

Considered Judgement Form

This form is a checklist of issues that may be considered by the Purchasing Guidance Advisory Group when making purchasing recommendations.

Meeting date: 9 September 2008

Topic: Intensive Exercise Programmes for Spinal Cord-Injured Individuals

Background and Purpose:

ACC currently receives requests from clients with spinal cord injuries to fund intensive semi-residential/outpatient exercise programmes following their discharge from post-acute rehabilitation. ACC currently funds post-acute inpatient spinal cord rehabilitation via the two spinal units (Auckland and Christchurch). Post-inpatient discharge, these units re-assess clients regularly. These reassessments are largely aimed at monitoring health status. There is currently no *standard* service for clients whose main desire is to engage in rehabilitation to restore physical function following hospital discharge. That said, surgery and aids are provided by the spinal units for some clients (e.g. tendon transfers, to improve function and aid recovery). It was, therefore, appropriate for ACC to review the evidence for the safety and efficacy of intensive exercise programmes that may be available for these patients; it was also appropriate to consider any individual therapeutic modalities that may be used in combination in these programmes. This included modalities that had exercise as a component e.g. Body weight supported treadmill training.

This report excluded case studies and case series of less than 10 participants, and focussed on studies reporting on walking parameter outcomes and whether these transferred to functional improvement. Studies were included irrespective of completeness of injury and at any vertebral level.

Although considered appropriate in the project brief, no studies were identified reporting on outcomes in children.

Health Technology

Distinct neuro-rehabilitative strategies and/or intensive exercise programmes

- **Massed Practice Therapy”/ Constraint Induced Therapy** – this strategy is based on the repetitive use of the affected (usually upper limb) to restore movement and function.
- **“Activity Based Recovery Therapy Programming”** - purports to activate central pattern generators within the individual’s nervous system to harness involuntary movements and modulate spasticity. Appropriate activities in this programme include body-weight supported treadmill training, cycling with electrical stimulation, robotic walking and aquatherapy.

- **“Coordinated Dynamic Therapy” (CDT)** - is the performance of repetitive rhythmical activities to recreate/restore the damaged/non-functioning neuronal connections that are present following injury or disease. This strategy is also based on the harnessing of ‘central pattern generators’. This programme uses specific equipment e.g. Giger MD.
- **“Project Walk”®** Is a customised intensive rehabilitation programme that uses an approach known as the Dardzinski Method™. It involves the patient progressing through five phases of recovery from simple muscle activation to at the other end of the spectrum, gait and functional training. This is a programme currently only offered in the United States.
- **“Reactivate”(Bruce’s Gym, Te Awamutu).** Is the only NZ based integrated programme for these clients. It is a semi-residential programme that uses a variety of therapeutic modality including electrical stimulation and treadmill training. Length and duration of the programme are tailored to the individual.
- **“Beyond Therapy Programme” (Centre for Spinal Cord Injury (CSCI® Rehabilitation Institute of Michigan):** The CSCI® describes its programme as a long-term, high-intensity, non-traditional activity-based therapy program that utilizes innovative exercise techniques to optimize recovery. These include use of the Giger MD equipment and closed kinetic chain activities, including Whole Body Vibration (WBV).

Individual therapeutic modalities

Body-weight supported treadmill training

Patients walk on a motorised treadmill with varying degrees of body-weight support via an overhead secured body harness. As the patient regains strength and voluntary limb control, the body-weight support is reduced.

An adjunct to BWSTT is the robotic gait-driven orthosis (The Lokomat®). This consists of a motorised-gait-orthosis akin to a motorised pair of lower limb callipers into which the patients' legs are placed. The callipers are computer controlled to move in a set gait pattern. The Lokomat® is used in conjunction with a standard treadmill. The patient may also have additional body-weight support via an overhead suspension system. Functional electrical stimulation may also be administered concurrently with BWSTT.

Neuromuscular Electrical Stimulation (NMS) includes the following sub-modalities: Functional Electrical Stimulation, Patterned Electrical Stimulation. Transcutaneous electrical nerve stimulation is reviewed under the PES section.

- **Functional Electrical Stimulation (FES):** is defined as electrical stimulation that is “directed at the attainment of purposeful movement such as walking or cycling”. Electrodes may be superficial or implanted. FES ambulation systems (e.g. Parastep I) consist of a number of stimulation channels, with electrodes placed over antigravity muscles in order to stimulate the muscles required for standing and/or walking. A control/stability walker is also part of the Parastep system.
- **Patterned Electrical Stimulation (PES):** is defined as electrical stimulation applied to specific muscle groups via implanted or surface electrodes to generate a muscle contraction. In contradistinction to FES, however, PES aims to produce muscle contractions that may be used to generate muscle force “such as an isometric condition”, and PES is used often to “train muscles for a subsequent FES training condition”.
- **Transcutaneous Electrical Nerve Stimulation (TENS):** is defined as electrical stimulation applied to the skin via surface electrodes to preferentially stimulate large diameter sensory fibres (e.g. Alpha fibres). By and large TENS is used for pain management purposes and is purported to largely be effective due to the gating of slow fibre pain impulse transmission at the spinal cord level (Gate Control Theory).

- **Electromyographic biofeedback (EMG biofeedback):** is a monitoring device used for a variety of neurological and musculoskeletal diseases and conditions. In rehabilitation settings it is commonly used to facilitate muscle contractions from individual muscles or groups of muscles where there is motor inhibition. Information regarding electrical activity in the body is relayed via surface electrodes and projected visually and/or auditorally back to the subject (speaker/monitor).

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency

Comment here on the extent to which the service/product/ procedure achieves the desired outcomes. Specific reference needs to be made to safety. Report number needed to treat and harm where possible, report any issues concerning the quantity of evidence and its methodological quality and the extent to which the evidence is directly applicable or generalisable to the New Zealand Population, and the degree of consistency demonstrated by the available evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence

Six distinct neuro-rehabilitative strategies and/or intensive exercise programmes were identified from literature searching. These were: 'Massed Practice Therapy'/AKA 'constraint induced therapy', 'Activity Based Recovery Therapy/Programming', 'Coordinated Dynamic Therapy', 'Project Walk®' (using the Dardzinski method), 'Beyond Therapy and 'Reactivate'.

One randomised controlled trial (RCT-Massed Practice Therapy) and three case studies (Activity Based Restoration (1) and Coordinated Dynamic Therapy (2)) reported on results for three separate programmes or neuro-rehabilitative philosophies only. The case studies identified were outside the project brief although are described briefly. It is unclear from the literature how these programmes were administered i.e. alone or in combination. Literature to date reports that CDT therapy is administered 4-5 hours per day for 3 months.

Four of the programmes offered an integrated rehabilitation programme comprising any number of individual rehabilitation modalities (Activity Based Recovery Therapy/Programming, Project Walk, Beyond Therapy and Reactivate); these programmes were customised to the patient as to which rehabilitation modalities used, how much and for how long. Programme content, frequency and duration were based on the individual's level of function as identified from lengthy assessment processes and the patients' treatment goals. Patient assessments are often undertaken by a multidisciplinary group of health professionals. It is common for such programmes to involve weeks and in some cases months of treatment. 'Reactivate' is one such programme and the only *intensive* exercise programme that is currently available in New Zealand (Bruce's Gym, Te Awamutu). Anecdotally there are a number of additional private rehabilitation providers throughout the country that offer outpatient exercise rehabilitation to spinal cord injured individuals. No information identified through general web-based searching indicated these providers adhered to specific rehabilitation philosophies or regimens.

Literature was identified and reviewed for the following individual modalities: body-weight-supported treadmill training (BWSTT), neuromuscular electrical stimulation (NMS; including PES and TENS) and EMG biofeedback. Six RCT's, two controlled trials and 18 case series were reviewed for these modalities.

Distinct neuro-rehabilitative philosophies or integrated exercise programmes

The single RCT that was identified and reviewed for this report compared the outcomes from Massed Practice Therapy (MP) and MP and somatosensory stimulation (SS). Massed Practice therapy (formerly/also known as Constraint induced therapy) involves the repetitive practice of specific movement or functional tasks by, predominantly, the affected upper limb. Results from a small sample of 10-C7 or above level incomplete spinal-cord injured subjects indicated small but significant ($p < 0.05$) improvements in hand function scores in the MP + SS group. The paper, however, was of low quality. The main criticism being an inappropriate control group; but also with non-blinded assessment, and lacked information regarding randomisation and concealment allocation.

Two case reports were identified that reported on the use of CDT with spinal cord-injured individuals.

Both were excluded from formal review as they involved <10 subjects and related to the acute-post-injury period.

Individual therapeutic modalities

The findings for these modalities are below:

- **Body-weight supported treadmill training (BWSTT)**

Some of these papers included concurrent or adjunct modalities e.g. motor driven gait orthoses (Lokomat®) and FES.

Three randomised controlled trials (RCT's), one non-randomised comparative study (two publications) and eight case series reported efficacy outcomes for BWSTT. Overall sample sizes varied from 14-89 with most clustered around the 20 subject mark. Case series' sample sizes were small ranging from 9-32, with three case series only (n=14-20) reporting functional and/or walking outcomes in any detail. Programme length varied from 8 weeks to 12 months. BWSTT was delivered concurrently with conventional therapy (one non-randomised comparative trial) and with concurrent FES to lower limb muscle groups (one RCT and three case series). The overall quality of the papers was poor. Both controlled trials (sizes (76 and 89), however were of such poor quality they have not been considered for the evidence summaries.

One RCT randomised subjects to one of four study groups: 1. overground walking (BWS overground walking (OG) with peroneal muscle stimulation (n=7)); BWS treadmill walking with physical therapist assistance (n=7); BWS treadmill training with peroneal muscle stimulation (TS) (n=7) and robotic treadmill training (Lokomat®) (n=6). All subjects' level of injury was above T10. Treadmill training was 45 minute sessions, 5 days/week for 12 weeks. Improvement in walking speed from baseline to follow-up was measured in *all* groups, with a mean increase of 55% (all groups combined) for the 6-metre walk to 37% for the two-minute walk. Only the TS (0.11-1.75m/s) and OG training groups' 6-metre walk speed (0.14-0.19 m/s) improvements were statistically significant. Study power was insufficient to compare the changes between groups at follow-up.

Whilst at first glance, the authors have chosen an appropriate methodology to investigate the impact of *different types* of treadmill training on walking parameters, this does not allow the reader to determine the efficacy as compared with usual care. This RCT was overall of poor quality with other methodological issues regarding assessor blinding and a failure to compare groups at baseline. The sample size was also small.

A further RCT assessed BWSTT with concurrent FES in a cohort of subjects with incomplete spinal cord injuries. Outcome measures were: the 6-minute walk, walking speed, stride length and steps/minute. This cohort included 9 subjects in the acute phase following injury. Results were reported for five subjects only per group (7/10 > 10 weeks post-injury). Subjects were randomised into control/intervention or intervention/control groups, the control being standard Physical Therapy 5 days/week; the intervention 5 days/week of BWSTT and FES (25 mins/max/session). Four weeks of treatment was then followed by a 4 day assessment (washout) period; the subjects then received the alternate treatment. Walking distance increased substantially for the five subjects following BWSTT and FES in the control/intervention group. The reverse was seen in the intervention/control group; greater distance was walked at the end of the control period compared with the end of the intervention period. This may reflect an additive effect of both treatment periods and therefore indicate an insufficient washout period. Results were poorly reported with a substantial amount of baseline data absent. Adverse events were not reported.

A randomised controlled trial standardly uses a control intervention which is the 'gold-standard' current treatment. Both the above RCT's, however, used multiple treatment arms with no true control. The authors justified this methodology by stating previous publications had proven the efficacy of BWSTT. The literature search undertaken for this EBH report did

not however identify literature to support this statement.

The final RCT randomised subjects into one of three treadmill training regimes (n=35 total, n=10 per group). The three trial arms were: (1) robotic-assisted BWSTT using the Lokomat®; (2) BWSTT assisted by a physical therapist and (3) overground ambulation with a mobile suspension system for safety. Complete and incomplete injuries (with some voluntary motor control in the lower limbs) only above T10 level were enrolled, with weekly treadmill training up to 90 minutes (usually 3 x 30 minute sessions) or walking up to 3km maximum per week. Results at eight weeks indicated there were no statistically significant differences between groups for Lower Extremity Motor Scale (LEMS) scores, spasticity, sitting or standing balance, Functional Independence Measure (FIM) or Walking Index for Spinal Cord Injury (WISCI) scores; despite this, data indicated some improvement from baseline to follow-up with respect to FIM, WISCI and LEMS scores across all groups (change data graphed only). This paper lacked detail regarding study design and reported results poorly. Five losses to follow-up were reported but not explained and other adverse events were not reported. Furthermore, the study included an unknown number of 'post-acute patients' (post-injury range from 14-180 days).

Eight publications reporting on seven case series enrolled subjects that were *largely* > 1 year post-injury. Two case series included an unknown number of patients in the acute and sub-acute (<80 days) phases post-injury. Of the three case series only (n=14-20) that reported functional and/or walking outcomes in any detail all demonstrated improvements in walking speeds and distance following treatment. They all, however, also involved substantially different programme durations (eight weeks -12 months). Two case series are discussed in further detail below to demonstrate the outcomes used and results seen across the studies.

One case series assessed walking outcomes following eight weeks of Lokomat® BWSTT training in 20 subjects. Significant improvements were reported in patients' 6-minute walking test scores and reductions in the 'Timed-up and go' walking test following treatment. WISCI-II scores, however, indicated two subjects only showed improvement over time (NSS[♦], p=0.22). None of the subjects who were unable to walk prior to the training regained walking ability following treatment. These are promising results in terms of walking time and distance, however, disappointing with respect to changes in functional walking ability. Eight weeks of treatment seems a reasonable treatment period, although it would be interesting to see if functional changes resulted if the programme was longer.

A further case series evaluated the effect of BWSTT following thrice weekly sessions over a longer period (12 months) in a group of 14 chronic SCI individuals. Four patients only improved their overground walking ability (by 1, 2, 2 and 4 points on the Modified Wernig scale[∞]) at 12 months. Walking speed, (0.5-1.4m/s; p<0.01) and distance (221.4-961.7m; p<0.01) did, however, significantly increase from baseline to 12 months. Again, improvements this time in walking speed and distance are seen, but transference to function did not result in the majority of subjects. Data from eight-month follow-up indicates that three of the four subjects that improved their overground walking scores from baseline to 12 months maintained these improvements at 20 months. No subjects with high levels of injury made significant progress either at 12 or 20 months.

Six further case series were reviewed, three of which included concurrent FES (quadriceps or

[♦] NSS=non-statistically significant

[∞] Modified Wernig Scale used for measuring functional walking in addition to distance, speed and body-weight support. Modified Wernig Scale; 0=No walking capability, even with help of two therapists; 1=Capable of walking <5 steps with the help of two therapists or along parallel bars; 2=Capable of walking ≥5 steps with the help of two therapists or along parallel bars; 3=Capable of walking >1 length of the parallel bars, requiring assistance to turn; 4=Capable of walking >1 length of the parallel bars, turning independently; 5=Capable of walking along railing (<5 steps) with the help of one therapist; 6=Capable of walking along railing (>5 steps) with the help of one therapist; 7=Capable of walking with a rolling walking frame >5 steps; 8=Capable of walking with canes or crutches >5 steps; 9=Capable of walking without devices >5 steps.

common peroneal nerve). Three further case series, two of which administered concurrent FES are discussed in more detail below.

Two case series by the same authors reported results following concurrent BWSTT and FES (19 and 14 subjects respectively). Both case series involved a regime of thrice weekly treatment over three months. One study reported mean overground walking speed increased from 0.12-0.21m/s ($p=0.0008$) from baseline to study end; treadmill walking speed increased from 0.23-0.49 m/s ($p=0.00003$) and LEM scores increased by a median of 3 points from baseline to follow-up ($p<0.005$). Long-term follow-up of four subjects (2 months-1 year) indicated overground walking speeds “as good” or “better” than that of their final post-study evaluations. No data, however, supports this conclusion.

The impact of BWSTT and manual therapy assistance was investigated in a group of 10 chronic incomplete spinal cord injured subjects. All but one subject improved walking function; WISCI-II scores improved from a mean of 6.4-9.8 ($p=0.027$) following an average of over 16 weeks of treatment. Six-minute walking distance also increased from a mean of 34.2-167.7m ($p<0.01$). Two subjects assessed 2.5 years following training maintained the walking gains. Adverse events were not reported.

In summary, the studies reviewed for BWSTT were consistent in reporting improvements in impairment parameters and function from baseline to varying follow-up time points (4 weeks-12 months) following treatment. Overall, however, the evidence for treatment efficacy is weak due to small samples and poor methodology and reporting. Significant heterogeneity existed across the studies in terms of populations enrolled and intervention parameters delivered; many studies also administered concurrent treatments.

One small case series only specifically considered safety aspects of BWSTT. This study reported Magnetic resonance imaging (MRI) results in the knee following 6 months of BWSTT and concurrent NMS. All 9 subjects had sustained cervical spinal cord lesions. Following six months of relatively low-level BWSTT (20-minute sessions, 2 sessions/week), four subjects were identified with radiological evidence of minor-moderate knee pathology. Three of the four were deemed clinically important. The authors acknowledged that determining whether the pathologies identified were as a result of atrophy over time or attributable to the BWSTT was difficult as pre-BWSTT imaging was not performed.

One other study (RCT) reported two withdrawals from a 4-week BWSTT training programme. Reasons for the subjects dropping out were not specified. Considering the purported risk of joint damage where muscular control is limited or absent, adverse events reporting is crucial and furthermore, with significant losses to follow-up in many studies, it is possible at least some of these were due to real adverse events.

In summary, there is weak positive evidence for the use of BWSTT for the post-acute phase after spinal cord injury. There is, however, insufficient evidence currently to conclude this is a safe intervention due to the lack of information from the trials to date.

- **Neuromuscular Electrical Stimulation (NMS)** (Functional Electrical Stimulation (FES, 10 case series), Patterned Electrical Stimulation (PES, 1 RCT) and Transcutaneous Electrical Nerve Stimulation, (TENS, 1 RCT))

Two RCT's were identified regarding neuromuscular stimulation (1 X PES, 1 X TENS). Two studies used quasi-randomisation methods, with a restricted randomisation process to ensure intervention groups were of a similar degree and level of injury. Ten case series reported results for FES interventions in this population. Three case series involved FES ambulatory systems specifically. The majority of the papers reporting on FES are for standing/walking. All studies consistently reported positive outcomes in terms of reduction in spasticity, and/or improvements in walking parameters. Functional outcomes were, however, reported in a few papers only, and only one of these employed a valid and reliable measure of function. The

quality of these papers was also poor and the samples small and populations heterogeneous.

Importantly, some BWSTT studies already discussed involve the concurrent use of FES. These studies are not considered in this section. One RCT investigated FES, however, this paper was excluded as it related to the acute post-operative period.

One RCT administered a *PES* regime over 16 weeks in a group of 39 incomplete cervical-cord injured subjects. The intervention groups (10 per group) were as follows:

1. EMG biofeedback (8 weeks) then physical exercise therapy (8 weeks)
2. EMG biofeedback (8 weeks) followed by PES (8 weeks)
3. PES (8 weeks) followed by physical exercise therapy (8 weeks)
4. Physical exercise therapy (16 weeks continuous).

EMG and NMS were applied to the biceps, triceps, wrist extensors and wrist flexors bilaterally. Exercise therapy included upper limb strengthening, mat mobility, wheelchair skills, self-care training and transfer skills. All interventions were administered thrice weekly for an unknown intensity and duration. These interventions generally targeted subjects' upper bodies. Results both at 8 and 16 weeks indicated gains in mean upper body manual muscle test scores, self-care scores, a mobility score and EMG recordings in all groups. No between-group differences were found either at 8 or 16 weeks. This study was of poor quality and involved a small sample.

An RCT methodology was used to assess the impact of either oral Baclofen or TENS on spinal cord-injured patients (n=21) receiving concurrent exercise therapy. Outcomes measured were spasticity parameters and functional independence. Interestingly, the purpose of the TENS application in this case was used with the aim of improving spasticity with potential carry over to improving physical function rather than for the purpose of improving pain. This study included some post-acute patients (mean time post-injury 11.5 months both groups, range 2-49 months). Five of the 11 subjects in the TENS group were female; all subjects in the Baclofen group were female. Subjects were randomised to eight weeks of medication (5mg increase every 3-5 days until "adequate clinical response" was achieved – maximum of 80mg/day) or TENS (bilateral tibial nerve stimulation, 15 minute sessions, once daily, maximum 15 sessions) with both groups receiving concurrent exercise therapy. Statistical and likely clinically significant improvements were seen in both groups across most variables from baseline to trial end, including FIM scores. (Baclofen group improved from 67 to 75.7; TENS=68.5 to 76.2). No statistically significant difference was seen between the two groups at last follow-up. This study is interesting in that results indicated that TENS and Baclofen both appear to have a similar positive impact on spasticity, and that this carries over into improved function. There is the question, however, whether, these improvements were at least, in part, the result of the concurrent physical therapy both groups received. Whether gender variability between the groups was important is also unknown. To identify a non-pharmacological option to assist in the management of spasticity would appear to be important, as spasticity can cause pain, result in joint contractures and contribute to the development of pressure sores. This study was overall poor quality due to randomisation and blinding issues.

Ten case series studied the effect of FES with chronic spinal cord-injured subjects. Three case series assessed the effect of the Parastep I FES ambulation system and two involved FES cycling. FES trials for standing and/or walking (including Parastep trials) involved overall, small samples (10-20 subjects). There was significant variability across all studies regarding degree of injury (complete vs incomplete) and level of injury. This would be expected for FES cycling, however, substantial variability was seen also amongst those case series using FES for standing and/or walking, including Parastep ambulation studies. Case series programme duration varied from 3 months to 4 years. Data beyond 12 months was very limited. The overall quality of these papers was low.

A small case series investigated FES for community walking. After one year, maximal

overground walking speed over 10m both with the FES orthosis had improved by 0.26 m/s ($p=0.001$; increase from 0.51-0.78m/s) and without the orthosis by 0.25 m/s ($p=0.000$; increase from 0.49-0.74m/s). Two subjects only failed to show any improvement in maximal overground walking speed. The authors also reported that subjects “reduced their dependence on walking aids”. No data, however, was provided to confirm this conclusion. This is a small study, although does provide some data that suggests the gains from FES assisted are substantial and result in walking improvements without the FES orthosis. This view conflicts with that of other researchers’ that FES walking is just an “exercise modality” and has no role in functional walking.

Further gains were demonstrated with non-orthosis walking in another case series. A statistically significant improvement in walking speed from baseline to follow-up after FES walking without the device ($n=47$, mixed cohort of spinal cord and stroke injuries) was reported (up to 180 weeks of treatment). Responses from an unvalidated questionnaire showed 73% agreed that the device helped them do the things that were important to them and 97% agreed they would like to continue FES for walking. Subjects reported that their ability to use FES long term affected by a lack of time and a lack of progress. The time and effort to don and doff the orthosis also appears to be substantial and contributed to compliance issues.

The remaining case series investigating FES concur that improvements in walking distance and/or speed (impairment gains) do in fact occur. The single study using FES for standing was undertaken with the purpose of indicating FES was a viable intervention.

Three case series only reported real-world walking ability improvements and/or improved ability to undertake functional tasks as a result of these impairment gains. The results, however, were all descriptive in nature (e.g. “all incomplete patients reported subjectively improved function and wellbeing after 3 months”) and the data to corroborate these conclusions is absent or unconvincing.

One case report and one case series addressing safety specifically with FES use were identified and three further case series reported adverse events across the NMS papers. Adverse events reported were significant; these ranged from surface burns from electrode-skin contact to bone microfracture (FES cycling) and fractures from falls (Parastep ambulation system).

Adverse events from a further small case series ($n=15$) also reported: pain from electrostimulation (1) pressure sore (1), transient ankle oedema (4), back pain (4), and four falls, one of which resulted in a sacral fracture following use of the Parastep I FES ambulation system.

In summary, there is weak but positive evidence to support the efficacy of a variety of NMS interventions in the sub-acute and chronic spinal cord population based on case series information. There is insufficient evidence currently to conclude this is a safe intervention due to the lack of information from the trials to date. Some significant adverse events have been thus far reported. Adverse events were otherwise poorly reported across this group of studies.

- **Electromyographic Biofeedback (EMG Biofeedback)**

One RCT reported the impact of EMG biofeedback as an adjunct to physical therapy training.

The purpose of trialling the EMG biofeedback in this paper was to create/encourage contraction of the muscles over which the surface electrodes were placed. Thirty-one subjects were randomised in to two groups based on their levels of injury. Both groups received 45 minutes of exercise therapy, 3 x per week and 30 minutes of neuromuscular stimulation 3 x per week to their upper body musculature for 12 weeks. The intervention group subsequently also received 3x 30 minute sessions of EMG biofeedback to their upper body musculature for 12 weeks.

Muscle strength measurements using a modified ASIA (Appendix 4 main report) muscle grading scale and an unspecified functional abilities scale (cannassing hygiene, feeding and dressing) indicated no differences between the groups at any time points, although both groups showed statistically significant improvements in both strength and function from baseline. This paper was of low quality with shortcomings with respect to blinding, concealment allocation. Adverse events were not reported.

There is insufficient evidence to support the safety and efficacy of EMG biofeedback for the purposes of improving standing/walking and or other aspects of function for individuals with chronic spinal cord injury. One RCT only was reviewed for this report. EMG biofeedback in this case was trialled as an adjunct to Physical Therapy. Adverse events were not reported although, considering the nature of the intervention are unlikely to be a significant issue.

2. Cost

Comment on any economic costs associated with this service, product or procedure

'Reactivate™': No accurate costs have been identified regarding the delivery of the integrated programme available in New Zealand. The daily rate for the 'Reactivate™' semi-residential programme offered in Te Awamutu is \$180. This presents a cost of up to \$1000 weekly if provided as suggested at 4-5 treatment days per week. The length of an individual's programme is customised and dependant on the patient's assessment findings. Commonly patients may stay for up to several weeks at a time, with further blocks of treatment planned based on progress.

BWSTT: Both spinal units have body-weight supported treadmill facilities that they use for specific purposes for specific levels of injury. This type of equipment is very costly. One system marketing its product as low cost is priced (the NUberwalker) at NZ\$20,500. It appears, however, the treadmill itself is an additional cost. Robotic gait driven treadmill systems are substantially more complex and expensive, a current quote for a base model is NZ\$ 452,310.40.

Neuromuscular stimulators for PES or non ambulatory FES conditions range from as little as NZ\$90.00. Those systems that are likely most suitable for spinal cord injured individuals are the more robust, expensive versions with a number of stimulation channels. These have been priced at over NZ\$4,000.

The cost of a **4 channel Parastep Ambulation FES** systems is currently NZ \$15,588.00 and the 6-channel, NZ\$16,897.00.

TENS machines are the cheapest of these modalities but likely to be the least useful for improving function as they are generally used for pain management in an intact nervous system. These are readily available from a number of suppliers from upwards of approximately NZ\$100.

All the *equipment* above can be used across patients in a clinic situation, with the relatively small cost of single-use electrodes for individual patients. Some public health providers hire portable neuromuscular stimulators/TENS machines to patients. This is not possible with treadmills, and patients need to live close to a provider if they seek outpatient treatment. It would be fair to say that the Parastep FES ambulation systems and Lokomat robotic driven gait orthoses are not used in New Zealand currently because of the cost.

EMG biofeedback units are commercially available in New Zealand, with costs ranging from approximately \$500-\$3700.

3. Clinical impact

Comment on the clinical impact e.g. size of population, magnitude of effect, relative benefit over other management options, resource implications, balance of risk and benefit.

There is currently a paucity of research regarding the efficacy of intensive exercise programmes for the purpose of physical functional restoration following spinal cord injury. There are a limited number

of providers of intensive rehabilitation for spinal cord injured subjects in their post-acute phase in New Zealand. This may well largely be due to both absent or unclear funding mechanisms and limited numbers of trained providers. Accessing the current provider in Te Awamutu would mean substantial travel and residential costs for any purchaser.

NMS and BWSTT are used currently to some degree in both the Auckland and Christchurch Spinal Injury Units. PES is more likely to be used than FES due to equipment costs and provider numbers. PES is for isolated muscular strength in preparation for FES training. Literature that may support the more widespread use of these modalities is not yet available.

This report did not review studies reporting these and other individual therapeutic modalities that are used for the purposes of mitigating secondary complications following spinal cord injury e.g. pressure sore development, cardiovascular disease risk. The costs involved with treating such secondary complications and the impact on the client's quality of life over the client's lifetime may mean investigating the evidence for this may be worthy. This would seem to be congruous with the vision of the ACC Rehabilitation framework.

4. Equity, Maori Health, Pacific Health, Acceptability

Comment on the extent to which the service, product or procedure reduces disparities in health status (equity of access, resources, health outcome), is consistent with the treaty of Waitangi and encourages Maori/ Pacific participation in providing and using service, product and procedures, and is consistent with values and expectations of New Zealanders.

Nil issues identified.

5. Possible Purchasing Options

List the possible purchasing options.

- Purchase integrated or individual therapeutic modalities on a case-by-case basis with clear programme parameters and regular outcome measure reporting.
- Do not purchase.

6. Evidence Statements

Summarise the advisory group's synthesis of evidence relating to this service, product or procedure, taking the above factors into account, and indicate the evidence level that applies.

- **Integrated intensive exercise programmes for clients with spinal cord injuries in the sub-acute and chronic phases:**

There is currently insufficient evidence to conclude that integrated exercises programmes for stable spinal cord injured clients are either effective or safe. Overall six programmes and or distinct philosophies were identified. One low quality RCT only was identified that reported on the efficacy of massed practice therapy.

- **Individual therapeutic modalities that are used often in combination with this population:**

Body-weight supported treadmill training (BWSTT):

There is weak evidence to support the effectiveness of a variety of BWSTT interventions with respect to improving impairment (e.g. walking distance/speed). Evidence comes from three low to moderate quality RCT's and 8 case series. The evidence is unclear as to whether functional gains (i.e. an enhanced ability to perform activities of daily living) result. The evidence is also unclear as to whether improvements of any kind are enduring.

There is insufficient evidence to date regarding the effectiveness of BWSTT with respect to determining the effectiveness of BWSTT interventions for specific:

- Levels of injury
- Pre-treatment Level of baseline physical ability
- Time since injury

This is due to the small volume of literature, intervention heterogeneity and inadequate data analysis. One small case series provides data to suggest cervical injuries appear to not make the impairment and functional gains from BWSTT as seen with lower level injuries.

The evidence for safety for all types of BWSTT is unclear. Evidence comes from one small case series specifically assessing the integrity of knees using MRI following BWSTT and concurrent NMS. Four of 9 subjects were identified with mild-moderate knee pathology.

NMS

Functional Electrical Stimulation (FES):

- There is weak evidence to support FES is beneficial for walking parameters (speed and/or distance). Evidence comes from ten relatively low quality, low sample size, case series.
- Evidence to suggest that walking speed and distance gains may also result in functional improvement comes from three case series only. Claims of functional improvement, however, cannot be adequately substantiated due to absent or unconvincing data.
- The evidence to support the safety of FES across the different interventions is unclear. There is evidence from two case series that serious adverse events have resulted from FES interventions. Both case series involved Parastep FES systems. The majority of case series, however, reported few and minor adverse events.

PES:

- There is insufficient evidence to support the safety effectiveness of PES for the purpose of improving function with sub-acute and chronic spinal cord-injured subjects. Evidence is from one small poor quality quasi- RCT that compared PES with standard physical therapy and biofeedback to the upper body over 16 weeks and one RCT involving TENS for spasticity. The TENS study was of low to moderate quality. Positive outcomes for spasticity and Functional Independence Scores as compared with Baclofen and exercise alone over an eight week period were reported.

EMG biofeedback:

- There is insufficient evidence to support the safety and efficacy of EMG biofeedback. Evidence comes from one RCT that was used as an adjunct to Physical Therapy. Adverse events were not reported.

7. Purchasing Recommendations

What recommendation(s) does the advisory group draw from this evidence?

- *Do not purchase intensive exercise programmes or the individual components of these programmes as there is only weak evidence that functional outcomes will be improved; there are also concerns about the safety of these interventions.*

