surveillance.

Annual review.

6. Governance arrangements

This policy relates purely to those with high level SCI (C0-C4) with intact phrenic nuclei. This is a low incidence condition and implantation experience currently rests within one regional SCI centre. Once robust screening criteria are adopted nationally in all SCI centres the likely annual incidence nationally of suitable cases is likely to be 2-5 per annum. It is recommended that the current treatment centre provides the service for the national population, but specialised commissioners retain the right to consider a second site in future, dependent upon identified demand, access and geographical considerations. In these circumstances the current treatment centre would provide mentorship and training at cost to the identified second provider.

The implanting centre will have the responsibility to provide ongoing audit of activity and outcome in all implanted cases and to provide this information to specialised commissioners on demand.

Robust audit data will be used to inform future commissioning of this service.

7. Epidemiology and needs assessment

The incidence of cervical SCI is about 1 per 60,000 people per year. This is about 1,000 cervical SCIs each year in England. Approximately 20% of these occur between the levels of C1 and C4² with the majority of SCIs caused in road traffic incidents.

Up to 4% of cases of SCI require long-term artificial respiratory device to support breathing³

The national incidence and prevalence figures for SCI would indicate 40 newly injured patients per annum would require mechanical ventilatory support. Using the current implant centre data as a reference would indicate 12% of these cases would likely require lifelong invasive ventilation (whilst the remaining 88% would wean from ventilation), and that 35% of this group (4-5 people) would be suitable for phrenic nerve implantation each year.

Experience from existing UK SCI phrenic nerve implanting centre from 1981-2005¹¹ indicated that of 189 traumatic SCI cases requiring ventilation on first admission, 55 (29%) required ventilation at discharge and this need remained life-long. 19 of these 55 cases (35%) were found to be suitable for phrenic nerve implantation.

8. Evidence base

Four studies were identified that provide low level evidence for the effectiveness of phrenic nerve stimulation via a thoracic or cervical approach. One non-randomised controlled trial of 64 patients was identified.⁷ The remaining three studies were case series reporting the total experience for patients with SCI in France (19 patients)⁶, Australia (14 patients)⁴, and the UK spinal phrenic treating centre.¹¹ Better quality study designs than those identified should in principle be possible. Although blinding of participants or researchers is not possible, given the nature of the intervention, randomisation would seem plausible. Recruitment for controlled trials is, however, made difficult by the small number of patients suitable for phrenic nerve stimulators and the small number of centres worldwide that undertake this procedure.

Of the four studies, the highest quality evidence comes from the non-randomised trial, which compared 32 patients treated with phrenic nerve stimulation to a similar number maintained on mechanical ventilation⁷ who were ineligible for phrenic nerve stimulation. All patients with an intact phrenic nerve received stimulation. The comparator group were patients with a similar level cervical spine injury being mechanically ventilated but without functioning phrenic nerves. The relatively small and fragile nature of the phrenic nerve and its proximity to the cervical spine means that there may not have been an underlying aetiological difference between the injuries in these two groups. The researchers thought that the two groups were similar enough apart from their difference in phrenic nerve status for a valid comparison. However the results should be treated with some caution, as the mechanically ventilated patients were older than those treated with phrenic nerve

stimulators. In this study the possibility of confounding by indication and age remains.

Two further case series do not allow effective quantification of the effectiveness of phrenic nerve stimulation in comparison to standard care. They do offer some insights into the safety, both long and short-term, of this intervention.

In the French case series, complete diaphragmatic reconditioning, defined as able to spend 8 hours under stimulation alone without a significant (less than 10%) drop in tidal volume, occurred in 18 of 20 patients at 36 months after the procedure. All these patients reported improved quality of life with fewer respiratory infections and less need for suction. Seven of the 18 patients died by 74 months after implantation of various causes (e.g. septic shock or intracranial haemorrhage) not thought to be attributable to the procedure or stimulation). This indicates a high mortality in these patients despite phrenic nerve stimulation. Tracheostomy removal was not proposed to these patients.

Amongst 19 patients (of whom 14 had SCI) reported in the Australian series, information was unavailable for three patients. Total pacing duration ranged from 1 to 21 years with a mean of 13 years, indicating that phrenic nerve stimulation is an intervention that can be sustained and tolerated over a long period of time.⁴

The fourth study is a retrospective, long term cohort study undertaken within the current treating centre.¹¹ It describes the centres experience of survival following short and long term ventilation, and includes reference to the 19 cases who, at the time of the study, undergone phrenic nerve implantation. When analysed regardless of age, the phrenic paced group had a significantly better survival than the group who used only mechanical ventilation, but most of the patients having phrenic nerve pacing were younger than the mechanical ventilation group. When analysed according to age (15 year age bands) the mean survival time was almost 2 years better within each age grouping although the values did not reach significance.

Outcomes and Quality of Life

The main outcomes considered in the studies reviewed were survival rates, complication and infection rates and quality of life measures. Changes to speech were also assessed. The changes to quality of life and speech were self-reported.

The best evidence comes from a non-randomised comparative trial⁷ of 64 patients (32 managed by mechanical ventilation and 32 including phrenic nerve stimulation). A number of outcomes were followed. There was a trend towards improved survival with phrenic nerve stimulation, however, those treated with PNS were younger and more likely to be male, the follow-up period was relatively short (median 3.4 years) and the difference was not statistically significant.

There was statistically significant difference in the incidence of respiratory infection between the two groups. Rates of respiratory infection were equivalent at baseline. The study reported a median of 1.43 infections per 100 days of rehabilitation in the phrenic nerve stimulation group compared with 1.33 in the mechanical ventilation group. Following intervention the phrenic nerve stimulation group experienced no respiratory infections (interquartile range 0 to 0.92) whereas the mechanical ventilator group had an increased median rate of 2.07 infections per 100 days of

rehabilitation (interquartile range 1.49 to 4.19) in the second phase of this study while both groups were institutionalised.

The main reason for premature death was respiratory complications. These occurred in 10 of the 14 deaths in the mechanical ventilator group and 3 of the 9 deaths in the phrenic nerve stimulation group, this difference maybe clinically important and statistically significant, though the phrenic nerve stimulation group was younger.

Self-reporting of symptoms by patient questionnaire and assessment by clinicians indicated an improvement in quality of life and speech. Postoperative respiratory infections were significantly lower in the group treated with phrenic nerve stimulation compared to the mechanically ventilated group.

It is not possible from the evidence published to determine if phrenic nerve stimulation impacts on life expectancy.

Long-term outcomes are reported in three recent case series from France, Australia and the United Kingdom. These suggest that a median of 13 years use is possible and that patients were able to achieve tolerance of up to 24 hours continuous usage. 8 hours use is more frequently reported with mechanical ventilation support through the night for some patients. The UK study highlighted the improved life expectancy of almost 2 years, for phrenic nerve implant cases in comparison with ventilator dependent cases.

Cost Effectiveness

Hirschfield, Exner et al. 2008 in a controlled study reported from Germany that the initial cost of the phrenic nerve stimulation device was offset by reduced need for nursing care and a reduction in treatment for respiratory infections within one year of implantation. The insurance-based health system in which this study was conducted is not directly comparable to the National Health Service. No other publications were identified that reported on the costs or cost effectiveness of this device.⁷

Khong, Lazzaro et al. 2010, reported a number of device failures that required revision surgery. These costs would need to be included in any economic evaluation. In addition part time use of phrenic nerve stimulation with the continued support of mechanical ventilators would need to be accounted for in assessing the overall cost impact of deploying this device in the NHS.⁴

The UK experience to date rests within the current implanting SCI centre. During 20 years of implanting, no surgical revisions have been required, nor have their been complications with surgery or death attributable to the procedure or device. The aim of phrenic pacing is for 24 hours ventilator-free breathing, but this has been possible in only 9 of the 19 cases. The care cost savings indicated in the Hirschfield et al study are not possible in the United Kingdom as the Continuing Health Care needs of this highly dependent group require 24 hour care.

There is little overall difference between the equipment costs for establishing a person at home on 24 hour ventilation, or 24 hour phrenic nerve pacing. The initial outlay and 10 year consumable costs are summarised below, and provided in detail in Appendix 3;

Initial set up costs;

Phrenic pacing (plus back-up ventilator)	£52,873.83
Ventilator dependent patient	£10,221.33

10 year equipment and consumable costs;

Phrenic pacing	£9,223.75
Ventilator dependent patient	£39,348.40
Price differential over 10 years(per annum);	£1,252.78

The additional cost for establishing a person on a phrenic pacing system is therefore £1,252.78, but the impact on patient-reported quality of life and increased life expectancy would perhaps outweigh this slightly increased cost.

However, possibly the greatest cost saving relates to the impact of phrenic pacing on reducing respiratory infection. The Hirschfeld et al.⁸ study notes a significant reduction in respiratory infection rates for mechanical ventilation versus phrenic paced cases ($p < 0.001$). A single hospitalisation episode for respiratory infection in this highly vulnerable patient group is lengthy and costly; chest infection without consolidation (approximately 2-4 weeks); with consolidation (approximately 4-6 months). Therefore whilst this cost remains unquantifiable, given the current level of evidence, the potential cost saving and impact on patient experience and function is considerable.

9. Rationale behind the policy statement

Based on the evidence reviewed, phrenic nerve stimulation has been shown to be a safe intervention as treatment for patients with ventilator-dependent SCIs who have a functioning phrenic nerve and diaphragm muscles.

However, the effectiveness of the procedure compared to alternatives is uncertain and can only be inferred from one small, confounded non-randomised trial and uncontrolled observational data from case series. It is likely that respiratory infections are fewer in people who receive phrenic nerve stimulation than those who rely on mechanical ventilation. This may be due to the selection of fitter patients for the phrenic nerve stimulation procedure. From this evidence base it is not possible to fully inform patients of the relative benefits of phrenic nerve stimulation compared to alternative options or to quantify the long term outcomes they might expect.

Those that accept the intervention do report improvements in quality of life and welcome the independence from mechanical ventilation that becomes possible in most cases.

There are several limitations to this evidence:

The absence of any well-designed randomised trials comparing patient important outcomes or reporting quality of life for patients treated with phrenic nerve stimulation compared to mechanical ventilation.

Small numbers of patients appear to have been entered into worldwide registers for this procedure.

The specialist nature of this intervention and the fact that only one UK centres have published outcome data imply that, should it be commissioned, this procedure may only be suitable for provision in designated centres with special arrangements for clinical governance, consent, and audit or research.

10. Mechanism for funding

The service will be provided under contract as described in the SCI Currencies Handbook. Activity will be coded as follows:

Final commissioning classifications (currencies) codes to be developed further through National SCI Strategy Board Spinal Currencies sub-group.

1. Patients who transfer to implanting centre before completion of rehabilitation following injury.

'Basic screening' assessment after injury, including discussion with patient and EMG testing: undertaken within patient's rehabilitation package in treating SCI or implanting centre.	Sub-section 34 or 470/470P
Tests, surgery to implant the device, postsurgical recovery and phrenic nerve conditioning, where undertaken by a SCIC other than the treating centre. This will include all equipment tests, scans, consumables, and everything else required, apart from the cost of the phrenic nerve stimulator.	470/470P
The cost of the implant device ie purchase price of phrenic nerve stimulator.	123
Continuation of rehabilitation at previous treating SCIC. This code will apply even if the patient remains at the implanting centre for	349

more than 3 calendar months.	
Annual review: undertaken within 'MOT'.	441/441P or 611/611P

2. Patients undertaking both rehabilitation and phrenic nerve stimulation at the implanting centre:

'Full screening' assessment after injury, including discussion with patient and extended testing: undertaken within patient's rehabilitation package	Sub-section 34
Tests, surgery to implant the device, postsurgical recovery and phrenic nerve conditioning This will include all equipment tests, scans, consumables, and everything else required, apart from the cost of the phrenic nerve stimulator.	470/470P
The cost of the implant device ie purchase price of phrenic nerve stimulator.	123
Continuation of rehabilitation. This code will apply even if the patient remains at the implanting centre for more than 3 calendar months.	349
Annual review: undertaken within 'MOT'	441/441P or 611/611P

3. Patients admitted to the implanting centre from the community:

Full screening assessment after injury, including discussion with patient and extended testing	420
Tests, surgery to implant the device, postsurgical recovery and phrenic nerve conditioning. This will include all equipment tests, scans, consumables, and everything else required, apart from the cost of the phrenic nerve stimulator. This code will apply even if the patient is implanted less than 3 months after the completion of rehabilitation.	470/470P
The cost of the implant device ie purchase price of phrenic nerve stimulator.	123
Annual review: undertaken within 'MOT'	441/441P or 611/611P

No additional payment will be made for replacing external transmitters, which will be replaced by the implanting centre.

11. Audit requirements

The implanting centre will be expected to lead on the audit the process of referral and treatment of all people receiving phrenic nerve implants. Where people return to a spinal injuries centre to continue their rehabilitation the responsibility for continuing to provide audit data rests with the local treating spinal consultant or nominated deputy.

12. Documents which have informed this policy

Solutions for Public Health (SPH), and Bazian. **Phrenic nerve stimulation for spinal cord injury.** Evidence review Commissioned by the National Specialised Services Transition Team (NSSTT) in England. September 2012.

13. Links to other policies

From April 2013 the NHS CB will be responsible for commissioning in line with this policy on behalf of the population of England.

14. Date of review

October 2014

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12. RISCII SCI Weaning Protocol.

Appendix 1: 10 year costing data

Ventilator dependent patient and phrenic pacer patient.

Phrenic Pacer							
Electrode	Atrotech OY	TF4A	2	£2,850.00	£5,700.00	£0.00	£6,697.50
Implant Stimulator	Atrotech OY	RX44-27-2CL	2	£5,570.00	£11,140.00	£0.00	£13,089.50
Stimulus Controller	Atrotech OY	PX244L(GB)	1	£16,430.00	£16,430.00	£0.00	£19,305.25
Programming module	Atrotech OY	PHS240+(GB)	1	£4,020.00	£4,020.00	£0.00	£4,723.50
Module cable	Atrotech OY	MC52	1	£105.00	£105.00	£0.00	£123.38
Shield cap	Atrotech OY	SC	1	£1,950.00	£1,950.00	£0.00	£2,291.25
Engery transfer coil	Atrotech OY	TCL23	6	£105.00	£630.00	£0.00	£740.25
Energy transfer cable	Atrotech OY	PCL80	6	£35.00	£210.00	£0.00	£246.75
9V battery charger BUK9	Atrotech OY	EC109	2	£20.00	£40.00	£0.00	£47.00
NiMH 9v 150mAh battery	Atrotech OY		2	£105.00	£210.00	£0.00	£246.75
12V battery charger	Atrotech OY	LBUK12	2	£110.00	£220.00	£0.00	£258.50
Lead Acid 12V battery	Atrotech OY	L12V	3	£93.00	£279.00	£0.00	£327.83
Leather case	Atrotech OY		1	£100.00	£100.00	£0.00	£117.50
NIPPY3+ ventilator	B&D Medical	0895-0913	1	£3,300.00	£3,300.00	£0.00	£3,877.50
N3+IPPV dry circuits incl HMEF &	B&D Medical	0793 / SP1	1	£254.00	£254.00	£0.00	£298.45

trache mount (10)								
N3+ IPPV wet circ incl HMEF, auto fill & trache mount(10)	B&D Medical	0814	1	£390.00	£390.00	£0.00	£458.25	
N3+ inlet filters (pack of 5)	B&D Medical	0584	3	£7.00	£21.00	£0.00	£24.68	
							Total	£52,873.83

Initial outlay for pacer

Phrenic Pacer - 10 yearly cost								
Engery transfer coil	Atrotech OY	TCL23	10	£105.00	£1,050.00	£0.00	£1,233.75	
Energy transfer cable	Atrotech OY	PCL80	20	£35.00	£700.00	£0.00	£822.50	
Lead Acid 12V battery	Atrotech OY	L12V	10	£93.00	£930.00	£0.00	£1,092.75	
12V battery charger	Atrotech OY	LBUK12	2	£110.00	£220.00	£0.00	£258.50	
NiMH 9v 150mAh battery	Atrotech OY		10	£105.00	£1,050.00	£0.00	£1,233.75	
N3+ IPPV wet circ incl HMEF, auto fill & trache mount(10)	B&D Medical	0814	10	£390.00	£3,900.00	£0.00	£4,582.50	
							Total	£9,223.75

Ventilated							
NIPPY3+ ventilator	B&D Medical	0895-0913	2	£3,300.00	£6,600.00	£0.00	£7,755.00
N3+ external battery pack	B&D Medical	0910	2	£310.00	£620.00	£0.00	£728.50
N3+ rucksack	B&D Medical	0932	2	£85.00	£170.00	£0.00	£199.75
N3+IPPV dry circuits incl HMEF & trache mount (10)	B&D Medical	0793 / SP1	2	£254.00	£508.00	£0.00	£596.90
N3+ IPPV wet circ incl HMEF, auto fill & trache mount(10)	B&D Medical	0814	2	£390.00	£780.00	£0.00	£916.50
N3+ inlet filters (pack of 5)	B&D Medical	0584	3	£7.00	£21.00	£0.00	£24.68
Total							£10,221.33

Initial outlay for trachy patient

Ventilator - 10 yearly cost							
N3+IPPV dry circuits incl HMEF & trache mount (10)	B&D Medical		52	£254.00	£13,208.00	£0.00	£15,519.40
N3+ IPPV wet circ incl HMEF, auto fill & trache mount(10)	B&D Medical		52	£390.00	£20,280.00	£0.00	£23,829.00
Total							£39,348.40

Appendix 2: RISCI Respiratory Information for Spinal Cord Injury UK

Weaning guidelines for Spinal Cord Injured patients in Critical Care Units

Introduction

It is an unfortunate fact that Spinal Cord Injury centres have limited resources to accept ventilated patients. These guidelines are intended to aid the ventilator weaning process to enable faster transfer out of critical care areas.

Spinal cord injured patients undergo physiological changes with time which tend to enable weaning in the majority.

The weaning technique advocated by Spinal Cord Injury centres is simple but needs to be followed rigorously to achieve ventilator independence efficiently. Weaning to complete ventilator independence can take up to several months.

A few patients will remain ventilator dependant and there are processes by which verbal independence and in some, safe swallowing should be achieved.

These guidelines are aimed primarily at adults.

Background pathophysiology

Respiratory dysfunction immediately following spinal cord injury is due to flaccid paralysis of respiratory muscles both inspiratory and expiratory. The degree of dysfunction is directly related to the level of cord injury.

Lumbar cord injuries will lose some expiratory abdominal activity.

Thoracic cord injuries will additionally lose intercostal activity and will frequently be complicated by rib fractures and pulmonary contusions. Haemothoraces may be present secondary to the thoracic spine fractures.

Low cervical cord injuries will have lost all intercostal activity.

High cervical injuries may also lose diaphragmatic and scalene activity. Ventilatory failure is rapid in these circumstances.

Autonomic disruption following on from cord injuries causes excessive bronchial secretions and a tendency to bronchoconstriction.

Some respiratory afferent information is lost; patients may not feel dyspnoeic or become tachypnoeic when failing.

Respiratory failure results from ineffective ventilation from compromised respiratory muscles acting on a flaccid rib cage aggravated by intrapulmonary compliance changes and an inability to spontaneously clear secretions.

It is occasionally possible using aggressive physiotherapy techniques and non invasive ventilation to support patients until pulmonary compliance improves to the point that unsupported ventilation is possible, but more commonly ventilatory failure occurs from minutes to days post injury requiring intubation and ventilation.

The physiological processes by which weaning becomes feasible include:

Resolution of cord oedema. It is common for the neurological level to improve slightly with time which may allow use of previously paralysed respiratory muscles.

Resolution of pulmonary pathology. **Pulmonary compliance needs to be as normal as possible for successful weaning.**

Development of spasticity. Return of intercostal tone reduces chest wall compliance and improves ventilatory mechanics.

Retraining of remaining functioning respiratory muscles.

Tracheostomy

Once intubated we recommend early tracheostomy as successful early extubation is rare.

Tracheostomy simplifies weaning, abolishes the need for sedation, improves communication and enables efficient secretion clearance.

There is no preference for percutaneous over surgical tracheostomy except with unstable cervical fractures where a surgical technique may cause less vertebral movement.

Tube changes for those patients requiring long term tracheostomies may be easier following surgical tracheostomy.

8 mm internal diameter tubes are optimal in adults.

Removable inner cannulae are recommended in the early stages.

Subglottic suction tubes may be of considerable benefit.

There is no evidence of benefit for fenestrated tubes but there is evidence that they are associated with overgranulation

Pre requisites for weaning:

Good pulmonary compliance : 50 ml/cm H₂O or greater

FiO₂ < 0.4

PEEP preferably around 5 cm H₂O

Awake and cooperative. Minimal opiates. Preferably no delirium

No active sepsis

Some evidence of spontaneous respiratory activity.

Ventilator triggering does not necessarily imply useful activity.

Many patients will appear to pass spontaneous breathing trials early following injury, but rapidly develop respiratory fatigue requiring re-ventilation.

Involved staff. Weaning proceeds more efficiently if a team of interested staff take control of the process.

Initial testing.

The premise for weaning is that some respiratory activity is present but weak, and a degree of respiratory muscle retraining is required.

The easiest and most reproducible measure of lung function for this is the vital capacity (VC). In the presence of low flows and low volumes a mechanical Wrights spirometer tends to perform better than electronic spirometers.

The vital capacity manoeuvre needs to be made by a cooperative patient completely free from ventilatory support. If still on relatively high PEEP a few breaths before the measurement is performed is advised.

A vital capacity as low as 150 mls is considered adequate to start weaning. A vital capacity approaching 1000ml predicts straightforward weaning.

With cord injuries at C4 and above, if there is doubt as to whether diaphragm activity is present, apnoea testing under sedation may be performed. This may show accessory muscle activity (Nasalis, sternomastoid) when the PaCO₂ rises above 6 Kpa without diaphragmatic activity if the cord injury involves the phrenic nerves. This does not necessarily imply permanent ventilator dependence but requires retesting at a later date.

Weaning principle

Based on the initial vital capacity measurement all ventilatory support is removed for a specified time and then re-instituted for a rest period. The common term for this is ventilator free breathing (VFB).

Suggested VFB times based on VC are:

1. If VC is less than 250 mls, start with 5 minutes VFB.
2. If VC is less than 500 mls, start with 15 minutes VFB.
3. If VC is greater than 750 mls, start with 30 minutes VFB

(Southport SCI unit)

The on-ventilator rest period should be at least 1-2 hours. Trials of VFB can be repeated during day time hours, as appropriate to patient status.

Weaning progression is achieved by increasing VFB time by specified amounts dependant on the previous day's results.

It is important that the patient is not fatigued which can be estimated by re-measuring the VC at the end of the VFB period. If it is less than 70% of the pre weaning VC then either the rest period should be extended or the VFB time reduced.

For Example:

If a patient with a VC of 200 mls successfully achieves 3 episodes of 5 minutes VFB with 2 hour rest periods on day 1, with an end VFB VC of 180 mls, then increase the

VFB time by 20% (to 6 mins) for day 2. If day 2 is satisfactory increase by 20% (8 mins) for day 3.

The initial aim is for VFB up to 18 hours during daytime, but for ventilation at night, as spinal cord injured patients can have significant REM sleep hypoventilation. To assess safe VFB overnight requires either PaCO₂ or TcCO₂ monitoring.

Adjuncts to weaning.

Biochemistry and nutrition should be addressed. It is recommended that cervical cord injured patients and potential slow weaners have gastrostomies inserted.

Regular salbutamol nebulisation may improve respiratory muscle function.

VFB periods should be performed **supine, not sitting**. There is a drop of up to 20% in VC from supine to sitting, so VFB periods will be better tolerated supine. Secretion clearance should be performed prior to VFB periods. Tenacious sputum may be treated with oral/PEG carbocysteine or nebulised acetylcysteine.

There is some evidence that during rest ventilation periods, high tidal volume ventilation whilst maintaining normocarbia accelerates weaning as it may reduce atelectasis.

Tracheostomy cuff deflation.

For all spinal cord injured patients the ability to communicate is paramount to rehabilitation and reintegration. Being in a critical care unit for considerable amounts of time without easy communication is at best frustrating and can contribute to psychological morbidity.

Cuff deflation can be achieved either on or off ventilation. Not only does this enable speech but also reduces microaspiration, restores laryngeal and pharyngeal reflexes leading to resumption of safe swallowing.

Off ventilator cuff deflation during VFB for fast weaners should be considered. If a subglottic suction tracheostomy is in place then this should be aspirated, otherwise a tracheal suction catheter placed to catch pooled saliva as it passes the deflating cuff. When deflated a speaking valve should be used, (if there is sufficient insufflation leak – if not consider downsizing) preferably a Passy Muir as they have favourable mechanics for spontaneously breathing low volume patients.

The use of a speaking valve introduces an element of PEEP which may improve respiratory mechanics and reduce the development of atelectasis.

On ventilator cuff deflation should be considered for slow weaners. Ventilator settings should be adjusted to allow for the resultant leak, either increases in IPAP or inspiratory time. Many ventilators will alarm continuously with this degree of leak so a change to simpler, domiciliary type device can be considered – contact your Spinal Cord Injury centre to ask what machine they use.

Many patients develop increased leaks when asleep, requiring partial or full cuff inflation in order to achieve adequate ventilation.

Optimal practice is to change cuffed for uncuffed tubes wherever possible when cuffs can be deflated for 24 hours.

Swallowing.

Attempts at swallowing with an inflated tracheostomy cuff are never safe. It is advisable to wait until cuff deflation is achieved and enlist the advice of a speech and language therapist.

Post weaning maintenance

Patients who have successfully weaned or who are ventilator free during the day are still at risk of respiratory decompensation.

Functional residual capacity and inspiratory muscle strength continue at a reduced level.

Intermittent IPPB or manual hyperinflation are of benefit in reducing atelectasis.

Further information

All UK Spinal Cord Injury centres have someone with an interest in respiratory management. Contacts can be found at www.risci.org.uk

RISCI is a multi-disciplinary group concerned with standards of care provided for spinal cord injured patients requiring respiratory support before and during admission to a Spinal Cord Injury centre, and after discharge.

Version control

Rf/KH JR TT amended	9th May 2012	
Formatted for NSCISB	10 th May 2012	