

Disability Related Health Supports - Policy Implementation

Bowel care consumables – Addendum to CAPS and SAS information

Bowel care consumables	<ul style="list-style-type: none"> Review what would be considered for NDIS funded bowel care consumables; e.g. enemas, washouts, anal plugs etc.
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This information is intended to be used in addition to the SAS and CAPS information.

Bowel care consumables

There is no specific 'bowel care consumables' subsidy scheme in Australia.

Bowel Care Australia is a Rotary initiative that provides an affordable \$15 bowel care screening kit. They do not provide consumables¹.

The CAPS 'continence consumables' payment rate for 2019-20 is up to \$609.70.

- As you do not need to provide receipts people may use this lump sum to contribute towards covering the cost of bowel care consumables as well. Often the purpose/scope of bowel care consumables and continence consumables are interchangeable.

Provide example: BrightSky Australia is your one-stop-shop for specialist healthcare products. BrightSky offers Australia-wide home delivery of an extensive range of everyday and "hard-to-find" healthcare products, including bowel care products².

A list of the bowel care consumables available through BrightSky and the associated cost can be found here on the: [Bowel Care Fibres, laxatives, enemas and bowel rinses page](#).

- In general the anal irrigation systems are the most expensive items ranging from \$149- \$368.

The issue for NDIS planners to consider is if these bowel care consumables meet the reasonable and necessary criteria when they are related to the person's disability.

- For example, a NDIS participant with a spinal cord injury, MS, CP, Spina Bifida or an ABI may require continence/bowel care consumables that are directly related to the participant's disability and are required for life.
- While for a participant with incontinence due to, for example, post-pregnancy muscle weakness, anxiety, or medication side effects, it would not be reasonable or necessary for the NDIS to fund continence/bowel consumables.

Bowel consumables pose a significant sustainability risk to the scheme if the reasonable and necessary criteria is not applied correctly. The Better Health Channel Victorian website states that:

- More than four million Australians regularly experience leakage from the bladder and bowel (incontinence)³.
- That is 1 in 6 Australians with some form of incontinence. That ratio could reasonably be assumed to be higher for the expected 460,000 NDIS participants.

¹ <http://www.bowelcare.org.au/>

² https://www.brightsky.com.au/epages/shop.sf/en_AU/?ObjectPath=/Shops/shop/Categories/About_Us

³ <https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/incontinence-and-continence-problems>



Research Request – Charcot orthotic restraint walker (CROW)

Brief	<p>We are unclear whether it is R&N for participant's already accepted into the NDIS and receiving supports to receive funding for a Charcot orthotic restraint walker (CROW) (an Assistive Technology device); potentially they may be under the Disability Related Health Supports criteria</p> <p>After discussion we would first like assistance with researching what are the arrangements in each State and Territory in terms of whether health or disability are funding the CROW's or whether perhaps neither are.</p> <p>If a funding source is identified what are the relevant eligibility criteria?</p>
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Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters

Summary

- Only the Victorian Aids and Equipment Program specifically states that the Charcot restraint orthotic walker is covered under its scheme
- All other states and territories (except the Northern Territory) have programs to assist people with accessing orthoses or specialised footwear through a loan scheme or subsidising the cost
 - **People who are eligible for the NDIS are automatically ineligible for these programs**
- These programs are most commonly administered through state health departments
- Unable to source any information on whether the Charcot restraint orthotic walker is prescribed/fitted through public outpatient or inpatient services
 - Contacted Australian Orthotic and Prosthetic Association and Australian Podiatry Associations for advice, however, did not receive a response from either organisation

Victoria

Victorian Aids and Equipment Program

The Victorian Aids and Equipment Program (VA&EP) provides eligible people with subsidised assistive technology (AT) to enhance independence in their home, facilitate community participation and support families and carers in their role. [1]

Target Population and Eligibility Criteria

To be eligible for the VA&EP applicants must meet the following criteria:

- Be a permanent resident of Victoria
- Or**
- Hold a Permanent Protection Visa or Humanitarian Visa or be an asylum seeker
- And**
- Require AT on a permanent or long-term basis for a health or ageing-related need. People with a disability who do not meet National Disability Insurance Scheme (NDIS) eligibility due to age, residency status or functional impairment level can also apply to the VA&EP
- All additional subprogram or scheme criteria, where applicable.

The following also applies:

- Department of Veterans' Affairs (DVA) Gold Card holders who do not have a DVA 'approved disability' can apply for VA&EP subsidies for a mobility scooter, a powered wheelchair and vehicle modification.
- Commonwealth Government residential aged care residents can only apply for an electronic communication device.
- Commonwealth Government levels 1 and 2 Home Care Package recipients can apply for all VA&EP assistive technology items except domiciliary oxygen. This should be part of their Home Care Package.

- Commonwealth Government levels 3 and 4 Home Care Package recipients can only apply for VA&EP subsidies for a mobility scooter, a powered wheelchair, home modification and electronic communication devices.

Ineligibility and exclusions

A person is **not eligible** to access supports from the VA&EP if:

- They are eligible to receive AT supports from other government-funded programs including the **NDIS, WorkSafe Victoria and the Transport Accident Commission**
- They live in a Commonwealth-funded aged care facility or are an inpatient in a public or private health facility
- The full cost of the AT can be claimed through their private health insurance (the VA&EP will fund any gap between the cost of the item and private health insurance refund if the gap does not exceed the maximum subsidy amount for the item)
- They have any form of compensation/legal settlements or court awards for AT. Note, in some circumstances, a person may be eligible to access the VA&EP once compensation/settlement funds for their AT has been fully expended.

What is provided?

The VA&EP provides a subsidy (a level of funding) toward the purchase price of a range of AT items. The VA&EP has set subsidy levels for different AT items. Some items have an annual subsidy limit – and some non-customised items are available at no cost.

Subsidies not provided

The VA&EP does not provide subsidies:

- For the cost of the assessment for the AT item or for the home/vehicle modification
- **Retrospectively** – the VA&EP will **not reimburse or fund** any costs associated with any AT that a person may have committed to before their application to the VA&EP has been submitted and approved regardless of their eligibility for a subsidy under the VA&EP
- For AT specifically for use at work, in an educational settings or for recreational pursuits
- For items associated with medical treatment or surgical interventions (with the exception of medical gas/oxygen, lymphoedema garments, laryngectomy items and subsequent orthoses to treat children who have a club foot but no other associated disabilities)
- To provide AT required for short periods such as post-surgery

Ownership

In relation to the SWEP the service provider retains ownership of the AT when the subsidy is more than 50% of the cost of the item.

AT items owned by the service provider that can be re-issued are provided on a long-term loan basis except in the case of:

- Home modifications
- Vehicle modifications

- Transfer aids such as ceiling hoist tracking and stair lifts, including tracking that is attached to a wall personal use items such as wigs, orthoses/shoes, lymphoedema garments and voice aids, and low-cost items such as over-toilet frames and bath seats.

The applicant can retain ownership of the asset where they contribute more than 50 per cent of the full cost of an item. As the owner of the item, the applicant is responsible for the cost of ongoing repairs, preventative maintenance and the annual electrical safety check (if applicable). In instances where an applicant wishes to own the item but the subsidy covers the full cost, the applicant must contribute more than 50% of the full cost. The VA&EP will subsidise the remaining cost.

Service Delivery

Six community service organisations are funded to administer the following VA&EP programs and schemes.

The [State-wide Equipment Program \(SWEP\)](#) is a business unit of Ballarat Health Services and is funded to administer the:

- Aids and Equipment Program
- Continence Aids Program
- Domiciliary Oxygen Program
- Supported Accommodation Equipment Assistance Scheme
- Vehicle Modification Subsidy Scheme (VMSS)
- Lymphoedema Compression Garment Program (LCGP)
- Laryngectomy Program
- Preventative Maintenance Program.

[Yooralla](#) is funded to administer the Electronic Communication Devices Scheme.

[MND Victoria](#) receives a contribution towards the cost of its equipment library for people who have motor neurone disease.

[Individual Solutions for Individual Needs](#) (Solve) is funded to design and manufacture specialised, customised equipment for eligible people.

[Expression Australia](#) (formerly Vicdeaf) is funded to administer the Smoke Alarm Scheme.

[Vision Australia Foundation](#) is funded to administer the Low Cost Vision Aids Scheme.

Orthoses

The VA&EP will fund:

- A orthosis that is custom made to modify the structural or functional characteristics of an applicant's limb
- One item per limb (where an AT practitioner requests more than one item for the same limb, the practitioner must confirm that each item is integral for the functionality of the other for the request to be considered)
- One replacement of footwear will be supplied after a minimum of 12 months, or six months in the case of a person under 18 years of age.

The VA&EP will not:

- Provide a shoe modifications subsidy in conjunction with custom-made footwear
- Fund over-the-counter aids such as; shoes; foam bands (tubular sponge protective devices) insoles/build-ups; wrist, ankle, knee braces/splints; back/hernia support or cervical collars.

Available items	Maximum Subsidy	Practitioner Qualifications
Knee-ankle-foot orthosis	\$2,200 per item	Current general AHPRA registration as an Occupational Therapist. OR Current general AHPRA registration as a Physiotherapist OR Current general AHPRA registration as a Podiatrist OR Orthotist/Prosthetist with full membership of the Australian Orthotics and Prosthetics Association.
<ul style="list-style-type: none"> • Basic lower limb; ankle, foot; knee and foot • Basic upper limb; wrist, hand; elbow; combined, static and functional • Basic spinal; lumbo-sacral or thoraco-lumbo-sacral • Charcot restraint orthotic walker • Dynamic upper limb orthoses • Dynamic ankle foot orthosis • Ground reaction force • Supra-malleolar orthosis • Functional electrical stimulation devices • Stance phase control devices • Paraplegic ambulatory device • Reciprocating gait orthosis • Brachial plexus devices • Boots and bars • Foot orthosis • Safety helmet (specialised/custom made) 	\$1,200 per item	
Specialised footwear	\$200 per item	
<ul style="list-style-type: none"> • shoe modifications 	\$200 per item	
<ul style="list-style-type: none"> • extra depth/width 	\$200 per item	
<ul style="list-style-type: none"> • custom made 	\$450 per item	

New South Wales

Aids and Equipment Program

The Aids and Equipment Program is a NSW Government initiative to assist eligible people in NSW, who have specific, short term or ongoing health needs to assist them to live and participate at home and in their community by providing appropriate AT. [2] EnableNSW implements this program on behalf of NSW Health.

Eligibility criteria

A person is eligible for EnableNSW AT programs if:

- They are a resident of NSW or Lord Howe Island, or are an asylum seeker, refugee or humanitarian visa holder residing in NSW or Lord Howe Island
- They are enrolled with Medicare
- The AT is prescribed to support a health need; and
- They are not receiving or eligible for assistive technology through a third party insurance or **other Commonwealth, state or territory government schemes** for the identified health need. Possible alternative funding sources are:
 - **NDIS**
 - Department of Veterans' Affairs
 - Australian Government aged care services
 - Compensation or damages for the condition requiring assistive technology (e.g. worker's compensation)

Orthoses

The Aids and Equipment program provides upper and lower limb orthoses and medical grade footwear under the category mobility and self-care. [2]

Western Australia

Community Aids and Equipment Program (CAEP)

The Community Aids and Equipment Program (CAEP) is funded by the State Government and administered by the Department of Communities to provide basic essential equipment for people who meet the eligibility criteria. [3]

CAEP-funded equipment and home modifications are provided to enhance the independence, function and safety of users and to assist carers in their roles.

Eligibility

In order to be eligible, individuals must have a permanent disability, live at home in the community most of the time, have a Pensioner Concession Card, Health Care Card or Commonwealth Seniors Health Card, or be a carer of a child with a permanent disability in receipt of a Carer Payment, or be able to demonstrate financial hardship.

CAEP will not fund people for equipment when it is available through other funding sources or programs such as:

- Commonwealth aged care packages
- compensation settlements that cover equipment, or
- **other Government funding programs through the Department of Veteran Affairs or NDIS**
 - For those people who have been found eligible for the NDIS, CAEP funding is available until their NDIS plan is implemented or until they move into aged care, at

which time the Department of Health becomes responsible for the provision of these supports and services.

Funded equipment

Equipment and home modifications funded by CAEP include:

- Bed equipment e.g. bed rails, pressure mattress
- Communication e.g. communication devices
- Daily living items e.g. height adjustable table
- Home modifications e.g. minor (grab rails) or major (widen the doorway)
- **Orthoses e.g. splints, surgical footwear**
- Personal care items e.g. shower chair, commodes
- Positioning and seating equipment e.g. standing frames
- Respiratory appliances e.g. ventilators
- Transfer aids e.g. hoists and transfer boards
- Walking aids e.g. walking frames
- Wheeled mobility devices e.g. manual and power wheelchairs.

Queensland

Medical Aids Subsidy Scheme (MASS)

Medical Aids Subsidy Scheme (MASS) provides funding for medical aids and equipment to eligible Queensland residents who have a permanent and stabilised condition or a disability. [4] The scheme helps people to live at home and avoid early or inappropriate residential care or hospitalisation.

Aids and equipment are subsidy funded on a permanent loan basis, through private ownership or the supply of consumables. If you pay for more than 50% of the cost for an item, you can choose to take ownership, rather than having a permanent loan. However, this means that you are responsible for all repairs to that item.

Eligibility

Administrative eligibility

The applicant must be a permanent Queensland resident and must hold one of the following eligibility cards in the name of the applicant:

- Centrelink Pensioner Concession Card
- Centrelink Health Care Card
- Centrelink Confirmation Concession Card Entitlement Form (excludes partial entitlement holders i.e. issued for travel concession)
- Department of Veteran Affairs (DVA) pensioner Concession Card (excludes DVA Gold Card holders)
- Queensland Government Seniors Card.

Clinical eligibility

- Clinical eligibility will be determined by the MASS Clinical Advisor based on information provided by the prescriber;
- The applicant has a permanent and stabilised condition or disability which impairs their ability to function independently in their home environment
- Clinical justification is documented by the prescribing health professional from a functional and clinical perspective, with regard to the applicant's prognosis, and the expected benefit to the applicant from the prescribed Assistive technology
- The applicant or carer can appropriately store and maintain the prescribed assistive technology.

Persons not eligible for MASS assistance

- Persons in receipt of assistance or funding for AT under one or more State or Commonwealth government funded programs including, but not limited to:
 - Department of Veterans' Affairs
 - National Disability Insurance Scheme (NDIS) participants;
 - National Injury Insurance Scheme (NIIS) participants
- Commonwealth residential care facility recipients, as follows:
 - for oxygen - all classifications
 - for other assistive technology - have a classification of a high rating in any domain category or a medium rating in two or more domain categories per the Aged Care Funding Instrument (ACFI) assessment as noted in the Quality of Care Principles 2014 Subsection 7 (6).
- Home Care Package
 - All Level 3 & Level 4 recipients of Aged Care (Living Longer Living Better) Bill 2013; For oxygen All Level 1 to 4 recipients
- Consumer Directed Care (CDC) high care program recipients
- Hospital in-patients
- Palliative care eligible persons
- Persons in receipt of compensation or damages in respect of their disability or engaged in a claim and have not acknowledged reimbursement to MASS for services provided when/if the claim is successful
- Children under the age of 5 years for continence pads and nappies

Approved assistive technology

Medical Grade Footwear	MASS Designated Prescriber
<ul style="list-style-type: none"> • Prefabricated medical grade footwear • Customised medical grade footwear • Custom made medical grade footwear 	Private: <ul style="list-style-type: none"> • Orthopaedic Surgeons • Vascular Surgeons • Neurologists

	<ul style="list-style-type: none"> • Medical Specialists in Rheumatology, Rehabilitation, Geriatrics and Endocrinology
Orthoses	
<ul style="list-style-type: none"> • Spinal orthoses • Lower limb orthoses 	Private: <ul style="list-style-type: none"> • Orthopaedic Surgeons • Neurologists • Medical Specialists in Rheumatology, Rehabilitation and Geriatrics

Australian Capital Territory

ACT Equipment Scheme (ACTES)

ACT Equipment Scheme (ACTES) is to assist eligible residents of the ACT who have a life-long or long-term disability to live and participate in their community with the provision of appropriately prescribed equipment, aids and appliances. [5]

Eligibility

All clients seeking assistance from the ACTES must meet all the following criteria to be eligible:

- Be a permanent Australian resident with a minimum of 6 months residency.
- Be a permanent Australian and ACT resident with a minimum of 6 months residency.
- Require assistance for a permanent disability of for a disability that has lasted for at least two years duration (as determined by the referring medical practitioner) or ne frail aged person.
- If a compensable client, agree to reimburse the ACT Government – Health Directorate in full upon settlement of the associated claim.

Financial eligibility

Clients must meet the above eligibility criteria AND the following financial criteria to be eligible for assistance:

- Under 16 years of age (birth certificate is required on initial application); or
- Over 16 years of age; and
 - In receipt of a full Australian Government Centrelink Pensioner Concession Card in their own name, for the ACT; or
 - Hold a current valid Centrelink Health Care Card in their own name, for the ACT.

Ineligibility

The client is not eligible if:

- They are an in-patient of a public or private hospital unless the equipment is required for discharge planning purposes and is approved for funding by the Advisory Committee Chairperson.
- They are able to claim the cost of the aid/equipment through a private health insurance policy. Consumers with private health insurance are required to ascertain whether their health fund will cover all, or part, of the cost of the prescribed device, before they apply to ACTES.
- **They are able to receive equivalent assistance from other government funded schemes, such as the National Disability Insurance Scheme (NDIS).**
- They are living in a residential care facility (i.e. nursing home) – some specialised and custom equipment may be considered by the Advisory Committee where the residential care facility is not required to provide, e.g. customised power wheelchair.
- If currently receiving a Department of Health Home Care package. Only equipment which is not included in the home package care will be considered for supply.
- A person with an advanced progressive disease which is determined to be palliative; hospitals are required to provide equipment for palliative care on loan for short-term use.
- Hold a current Centrelink Commonwealth Seniors Health Care Card or a Mobility Allowance Health Care Card

Equipment supplied

Types of equipment supplied by the ACTES include, but are not restricted to:

Standard and Bariatric

- Shower Chair
- Shower Stool
- Over Toilet Frame
- Toilet Surround
- Toilet Throne Accessory
- Toilet Seat Raiser
- Seat Walker with Hand Brakes or Push Down Brakes
- Tri Wheel Walker
- Manual Wheelchair
- Power Wheelchair
- Specialised Seating
- Bedside Commode
- Shower Commode
- Pressure Care Cushion
- Swivel Bather
- Bath Board
- Walking Frames
- Monkey bars (self-help poles)
- Utility chairs
- Hilite / Ataama Chairs
- Adjustable overbed/chair tables

- Medical Grade Footwear and/or Orthotic appliances
- Specialised compression garments such as Second Skin
- TheraTogs
- Electro larynx and Speech aids.

Tasmania

TasEquip

TasEquip provides equipment to eligible clients who are permanent Tasmanian residents and who have a proven financial need for assistance to access the range of equipment in scope for TasEquip. [6]

Eligibility

To be eligible, clients need to meet the following criteria:

1. Permanent Tasmanian resident, and
2. Centrelink benefit recipient – Health Care, Pensioner Concession, and
3. Living in the community, and
4. Ineligible for Home Care Package level 3 or 4, Workers Compensation, MAIB, DVA* or NDIS**.

Those who do not meet the above eligibility criteria may, in certain restricted circumstances still be able to access equipment through TasEquip. If they are unable to source the equipment privately and if either of the following apply:

1. Equipment is required for discharge from public hospital or public bed in private hospital
2. They are a client of the Specialist Palliative Care Service, or have a prognosis of less than 6 months.

Those not eligible for TasEquip should always consider the option to privately hire or purchase.

Equipment supplied

It is not clear precisely what equipment is approved/available for use.

Orthotic Prosthetic Services Tasmania

Orthotic Prosthetic Services Tasmania (OPST) is a state-wide service with facilities in Burnie (NWRH), Hobart (94 Davey St) and Launceston (LGH). OPST plays an important role in the treatment and rehabilitation of clients through the provision of orthotic, prosthetic and specialised seating services. [7]

Inpatient and outpatient orthotic and prosthetic services are provided at all three facilities.

Access to OPST is prioritised dependent upon urgency and accordingly attended to within acceptable time-frames. Clients funded through third party compensable bodies such as DVA, MAIB and Workers Compensation may also access the service.

Outpatients are seen by appointment only and require a letter or referral form to be sent by post, fax or email, so that the client's priority can be assessed and a place on the waiting list allocated.

Unclear exactly whether orthoses/CROW are funded through this clinic or patients are required to pay for the AT.

South Australia

Domiciliary Equipment Service

The Equipment Program funds and arranges equipment and home modifications for South Australians who are otherwise **unfunded for these services through Commonwealth Government options.** [8]

Eligibility

Services are provided to people who are:

- Requiring an Advanced Palliative Equipment Response (APER), or
- Aged 65 years or over, are clients of the Commonwealth Continuity of Support Programme (CoS) and already have equipment or require customised mobility equipment, or
- Adults with chronic health conditions, or
- Requiring wigs or orthoses.

Funding is not available for people who are eligible for the National Disability Insurance Scheme (NDIS).

Qualified health professionals and registered nurses' complete assessments and make equipment selections.

Foot Orthoses and Ankle Foot Orthoses

Foot Orthoses / Ankle Foot Orthoses - Prefabricated	Off the shelf orthoses that are fitted to the foot and shoe (length, width and depth may be adjusted) includes Foot Orthoses, foot-up splints and prefabricated Ankle Foot Orthoses; includes situations when the prefabricated option needs to be customised to the individual's needs
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Foot Orthoses / Ankle Foot Orthoses - Custom Made	Foot Orthoses and Ankle Foot Orthoses that are custom made to the needs and measurements of the person
Ankle and knee supports	May include shaped support banadages (e.g. tubigrip) and knee braces/immobilisers

Foot Orthoses and Ankle Foot Orthoses will be provided in the following circumstances with prescription by an Approved Prescriber and when it can be demonstrated that:

1. One or more of the following key approval criteria for equipment apply:

- **Safety:** Orthoses will minimise the risk of serious injury to the client.
- **Independence/function:** without Orthoses the client is compromised when completing daily living tasks.
- **Prevention of deterioration:** Orthoses will reduce progression of functional and or postural deterioration.
- **Potential for functional gain:** Orthoses will facilitate the client to make improvements in their functional capacity.

2. Provided as clinically required

Foot Orthoses and Ankle Foot Orthoses will be provided when the Approved Prescriber can prove they are clinically required for the client. In all situations the most cost effective method to address the concerns of the person will be implemented first. The Foot Orthoses and Ankle Foot Orthoses provided includes:

- **Foot Orthoses / Ankle Foot Orthoses – Prefabricated**
- **Foot Orthoses / Ankle Foot Orthoses – Custom Made**

3. Not Provided

- For aesthetic reasons
- When a client has had intervention by an acute care service provider (e.g. hospital) –the external service is responsible for the issue of the Foot Orthoses / Ankle Foot Orthoses (i.e. orthoses to relieve pressure from an acute wound being treated in an acute care setting).
- Foot Orthoses will not be provided to clients who are non-weight bearing.
- Repairs to any privately purchased Foot Orthoses / Ankle Foot Orthoses will not be provided by DCSI Equipment program

Northern Territory

Territory Equipment Program

Does not provide any information on orthoses or custom footwear relating to lower limbs. [9]

High Risk Foot Service

The High Risk Foot Service (HRFS) offers specialised multi-disciplinary care for people with active wound complications as a result of advanced diabetes. [10]

The team assesses and manages people who have diabetes-related foot problems such as:

- foot ulceration
- **Charcot foot**
- cellulitis
- osteomyelitis
- Acute lower limb ischaemia.

No mention as to whether AT devices/orthoses are provided through this service.

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Research – Omeo powered mobility device

The Omeo powered mobility device is being prescribed for participants as an alternative to standard power wheelchairs. The device is based on Segway technology, and is controlled through seating (core) adjustments of the user and/or hand controls.

The Agency has evidence of at least one incident where the participant has been thrown from the device, and as part of a current AAT matter, we are being requested to provide sufficient response as to why we consider the device is not safe and therefore does not meet reasonable and necessary. (The provider has stated that the incident was due to user error).

Brief

1. Can you please identify any evidence of Segway based seated powered mobility and Segway based standing powered mobility devices and identify any data regarding safety (injuries and accidents).
2. Can you please identify whether the Omeo device meets any Australian Safety Standards?
3. Can you please identify whether devices which are being used in the context of providing mobility to people with functional/physical mobility issues should be approved by the Therapeutic Goods Administration?
4. Can you identify if there are any consumer reports regarding the Omeo device?

Date	17/03/21
Requester(s)	Naomi ^{s47F - personal pr} - Senior Technical Advisor (TAB)
Researcher	Jane ^{s47F - personal priv} (Research Team Leader - TAB)
Cleared	N/A

Please note:

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2 Summary

- No information on whether the device meets Australian Standards
 - At this time, no information on safety has been provided by the manufacturer
- Device is not listed on the ARTG, however, this is due to its classification as a personalised mobility device
- Very little evidence investigating these types of seated Segway devices
 - A conference presentation and one paper show various issues relating to braking distance, safety, stability and trunk support
 - Wheelchair skills and confidence testing showed that scores in manual wheelchairs were significantly higher compared to the Nino

3 Contact with suppliers and manufactures

Spoke to [s47F - personal privacy](#) at [electric vehicles oceania](#) on 17/03/21. [s47F -](#) stated that recent changes to TGA requirements meant that personal mobility device such as the Omeo and the Genny (a very similar device) are no longer required to obtain regulatory approval. [s47F -](#) wasn't clear as to why this was but one can assume it is because they are considered personal mobility

devices rather than a medical device. ^{s47F - perso} also stated that the Genny had previously obtained TGA approval before the certification requirements were changed. ^{s47F -} did not know whether the Omeo met any Australian Standards but was keen to find out ^{s47F - personal privacy} stated that ^{s47F -} would contact [s47F - personal privacy](#) Omeo Technology.

When asked about client testimonials ^{s47F - perso} commented that 100% of those who had purchased the Omeo found them to be life changing. When asked about the lack of straps to hold the participant in the device ^{s47F -} commented that this would be worse as then the person would become stuck under the device if it were to flip/roll over. I asked a follow up question about the device rolling over and ^{s47F -} said that ^{s47F -} had heard of cases of clients falling out of the Omeo but this was due to 'misuse' of the device.

An email enquiry was sent to Omeo Technology [s47F - personal privacy](#) on 17/03/21. Still awaiting a response.

4 Research Evidence

A systematic review of the literature focusing on Segway Personal Transporter relating injuries was conducted by [1] in 2017. A total of six articles were included in the study that included data on 135 patients. Sample size per study varied from 1 to 41 patients. Studies occurred in both the emergency department and inpatient settings, including medical-surgical wards, and intensive care units. The most commonly reported injuries were orthopedic cases (n = 45), maxillofacial cases (n = 13), neurologic cases (n = 8), and thoracic cases (n = 10). Conclusions: The Segway Personal Transporter is an innovative transportation method; however, its use is associated with a wide range of injuries. Many of these injuries require hospital admission and surgical intervention, incurring significant morbidity and high costs. Due to voluntary nature of the included studies, the true incidence of Segway injuries is likely much higher.

An abstract investigating the potential hazards of the Nino two-wheeled electric auto-balancing seated vehicle was presented at the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) annual conference in 2019 [2]. The authors found a hazard relating to stopping distance. Braking requires the user to lean backwards so that the whole device tilts, good core strength/centre of gravity is required to perform this function. The braking distances of the Nino ranged from 1.5 to 6.1 m depending on speed. At higher speeds, the measurement was higher than the company's reported braking distance of 4 m. The measured and reported braking distances are also much higher than those of conventional PWCs, which have braking distances of about 1.3 m from speeds of 6 to 12 km/h [3]. "The braking distance of the Nino may be a concern for end-users and prescribers, especially depending on the use cases". During testing of the emergency braking, for an unknown reason the left wheel stopped braking causing a 90° spin. The tester had to put feet down to keep from falling [2].

The Nino has also been investigated in a single-site cross sectional study including 12 participants with spinal cord injury or multiple sclerosis [4]. The Wheelchair Skills Test and the Wheelchair Use Confidence Scale were used to compare skills across manual wheelchairs and the Nino. Scores were significantly higher for manual wheelchair compared to the Nino across all tests. Tasks participants were most challenged with included skills such as:

- Turning 90 degrees while rolling backwards

- Parallel parking
- Descending 5 and 10 degree slopes
- Picking items up from the floor
- Avoiding moving obstacles

While additional training and experience with the Nino would likely improve users' ability to do these skills, these potential limitations could have a negative impact on users' day to day activity and participation.

Several safety concerns about use of the Nino emerged from this study. For instance, researchers observed participants having difficulties stopping quickly and avoiding unpredictable obstacles. Those with higher-level injuries or decreased hand function appeared to have more difficulty with turning and fine movements. And many participant's spoke of how lack of trunk support contributed to negative impressions of safety and stability

Results from this study indicate that the Nino may not be a suitable device to replace a motorised wheelchairs at this time as it lacks the necessary adaptability, safety, and functionality required for typical users. The data suggested that the Nino may be beneficial as a tool to conserve energy during mobility related occupations, recreational or outdoor mobility device however further research must be conducted to assess this potential.

5 Assistive Technology Standards, License and Insurance

Assistive Technology Australia lists the below standards for assistive technology and licensing in NSW [5].

5.1 Standards

Some assistive technology needs to meet Australian or other standards. Standards may relate to materials, manufacturing and installation. Products that meet Australian or international standards will have written certification. To find out if a product meets Australian Standards ask the supplier to show you the certificate. For more information about standards also see http://at-aust.org/home/assistive_technology/standards.html

5.2 TGA

Many of the items on the Assistive Technology Australia website are categorised as a Medical Device. Medical devices that are approved for use in Australia have been entered into a national database called the Australian Register of Therapeutic Goods (ARTG), which is maintained by the Therapeutic Goods Administration (TGA). You can ask the supplier for the ARTG number for the device you wish to purchase and search the ARTG for the entry. To access information on the ARTG visit www.tga.gov.au

When buying a medical device it is advisable to only choose a medical device that is recommended by a healthcare professional and has been included on the ARTG.

5.3 Licence & Insurance Requirements

In NSW, motorised wheelchairs that weigh less than 110 kg and cannot travel at more than 10 km/h do not have to be registered, provided they are being used by a person with mobility problems. A person driving a motorised wheelchair under these circumstances is defined as a pedestrian under the Australian Road Rules and is permitted to travel on a footpath or nature strip adjacent to the road.

Vehicles exempt from registration are covered by the nominal defendant scheme (administered by the State Insurance Regulatory Authority) if they are at fault in an accident in NSW on a road or road-related area and cause injury to another person. However, this cover is only valid in NSW.

6 RACV Report on New Recreational Transport Devices

The Australian Road Rules specify rules for motorists, motorcyclists, cyclists and pedestrians. In the Road Rules, wheeled recreational devices and wheeled toy users are treated as pedestrians. Current regulations and safety advice is provided for recreational wheeled devices across Australia in a report by the RACV. Below will summarise the regulations/rules surrounding Segway's.

6.1 Victoria

Regulation: Segway's can only be used on private property with property owner's approval. Devices can also be used on footpaths or predetermined routes with a commercial tour operator's licence.

Safety equipment: The safety equipment requirements depend on individual tour operators.

6.2 Northern Territory

- Riders must be 12 years and above, with supervision required for those between 12 and 15 years.
- Not to be used on roadways; use is limited to footpaths and nature strips with a speed limit of 12 km/h. Segway's must adhere to the normal rules when on a footpath/shared path; i.e. keep left and give way to pedestrians.
- There are requirements for fitting a warning device (bell or horn) and wearing an approved helmet. There is a further requirement for lights when the device is used at night.
- Segways are currently exempt from registration, motor accident compensation, vehicle design standards and driver licensing requirements when ridden on a footpath or shared path. They may, however, be used on roads in specific circumstances:
 - Where there is an obstruction on the path, and the Segway travels less than 50 m on a road to avoid the obstruction
 - Where use is permitted by the relevant authority with control and management of the road, provided care is exercised.

6.3 Queensland

Individuals do not require a commercial tour licence to operate these devices. The rules surrounding their use include footpath and nature strip use only (unless there is an obstruction), minimum rider age of 12, helmet wearing at all times, prohibition of mobile phone use, and adult supervision of riders aged 12–15. The device must also be fitted with a horn or bell.

Exemptions apply in Queensland to the Australian Design Rules for Segway's and other devices that fit the personal mobility device definition.

6.4 Australian Capital Territory

The ACT permits the use of Segway's for licensed commercial tour operators. The legislation permitting Segway use stipulates that the devices be:

- Speed limited to a maximum speed of 12 km/h
- Be fitted with reflectors and warning devices
- Minimum age of 12 years
- Use of bike helmets and a minimum height requirement

There is a predetermined route and area for Segway use and additional road rules such as prohibiting pushing or towing of devices across pedestrian crossings, prohibiting riding on a dividing strip or median and complying with pedestrian road rules also apply.

6.5 New South Wales

Road rules for wheeled recreational devices in NSW are similar to the Australian Road Rules. The definition of a wheeled recreational device is also similar to that of Victoria and in the Australian Road Rules, where motorised devices are not considered wheeled recreational devices.

In NSW, motorised wheeled recreational devices (such as a Segway), regardless of output or speed, are classified as vehicles. Therefore, they require registration, licensing and third party insurance cover. As these devices do not meet the minimum requirement under the Australian Design Rules and therefore cannot be registered, and this restricts their usage to private property.

6.6 South Australia

The rules for wheeled recreational devices and the definition of these devices is similar to the Australian Road Rules. The rules state that motorised wheeled recreational devices cannot be used on footpaths, public roads or nature strips and can only be used on private property. Segway's are included in this definition and therefore it is considered illegal to use them outside of private property.

6.7 Tasmania

The rules for wheeled recreational devices and the definition of these devices is similar to the Australian Road Rules. Furthermore, motorised scooters with a maximum power output of up to 200 watts can be used on footpaths, nature strips and public roads.

Segway's can be used on public roads with a commercial tour operator licence, otherwise they can only be used on private property. In the case of tour operators, similar rules to those in Queensland apply; i.e. the device is speed limited to 12 km/h and the user must wear a helmet, and be 12 years or older. Weight and height restrictions apply. Route and other rules are also stipulated.

Motorised wheeled recreational devices with an output of more than 200 watts (regardless of top speed) are classified as 'vehicles', but as stated previously, they do not meet the requirements of the Australian Design Rules.

6.8 Western Australia

The rules for wheeled recreational devices in Western Australia are similar to the Australian Road Rules and Australian Design Rules.

Motorised wheeled recreational devices cannot be used on footpaths, nature strips or public roads. They can be used on private property.

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24 hour Postural Management Programmes

The content of this document is OFFICIAL.

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters. The researcher is not a subject matter expert.

Research question: What are the recommended features of a best practice 24 hour postural management programme for a person with a physical or neurological disability?

Date: 24/09/2021

Requestor: Brigid s47F - personal privacy

Endorsed by (requestor's EL1): Sandi s47F - personal privacy

Cleared by: Sandi s47F - personal privacy

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2. Summary

24 hour postural management (24PM) programmes are complex and multi-faceted interventions to address a variety of health and functional outcomes. Some interventions such as seating or sleep systems are frequently requested for inclusion in a participant’s NDIS plan. Delegates and TAB advisors have a dilemma when determining whether these requests meet the reasonable and necessary criteria. That is, while there is very little good quality evidence to substantiate their benefits (refer to [6. Literature Review](#)), 24PM programmes and interventions continue to be scripted and recommended by allied health professional and professional organisations. There are arguments suggesting the quality of evidence is an artefact of the complexity and individuality of 24PM programmes and therefore is not something that can be fixed by further research (refer to [4. Evidence for best practice](#)). Regardless, it is very difficult to generalise about the benefits or risks of 24PM separate from anecdotal evidence about individual interventions or small studies relating to specific interventions for specific cohorts.

3. 24 hour postural management

Postural management is “the use of any technique to minimize postural abnormality and enhance function” [5]. A postural management programme is “a planned approach encompassing all activities and interventions which impact on an individual’s posture and function.” [7]. 24 hour postural management (24PM), also called 24 hour postural care or 24 hour body positioning, is a treatment or prevention strategy that attempts to maximise a person’s function, comfort, and participation in activities over the whole day [2,4,23]. The 24 hour approach emphasises that postural support may be required for both night and day and for all activities a person engages in. This approach can be useful for anyone who is not able

to reposition themselves [5]. It needs to be implemented everywhere the person spends time. For example, supports can be implemented at home, school, workplace or care facility.

24PM programmes are individualised [7]. They can include:

- provision of assistive technology such as orthotics, adaptive seating, sleep systems or standing frames
- development of specific handling techniques
- individual therapy sessions
- active exercise
- education and training for all carers including staff, family and allied health [2,4,7].

Postural management can also involve surgery though the 24PM approach is often considered a less invasive alternative to surgery [17].

Poor body position and posture can affect bodily functions such as digestion, breathing and sleep. It can also influence capacity to complete daily activities such as eating, showering, toileting, and mobility. Correcting body position can greatly affect overall health and comfort [2,4,5]. 24PM is perceived to have a positive effect on quality of life [4].

Designing and implementing a 24PM programme is likely to be time consuming and expensive [1,4,9]. There is no research explicitly focussing on its cost effectiveness. Castle et al found that although approximately 50% of members of multi-disciplinary teams made referrals for 24PM, most of them did not know the purpose of postural management programmes [2].

4. Evidence for best practice

It is generally recognised that the quality of the evidence for the effectiveness of 24PM tends to be low and there are significant gaps in the research [1,13,17,18,20].

An early systematic review found a robust link between abnormalities of posture and physiological function including blood flow and lung capacity. The same study found evidence that physical therapy and equipment improves body position and performance, but the quality of this evidence was low to moderate [5]. Besides this 2003 systematic review, I could not find any other papers that focus on the benefits of 24PM in general. Rather, the focus is on specific interventions for specific cohorts.

Research into 24PM is difficult for a few reasons. 24PM programmes are individualised and complex, equipment / supports are interdependent and planning makes use of multiple disciplines. Implementation of the programme depends on allied health and medical professionals, the individual, their family, carers, equipment providers and funding bodies. [13,18,22]. For these reasons, randomised control trials are difficult to design and execute [8].

The lack of high quality research and the complexity of 24PM programmes means it is difficult to make judgements about best practice [11,18,24]. The contrast between the level of

evidence and the continued practice of scripting 24PM programmes has led to some push back from researchers. For example, Kittelson-Aldred and Hoffman [13] argue:

Professionally, the use of evidence-based practice is emphasized strongly, yet there is a paucity of high-level research directly supporting the effectiveness of therapeutic positioning over 24 hours in a day, especially at night. In such situations, however, an evidence-informed approach is useful. ...[E]vidence-informed practice incorporates the best available research evidence with theory, client values and choices, and practitioner clinical judgement, into the decision-making process when planning interventions.

Reivonen, Sim, and Bulley [2021] also argue that 24PM is not amenable to the particular standard of evidence defined by evidence-based practice guidelines. They suggest Realist review as an alternative that might be better suited to the complexities of 24PM [18,19].

4.1 An example: Children with Cerebral Palsy

One complexity is the need for research targeted at interventions for specific cohorts. For example, several studies have been conducted investigating the effect of 24PM for children with cerebral palsy. Drawing conclusions even about this specific cohort proves difficult.

In 2006, a group of 23 medical and allied health professionals developed a consensus statement on postural management for children with Cerebral Palsy. They recommend the use of postural management programs from soon after birth [7].

A 2009 study into the use of Chailey postural management equipment lends some weight to this consensus, finding children that use the equipment have a greater chance of less than 33% hip migration by the age of 5. The authors also found a reduction in need for surgery [17]. The research quality is affected by use of a historical control group and inability to control for variables such as changes in surgical practice.

Problematising the consensus is a 2015 Cochrane review into the effect of postural management on hip migration. The authors found no randomised control trials investigating the benefit of sleep positioning systems on hip migration. They found two studies examining the benefits of sleep positioning systems for children with Cerebral Palsy. One study found sleep systems do not affect pain levels. Both studies found sleep systems do not affect sleep quality. However, the quality of both studies was very low on the GRADE scale [1].

A 2010 systematic review into the use of standing frames by children with cerebral palsy concludes that there is some limited evidence to support the benefit of standing frame use on bone mineral density, short term changes in muscle tone and improving hip joint development. Though there is little evidence to support physiological or psychosocial benefits [Bush et al. 2010]. A 2013 systematic review endorses the beneficial effect of standing programmes for bone mineral density but notes that this may not have a follow on effect for activity or participation [15].

Goodwin et al [8] note there is reason to think that standing frames improve bone structure, function, activity and participation. However they also note that there is little strong evidence

for the benefits and little evidence that the benefits outweigh the reported and predicted disadvantages such as pain and discomfort, cost and investment of time for family and carers.

Gough looks at the use of 24PM programmes in the prevention of deformity in children with CP and notes that there is little evidence for the use of specific seating systems and that in general there is little evidence to suggest specialised seating systems improve the child's posture. He argues that the evidence for benefit of 24PM is ambiguous and concludes:

A continuous physical postural management program aimed at preventing deformity may not be needed for some children with CP and may not be effective in others. We need to define the subgroup of children with CP who may benefit [9].

5. Measuring benefits of 24 hour postural management

In the context of seating interventions, Field and Livingstone argue that an assessment of the overall benefit of 24PM interventions should account for all components of the International Classification of Functioning, Disability and Health (ICF) [6]. These components include:

- Body Functions and Structures
- Activities and Participation
- Environmental Factors
- Personal factors [12]

Field and Livingstone assessed 19 measurement scales for seating ability using COSMIN checklist and the McMaster rating system. They report poor ratings for most of the scales and note that none of the scales in use address all the components of the ICF [6].

There is an evidence base for several general tools for assessing posture. Reliability and validity have been demonstrated for The Chailey Levels of Ability [16]. The Posture and Postural Ability Scale (PPAS) is based on the Chailey scale, revised and expanded to separate the quality (body shape and alignment) and quantity (ability) of posture. PPAS is a reliable and valid measure of posture in both children and adults [21]. Inter- and intra-rater reliability has been demonstrated for Goldsmith indices of body symmetry [10].

6. Reasonable and Necessary

Current research into the effectiveness of 24PM raises concerns with support requests meeting the s34(1) reasonable and necessary criteria [14].

In particular, if there is research indicating that a 24PM programme has little or no benefit to people with physical or neurological disabilities, this makes it unlikely to meet s34(1)d. If the delegate cannot be confident that the support meets s34(1)d then they may not be able to determine if the supports meets s34(1)a-c.

While there is good evidence that posture/body position effects health and functional outcomes, the quality of the evidence for the general effectiveness of 24PM programmes on quality of life and related measures is low. This is significantly due to small sample sizes of current studies, the lack of randomised control trials and gaps in evidence for specific populations. It is worth reiterating however that while the evidence is generally of low quality, there is evidence for benefits of certain aspects of a 24PM programme. It is also worth noting that allied health and medical professionals continue to script postural programmes and refer patients to physiotherapists or occupational therapists for the development of postural programmes. Professional bodies also continue to recommend provision of these supports.

In order to determine whether a request for postural management equipment, training, exercises etc. meet s34(1)a-d, the delegate should rely on specific recommendations of treating professionals. The recommendations should include trials of equipment where possible to ascertain whether a benefit is achieved for the individual participant. Where trials are not possible (as in the case of heavily customised equipment), delegates should expect the assessor/treating professional should demonstrate how the participant's circumstances are sufficiently similar to others in which there has been a demonstrated benefit to 24PM.

In order to determine whether the support will be effective and beneficial, delegates should look for evidence of risk. For example, if there is evidence that a sleep positioning system reduces a participant's discomfort or improves their mood during the day, but reduces their quality and length of sleep, then these risks and benefits will have to be weighed by the participant and their support network.

Purported benefits of 24PM programmes include health outcomes such as alleviating breathing difficulties, assisting with sleep quality, aiding digestion and reducing risk of choking. Components of a 24PM programme can include surgery, medication, and time limited therapies. This raises the question of whether and to what extent the supports meet s34(1)f. Is the request a disability related health support? Is it more appropriately funded by state health services? Answers to these questions may depend on the primary motivation for the intervention. Is it intended more to address functional or health outcomes?

If a support is scripted and requested as part of a 24PM programme, details of the programme should be included with other evidence so that the delegate can make an R&N decision in the context of the full programme and so that the TAB advisor is able to judge the support request against R&N criteria.

7. Literature Review

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
Castle, Stubbs, Clayton, Soundy April 2014	A 24-hour postural care service: Views, understanding and training needs of referring multidisciplinary staff	International Journal of Therapy and Rehabilitation VOL. 21, NO. 3	To consider the views, understanding and training needs of members of a multidisciplinary team (MDT) around 24-hour postural care. These MDT members refer individuals with profound and multiple learning disabilities (PMLD) and postural care needs to a 24-hour postural care service.	Two phase mixed method sequential explanatory design. Phase 1: online survey of 57 multidisciplinary team members views experiences and understanding of 24 postural support. Phase 2: 14 semi-structured interviews and 3 profession specific focus groups.	Members of multi-disciplinary team generally lacked understanding of 24hr postural management but nevertheless continued to make referrals.	LOW. Small and probably non-representative sample size and the presence of possible bias in selecting study participants.
Gericke 2006	Postural management for children with cerebral palsy: consensus statement	Developmental Medicine & Child Neurology 2006, 48: 244–244	To provide a consensus statement of the best practice interventions to support posture of children with cerebral palsy including recommendations for further research	NIL	An 8 point consensus statement in which contributors agree to, on the one hand, the benefit of 24 hour postural care for children with CP and on the other hand, the need for more research and greater consensus on standards for assessing postural management programmes.	LOW. While undoubtedly evidenced based and based on clinical experience of 23 professionals, this is a policy statement rather than a clinical study.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
Stinson, Crawford, Madden June 2021	Current clinical practice in 24-hour postural management and the impact on carers and service users with severe neurodisability	The British Journal of Occupational Therapy; London Vol. 84, Iss. 6,	To investigate the use of 24-hour postural management by occupational therapists and to explore its impact on service users with neurodisability and their carers.	Two phase data gathering: 1. Online survey of 96 Occupational Therapists to get responses relating to understanding and experience of 24hr postural management; 2. Two focus groups of 4 or 5 people comprising people with a neuro-disability and carers of people with a neuro-disability to elicit discussion of understanding and experience of 24hr postural management. Phase 1 data were analysed for correlation between responses. Phase 2 data were coded, themes extrapolated and conclusions drawn.	Occupational therapists' skills in 24-hour postural management improve with frequency of use. Reliance on postural management equipment leads to service user and caregiver frustrations that need to be addressed	LOW. Phase 1 results based on adequate sample size for a population of UK OTs, but may not generalise to AUST or other regions. Phase 2 qualitative results based on small sample and themes may not generalise for other regions.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
Crawford, Stinson 2015	Management of 24 hr-Body Positioning	International Handbook of Occupational Therapy Interventions (Ed. Söderback)	To introduce 24 hr body positioning, its benefits, target patients and evidence base.	Contains sample lit review of 7 items found via database search. Larger narrative review describing the procedure, best practice interventions, additional considerations etc.	24hour positioning is essential to the care of people unable to reposition themselves. Further research is required to determine the long term benefits of the intervention.	LOW. Effectively a narrative review used as a tool to introduce OT students to the subject area.
Field, Livingstone Nov 2013	Clinical tools that measure sitting posture, seated postural control or functional abilities in children with motor impairments: a systematic review	Clinical Rehabilitation; London Vol. 27, Iss. 11	“To identify and critically appraise clinical measurement tools used to assess sitting posture, seated postural control or functional abilities for children with motor impairment who are candidates for seating interventions.”	Systematic review	“Evidence supporting reliability and validity varied, with small sample sizes influencing quality ratings. Evidence of the tools’ reliability was more prevalent than evidence of the tools’ validity. Only four tools reported on responsiveness, an important consideration for evaluating change. Little information on clinical utility was provided. Although a number of tools are available, evidence supporting their use for seating	HIGH

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
					interventions is limited, as is the evidence supporting the strength of their measurement properties. Few tools address participation, environmental factors or the child's and family's perspective."	
Robertson et al 2016	Postural care for people with intellectual disabilities and severely impaired motor function: A scoping review	Journal of Applied Research in Intellectual Disability	To map and summarize existing evidence regarding postural care for people with intellectual disabilities and severely impaired motor function	Systematic review. Studies were identified via electronic database searches covering January 1990 to March 2016, and email requests to researcher networks. Results were collated via descriptive numerical summary of studies and thematic analysis.	"The evidence base relating to postural care for people with intellectual disabilities and severely impaired motor function is small and lacking in studies that employ robust methodological designs."	HIGH
Farley et al Oct 2003	What is the evidence for the effectiveness of postural management?	International Journal of Therapy and Rehabilitation. 10/10	To provide an overview of evidence base for the link between postural management and positive health outcomes.	Systematic review organising literature into 8 themes including: physiological function, neonates and children under	Scientific quality of evidence varies according to Sackett's levels. Evidence of link physiological outcomes was	MODERATE. Methodology is reasonably strong but age of the paper means the conclusions may not be reliable,

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
				5, progressive muscular disorders, cerebral palsy, ADLs, older people, neuromuscular scoliosis, neurological disorder. Studies were assessed using Sackett's levels of evidence.	stronger than evidence for functional outcomes. However there is some reliable evidence of a benefit from postural support on activities of daily living, possibly mediated by comfort and physical enabling.	especially relating to comments on lack of high quality evidence for certain interventions.
Blake et al 2015	Sleep positioning systems for children with cerebral palsy	Cochrane Database of Systematic Reviews	“To determine whether commercially-available sleep positioning systems, compared with usual care, reduce or prevent hip migration in children with cerebral palsy. Any negative effect of sleep positioning systems on hip migration will be considered within this objective. Secondary objectives were to determine the effect of sleep positioning systems on: (1) number or frequency of hip problems; (2) sleep patterns and quality; (3) quality of life of the	Systematic review of “all randomised controlled trials (RCTs) evaluating whole body sleep positioning systems for children and adolescents (up to 18 years of age) with cerebral palsy”.	“No randomised controlled trials were found that evaluated the effectiveness of sleep positioning systems to reduce or prevent hip migration.” Researchers found two RCTs related to sleep quality of children with CP while using sleep positioning systems. However the “quality of the current evidence regarding the effectiveness of sleep positioning	HIGH

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
			child and family; (4) pain; and (5) physical functioning. We also sought to identify any adverse effects from using sleep positioning systems.”		systems for children with cerebral palsy is very low and more robust research is needed to help families and professionals make informed decisions about whether to use this intervention.”	
Humphreys et al. 2019	Sleep positioning systems for children and adults with a neurodisability: A systematic review	British Journal of Occupational Therapy, VOL 82/1	To identify and summarise studies of people with neurodisability using sleep positioning systems	Systematic review of academic and non-academic literature on sleep positioning use by people with neurodisability. Search results current at Feb 2018.	The review “found some evidence that there are potential benefits in hip stability, improved sleep quality and an improved quality of life for users that can tolerate using a sleep positioning system but the quality of the evidence is very poor. No statistically or clinically significant differences were found in respiratory function in or out of a sleep positioning system.”	HIGH

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
Stephens, Bartley, Priestly 2018	Evaluation of night time therapeutic positioning system for adults with complex postural problems	University of Salford, monograph	To evaluate the Simple Stuff Works sleep positioning system for effectiveness based on pain, physiological observations, oxygen saturation, nutrition and fluid intake, weight, Waterlow risk score, sleep score, choke risk score, skin integrity, comfort and quality of life.		Sleep system showed beneficial effects on pain, sleep, weight, choke risk, Waterlow score, food/fluid intake, depression score, medication, and analgesia.	LOW. Small sample size and difficult to generalise for the effectiveness of sleep systems as a whole. So far unpublished.
Crawford, Curran 2014	24 hour postural management for community dwelling adults with learning disabilities	Posture and Mobility, Volume 31	To investigate the clinical impact of 24 hour postural management programme on people with learning disabilities and severe motor impairment.	Survey of family and carers after provision of 24 postural management programme.	Overall positive impression of family and carers on increase in quality of life of service users.	LOW. Small sample and subjective measures.
Gough 2009	Continuous postural management and the prevention of deformity in children with cerebral palsy: an appraisal	Developmental Medicine and Child Neurology, 51	To assess the evidence for effectiveness of postural management for the prevention of deformity in children with Cerebral Palsy.	Narrative review	Postural management programs require further research. We need to determine which cohorts of children with CP will benefit from postural management and which will not. We need to redirect focus from body	LOW. Narrative review without stated method or stated criteria for assessing the evidence.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
					shape to function to promote the activity and independence of children with CP.	
Goodwin et al. 2018	Standing frames for children with cerebral palsy: a mixed-methods feasibility study	Health Technol Assess. 22(50):1–232	To determine the likelihood of a possible trial of standing equipment for children with cerebral palsy.	Survey of 551 clinicians and parents, focus groups, in depth interviews.	It is not feasible to progress to a full randomised control trial to test the effectiveness of standing frame intervention.	MODERATE. While conclusions depend on qualitative data, the phenomenon they were investigating was apt for that style of investigation. Conclusions are modest.
Holmes, Fredrickson, Brock, Morgan. 2021	The intra- and inter-rater reliability of the Goldsmith indices of body symmetry in non-ambulant adults with cerebral palsy.	Disabil Rehabil. 43(18):2640–6.	To establish intra- and inter-rater reliability of the Goldsmith Indices of Body Symmetry in nonambulant adults with CP.	17 males with CP and 48 young people without CP were tested using the Goldsmith Indices multiple times by a single clinician and multiple times by multiple different clinicians.	Good inter and intra-rater reliability for measuring thoracic shape and symmetry, pelvic orientation and hip range.	MODERATE. Presence of controls but small sample size.
Paleg, Smith, Glickman. 2013	Systematic review and evidence-based clinical recommendations for dosing of pediatric supported standing programs.	Pediatr Phys Ther. 25(3):232–47	To produce evidence based recommendations for dosing of paediatric standing programs.	Systematic review.	“Standing programs 5 days per week positively affect bone mineral density (60 to 90 min/d); hip stability (60 min/d in 30° to 60° of total bilateral	HIGH.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
					hip abduction); range of motion of hip, knee, and ankle (45 to 60 min/d); and spasticity (30 to 45 min/d).”	
Pountney et al. 1999.	Content and criterion validation of the Chailey levels of ability.	Physiotherapy 85(8):410–6	To validate the Chailey levels of ability scale.	Content validity established by appeal to data set of 38 infants and 85 children with CP. Criterion validity testing was performed by correlating the Chailey scale with Alberta Infant Motor Scale and Gross Motor Function Measure.	The study established content and criterion validity for Chailey scale.	MODERATE. Some discrepancy in establishing criterion validity.
Pountney et al. 2009	Hip subluxation and dislocation in cerebral palsy - a prospective study on the effectiveness of postural management programmes.	Physiother Res Int. 14(2):116–27	To investigate the effectiveness of early postural management programmes on hip subluxation and dislocation in children with CP.	Group of 39 children with CP commenced using postural supports. Xrays of children’s hips and 30 and 60 months. Compared with rates of hip problems in control group.	Early use of postural management programmes can assist in reducing number of hip problems and need for treatment in children under 5 years old.	MODERATE. Historical control present but could not control for missing data and changes in surgical practice.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
Rodby-Bousquet, Persson-Bunke, Czuba.	Psychometric evaluation of the Posture and Postural Ability Scale for children with cerebral palsy.	Clin Rehabil. 2016;30(7):697–704	“To evaluate construct validity, internal consistency and inter-rater reliability of the Posture and Postural Ability Scale for children with cerebral palsy”.	29 children with CP were tested by 3 different clinicians using the Posture and Postural Ability Scale.	“The Posture and Postural Ability Scale shows high psychometric properties for children with cerebral palsy, as previously seen when evaluated for adults. It enables detection of postural deficits and asymmetries indicating potential need for support and where it needs to be applied”	LOW. Reasonable sample of test subjects but very small number of clinicians testing the measure.

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9. Version control

Version	Amended by	Brief Description of Change	Status	Date
0.1	AHR908	Draft research paper focussing on effectiveness of 24 hour postural care programmes.	DRAFT	2021-09-13
0.2	SLL928	Cleared	DRAFT	2021-09-24
1.0	AHR908	Position paper and literature review on the effectiveness of 24 hour postural management programmes	APPROVED	2021-09-24

Rotating Beds

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Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters.

Research question: What are the benefits of a rotating/powered turning bed compared to manual night-time repositioning for people who are unable to reposition themselves overnight?

Date: 23/12/2021

Requestor: Brigid s47F - personal privacy

Endorsed by (EL1 or above): Sandi s47F - personal privacy

Cleared by: Megan s47F - personal privacy

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2. Summary

For people who are unable to reposition themselves at night, a carer may assist to help them to adjust their positioning. There is limited research on the benefits of night-time repositioning for people with disabilities, except in the acute stages of an injury such as Spinal Cord Injury where the person is generally unable to leave their bed and is likely in hospital. Continuous Lateral Rotation Therapy (CLRT) is the use of a bed which automatically moves a person from side to side and is most commonly used in hospitals for critically ill patients in intensive care. CLRT is only likely to be beneficial for participants who are unable to be safely repositioned by a carer due to a safety risk to the carer or participant. Manual repositioning is more beneficial as the carer can move the participant into a greater variety of positions (supine, side and prone). Many participants who are unable to reposition themselves at night may not be required to adjust their position, with other supports such as wheelchair tilt/recline systems, standing systems and recliner chairs enabling them to change positions throughout the day and therefore reduce the chance of developing pressure ulcers. Guidelines recommend that regular repositioning at two hour intervals is only required when the person is in the acute or rehabilitation stages.

3. Patient Repositioning

People who are unable to transfer from their bed due to their disability or because they are critically ill in hospital benefit from being regularly repositioned to prevent pressure ulcers forming and to reduce the risk of respiratory complications such as pneumonia [1]. Continuous lateral rotation therapy (CLRT) is the use of a moving bed which automatically shifts a person from side to side. It is most often used in hospitals for critically ill, immobile patients in the intensive care unit [1].

4. Continuous Lateral Rotation Therapy

Research on the benefits of CLRT primarily focuses on critically ill patients in hospital intensive care units [1]. Although no research specifically on CLRT for people with disability was found, in this section we discuss how the benefits of CLRT to critically ill patients may relate to people with disability. The primary benefits of CLRT for critically ill hospital patients are prevention of pressure ulcers and prevention of respiratory complications [1].

4.1 Prevention of Pressure Ulcers

For people with disability, regular repositioning can reduce the chance of developing pressure ulcers, with people with disability who have limited mobility benefiting from regular standing, adjusting the tilt/recline position of their wheelchair, and regular repositioning at night [2,3,4]. Although there are no studies investigating the benefits of CLTR for people with disability, the effects of CLTR on the risk of pressure ulcers has been investigated in the context of a critically ill hospital patient [5]. In people who are healthy and do not have a disability, CLTR

has been found to reduce pressure on the ischial tuberosities (part of the pelvis), therefore possibly reducing the risk of pressure ulcers developing around the buttocks or sacrum [6]. However, the results are less clear in studies on critically ill hospital patients. A literature review investigating the impact of regular repositioning and pressure ulcers found that there is no clear evidence that regular repositioning reduces the risk of developing pressure ulcers [7]. There is also limited evidence that for people over 60, CLTR may speed up the healing time of pressure ulcers [8]. It is possible that the results from these studies could differ for people with disability who are at increased risk of developing pressure ulcers such as people with Spinal Cord Injury (SCI) [9].

There is evidence that regular repositioning in bed is beneficial for people with disability who have limited mobility, particularly people with SCI, to prevent pressure ulcers [4]. The Clinical Practice Guideline for Pressure Ulcer Prevention from the Journal of Spinal Cord Medicine recommend that in the acute and rehabilitation phases of SCI, patients should be turned every two hours to prevent pressure ulcers forming [4]. The technique used to reposition the patient is important to prevent friction on the bed causing skin breakdown. Using lifting devices such as hoists can prevent skin breakdown due to friction. Poor turning and transfers can also be ineffective at reducing the risk of pressure ulcers if done incorrectly [4]. As these guidelines recommend that skin is inspected between turns to ensure that skin breakdown is minimised, pillows or wedges should be used and the patient should be positioned in all body positions if tolerated (supine, side, and prone). CLRT may not be suitable for these patients. CLTR can only rotate the patient laterally and cannot adjust their position from supine to side and prone positions.

Once the person with SCI is beyond the acute and rehabilitation phases, regular repositioning during the night is no longer required [4]. Many other supports such as standing frames, power wheelchair standing systems, and wheelchair tilt/recline systems can reduce the risk of developing pressure ulcers [2, 3]. These supports also offer additional benefits for people with disability such as increased independence and social and community participation [2, 3].

4.2 Prevention of Respiratory Complications

For critically ill hospital patients, prolonged immobilisation increases the risk of respiratory complications such as pneumonia, particularly in patients who are mechanically ventilated [1]. A recent systematic review and meta-analysis found that CLRT is an effective method of preventing pneumonia in critically ill patients [1]. This is likely to be because continuous rotation reduces the amount of fluid in the lungs, improves the ventilation-perfusion relationship [10] and reduces the chance of lung collapse [11].

For some people their disability puts them at higher risk of respiratory complications. For example, pneumonia is one of the most common causes of death in children with Cerebral Palsy (CP) as some people with CP have reduced cough reflexes and aspirate more frequently due to impaired swallowing mechanisms and gastro-oesophageal reflux [12]. For people with CP, respiratory symptoms are managed through use of a Continuous Positive

Airway Pressure (CPAP) machine and/or a feeding tube [12, 13]. Similarly, people with cervical SCI are prone to respiratory infections such as pneumonia due to dysphagia which can lead to aspiration [14]. Additionally, for people with SCI in the early stage of their injury, repositioning can assist to reduce the risk of pneumonia [15]. For people with cervical spinal cord injury with dysphagia, early implementation of a PEG feeding tube can reduce the risk of pneumonia [14]. Risk of respiratory infections is also higher for people with other disabilities such as stroke and muscular dystrophy due to dysphagia [16, 17].

Many people with disability who are at higher risk of respiratory complications such as pneumonia are at greater risk due to frequent aspiration [12, 14, 16-17]. This is a different mechanism to critically ill hospitalised patients who are at risk of respiratory complications due to factors such as prolonged immobilisation, mechanical ventilation, and because they are critically ill [1]. It appears that regular bed repositioning only has respiratory benefits for patients in the acute stage of their injury and are unable to leave their bed and likely in hospital [15]. It is therefore unlikely that CLTR would be beneficial to prevent respiratory complications for people with disability unless they are in the acute stages.

5. Conclusion

As the majority of research on CLTR focuses on critically ill hospital patients, it is challenging to determine the benefits for people with disability. The respiratory benefits of CLTR in intensive care units is unlikely to be relevant to many people with disability unless they are in the acute stages of an injury (such as SCI, stroke, acquired brain injury) and are unable to reposition or transfer from a bed.

Both critically ill hospital patients and some people with disability, particularly people with SCI, are at increased risk of pressure ulcers due to prolonged immobilisation [1, 9]. It is important to note that critically ill hospital patients do not mobilise during the day and without CLTR or conventional patient repositioning are in a supine position 24 hours a day. In contrast, many people with disability who have limited mobility are able to mobilise when they are not sleeping by using Assistive Technology such as manual and power wheelchairs, or with assistance from carers. They are also able to reposition by using supports such as standing frames, standing systems, wheelchair tilt/recline systems, wheelchair elevating leg rests, or recliner chairs. These supports can reduce the risk of pressure ulcers [2,3]. Supports such as carers and hoists can assist with transfers to and from the bed if the person is unable to transfer independently. The Clinical Practice Guidelines from the Journal of Spinal Cord Medicine outline that repositioning should be used during the acute and rehabilitation stages of an injury, but do not mention bed repositioning during sleep being used after this point for people with SCI [4].

If a participant is unable to leave their bed, such as if they are in the acute or rehabilitation phases of a disability such as a stroke, SCI, or acquired brain injury, they will need to be repositioned regularly to reduce the risk of pressure ulcers forming [4]. The Clinical Practice Guidelines from the Journal of Spinal Cord Medicine specify that repositioning should include

inspection of the skin for signs of damage, the use of pillows or foam wedges, and all body positions should be used if the patient is able to tolerate all positions [4]. It is therefore unlikely that CLRT would be as beneficial as manual repositioning as the participant is unable to be positioned on their side or in a prone position using CLRT. However, risk of injury to the carer(s) repositioning the participant must be taken into account. Factors such as the patient's weight may make it unsafe for a carer to reposition the participant [18]. Assistive Technology such as hoists can assist in making repositioning safer for the participant and carer [4]. If the participant unable to be safely repositioned in bed even with the aid of Assistive Technology such as hoists, a CLRT would possibly be appropriate to reduce the risk of pressure ulcers due to evidence that CLRT significantly reduces pressure on the pelvis [6]. However it may not be as effective as manual repositioning [4]. It is important to note that CLRT also increases the pressure in the heels, so heel-protection devices (for example heel pressure relief boots or heel elevation cushions) may be required to prevent pressure ulcers developing on the feet if CLRT is regularly used [6].

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7. Version control

Version	Amended by	Brief Description of Change	Status	Date
1.0	MBK223	Research paper investigating the benefits of rotating beds.	Approved	23/12/2021

Safety of front versus second or third row vehicle conversion for wheelchairs

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The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters

Research question: Is it less safe to sit in the front passenger or driver position of a vehicle in a wheelchair, compared to second or third row?

Date: 05/10/2021

Requestor: Sally s47F - personal privac

Endorsed by (EL1 or above): Nicole s47F - personal privac

Cleared by: Felicity s47F - personal priv

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2. Summary

Wheelchair users who are unable to be transferred into car seats require car modifications to be safely transported while seated in their wheelchair. Passengers who are seated in a wheelchair are more likely to be involved in crashes and experience non-crash related injuries than passengers seated in car seats.

The Australian Transport Safety Guidelines for People with a Disability and the NSW Guidelines for Modifying Vehicles for People with Disability outline guidance for vehicle modifications for wheelchair seated passengers based on the Australia/New Zealand requirements for Technical Systems and Aids for People with Disability.

None of these guidelines specifically recommend that the front or back car seats are safer for a wheelchair seated passenger. However, they outline important considerations for deciding where a wheelchair seated passenger should be positioned in a vehicle, such as the amount of head room, the size and model of the wheelchair, the type of vehicle, and the preference of the wheelchair seated passenger.

Research shows that the front passenger seat is safest for those seated in car seats aged over 15 as airbags prevent serious injury for older passengers, however there are no studies specifically investigating the differences in risk of injury between front and rear seated wheelchair passengers. Limited evidence suggests that airbags are beneficial for many adult wheelchair seated vehicle occupants.

Due to the lack of research on the impact of seat position on safety for wheelchair seated passengers, it is most important to focus on ensuring that the vehicle modification complies with the AUS/NZ requirements for Technical Systems and Aids for People with Disability. The position of the wheelchair seated passenger in the vehicle should be in a position where the safety requirements are best met, which may be in either the front or back rows depending on factors such as the model of the wheelchair and vehicle.

3. Vehicle transportation safety issues for wheelchair passengers

When travelling in a vehicle it is safest to be seated in the original equipment manufacturer's seat [1]. However, some people with disability who use wheelchairs are unable to transfer into a car seat or are required to remain in their wheelchair for posture support [2]. These passengers enter and travel inside the vehicle while remaining seated in their wheelchair, with the wheelchair secured to the car using a four-point strap tiedown system [3] or a wheelchair docking system [4].

Vehicle drivers and passengers who remain in their wheelchair are more likely to be involved in crashes than those who transfer to standard vehicle seats [1]. Wheelchair passengers are also more likely to experience non-crash related injuries, particularly in private vehicles [1].

The most common causes of serious or fatal injuries to passengers seated in wheelchairs are improper, incomplete or non-use of seat belt restraints [5], and incorrect wheelchair securement [6]. Improper seat-belt use can be due to wheelchair designs that make positioning the seatbelt properly difficult, or inadequate training of wheelchair user or caregiver on the procedure for properly positioning seatbelts [5]. Wheelchair seated passengers are also at greater risk of serious injury if they are facing sideways or backwards [3].

4. Wheelchair seated passenger safety guidelines in Australia

4.1 NSW Guidelines for Modifying Vehicles for People with Disability

According to the NSW Guidelines for modifying vehicles for people with disability, a wheelchair occupant must be secured using the vehicle's original seatbelt, with the frame of the wheelchair restrained separately [7]. The Wheelchair Tie-down and Occupant Restraint System (WTORS) must comply with the Australian/New Zealand guidelines, including:

- OEM seatbelts incorporating pre-tensioners should be retained as part of a vehicle's supplementary restraint system if the modification allows.
- A lap-only seatbelt should not be fitted where the WTORS is replacing an occupant seat that was previously fitted with a lap-sash seatbelt.
- Adequate space for forward head excursion, that being:
 - 950mm when used with a lap-only seatbelt
 - 650mm when used with a lap-sash seatbelt.
- The wheelchair's own postural support shall not be used unless certified as a wheelchair anchored belt restraint.
- Seatbelts and restraints shall be kept clean and coiled within the retractor when not in use.
- Seatbelt and WTORS webbing shall be protected from sharp edges or protrusions.
- A WTORS release mechanism should be within reach of the wheelchair occupant and marked or labelled to assist the user.
- Seatbelts and WTORS should be able to be released using one hand.

The guidelines outline that a wheelchair docking system can also be used to secure the wheelchair inside the vehicle. The docking system must comply with the AUS/NS standards

and be compatible with the passenger's wheelchair. A headrest and backrest with enough strength to reduce risk of injury in the event of a crash is also required.

4.2 Australian Transport Safety Guidelines for People with a Disability

The Transport Safety Guidelines for People with a Disability outlines a checklist for key considerations when deciding the type of vehicle modification to suit a wheelchair user's needs [8]:

- Overall height of the person sitting in the wheelchair, e.g. top of head to ground. Check door opening and height.
- Does the wheelchair need additional room to be restrained (is wheelchair longer/wider than most?).
- Where the passenger would like the wheelchair passenger to be positioned in the vehicle.
- Number of other passengers to travel in the modified vehicle with the wheelchair passenger.
- Positioning of rear compartment seats in relation to the wheelchair position.
- Position of wheelchair passenger in relation to other fittings in the rear compartment e.g. air conditioning vents.
- Door opening height of garage/carport.
- Clear area for wheelchair passenger to enter/exit the vehicle.
- Is rear or side access best for your needs?

5. Safety of front row versus back row seats for wheelchair seated passengers

Both the NSW and Australian Transport Safety guidelines offer no specific recommendation for whether the front passenger or back row seats are safer for wheelchair seated passengers [7,8]. The only specific recommendation for seating position in these guidelines is that wheelchair seated passengers should face forward. These guidelines outline many considerations when deciding how to modify a car for a wheelchair seated passenger, including the preference of the wheelchair user, the number of passengers travelling in the modified vehicle, the height of the wheelchair user, the car model, and the position of the wheelchair passenger relative to other fittings in the car. These different considerations would likely mean that the safety difference between the front and the back seats would depend on many factors such as the car model, the wheelchair model, and the passengers using the vehicle.

There is a lack of research on the impact of seat position on safety of wheelchair seated passengers. Most research on vehicle transport safety for wheelchair seated passengers focuses on comparing the effectiveness of different wheelchair restraint systems, different wheelchair models, and the use of seatbelts [5-6, 9-14]. For car seated passengers in cars manufactured after 1996, front seats are safer than back row seats for occupants over 15 years old, and back row seats are safer for passengers 15 years and younger [15]. It is not known if these results are the same for wheelchair seated passengers. The difference in safety between front and back row seats for car seated passengers is due to the deployment of airbags in the front seats, but not back seats, in the event of a crash. Airbags prevent serious injury for older passengers but can cause injury in children [16].

The Australian Transport Safety Guidelines provide no guidance around airbags for wheelchair seated passengers [8]. The NSW guidelines state that an exemption from the NSW Road and Maritime services is required if airbags are deactivated or removed as part of a vehicle modification [7]. There is no research investigating the effectiveness of airbags for wheelchair seated passengers, however there is one study which investigated the effectiveness of airbags for wheelchair seated drivers [17]. This study found that airbags are generally effective at reducing the risk of head and neck injuries for wheelchair seated drivers, however the airbags can cause serious injury if the driver is required to sit very close to the airbag module in order to operate the modified vehicle. It is therefore possible that airbags could be beneficial for adult wheelchair seated passengers if they are not seated too close to the airbag module. It is important to note that this study only investigated frontal impact crashes in one car model and one wheelchair type, so further research is required to confirm if airbags are effective for all wheelchair seated vehicle occupants under different crash conditions [17]. This study also only investigated the effectiveness of airbags on adults in wheelchairs, however it is likely that if airbags cause injury to car seated children aged 15 and under [16], they could also cause injury to wheelchair seated children.

Due to the lack of research on the impact of seat position on safety for wheelchair seated passengers, it is most important to focus on ensuring that the vehicle modification complies with the AUS/NZ requirements for Technical Systems and Aids for People with Disability to ensure that the passenger is safe [7,8]. This includes the correct amount of head room, correct Wheelchair Tie-down and Occupant Restraint System and seatbelt, and ensuring that the wheelchair is facing forward. The position of a wheelchair seated passenger in the vehicle should be where the safety requirements are best met and considers the preference of the passenger. The safest position in the vehicle may be in either the front or back rows depending on factors such as the wheelchair model, vehicle model, and the vehicle passengers [7,8]. The location of airbags and may also be considered when deciding seating position, with some evidence suggesting that airbags can prevent serious injury for wheelchair seated adults [17] but are known to cause injury to car seated children aged 15 and under [16].

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7. Version control

Version	Amended by	Brief Description of Change	Status	Date
0.1	MBK223	First draft	First Draft	12/10/2021
0.2	AHR908	Comments and revisions	-	12/10/2021
0.3	MBK223	Interim Revisions	Second Draft	12/10/2021
1.0	FFM634	Final revisions	Final Version	23/11/2021

Alternative seating system for wheelchair users

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Please note:

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The Research Team are unable to ensure that the information listed below provides an accurate and up-to-date snapshot of these matters.

Research question: What are the benefits of a secondary or alternative seating system for a wheelchair user with tilt, recline and standing features in their primary mobility device?

Date: 19/01/2022

Requestor: Brigid s47F - personal privacy

Endorsed by (EL1 or above): Sandi s47F - personal privacy

Researcher: Aaron s47F - personal privacy

Cleared by: Illya s47F - personal privacy

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2. Summary

NDIA receives requests for secondary or alternative seating systems for participants who use wheelchairs as their primary form of mobility and seating. Alternative seating systems might be requested to meet the pressure care needs of the participant, to meet their postural needs or to provide a comfortable and supportive seating option.

There is disagreement about whether alternative seating systems are generally reasonable and necessary and what kind of evidence is required to demonstrate compliance with section 34 of the NDIS Act.

There does not appear to be any good quality peer-reviewed evidence demonstrating the need for an alternative seating system for wheelchair users. There is an evidence base that can inform clinical judgement. Based on this evidence, we should not assume that multiple seating systems are required. For some participants a single seating system may meet their postural and pressure care needs. There may be some cases where an alternative seating system is reasonable and necessary but it will depend on the individual needs and resources of the participant.

This paper is a supplement to other TAB research papers relating to postural supports. It refers to:

- [RES 204 – 24 hour Postural Management Programmes](#)
- [RES 214 – Rotating Beds](#)
- [RES 215 – The Benefits of Power Wheelchair Tilt, Recline and Leg Rests, Power Wheelchair Standing Systems, and Standing Frames for Power Wheelchair Users](#)

3. Alternative seating systems

I have not found any reliable, high quality, current research directly focussing on the need for both a primary and secondary seating system. A search of PubMed database for the phrases “secondary seating system”, “secondary seating” and “second seating system” yielded no results. A search of Google Scholar for the phrase “secondary seating system” yielded no results and while the phrases “second seating system” and “secondary seating” were used, none of the results were relevant to this question. I obtained similar results searching multiple databases with the phrases “alternative seating system”, “alternate seating system”, “alternate seating” and “alternative seating”.

A 2002 clinical review referred to the possibility of secondary seating, saying that some people “have a need for both armchair and wheelchair seating and often have to resort to using the wheelchair as an armchair, as it will normally meet their postural needs” (Collins, 2002, p.16). The author is here differentiating between postural needs and pressure care needs (p.17).

Some seating system manufacturers or retailers market their products as good secondary seating ([Beanseat](#); [Inspired by Drive P Pod](#); Smith, [5 Expert Tips](#)). Steve Fischer of Bergeron

Health Care argues that both primary and secondary seating is necessary. He says “[y]ou don’t sit in the same chair all day then all night. Your body needs different textures and points of contact to prevent skin shearing & breakdown and maintain healthy blood flow” (Smith, [5 Expert Tips](#)). This assumes that a primary seating system is not able to provide the variability in textures and points of contact that are required to maintain the user’s health. This claim is made in the context of marketing material and is not explicitly backed up by evidence.

Previous TAB advice varies on this issue. Advice from 2020 states a rule that it “is considered reasonable and necessary to fund one mobility aid and one alternative seating option for participants” (ADV 2020 0457-9). Advice from 2019 also acknowledges that a mobility aid such as a wheelchair and postural support aid could be funded separately (ADV 2019 6517). Other advice from 2019 argues that where a participant’s mobility aid is “configurable and customised” and can meet the participant’s “mobility, seating, safe positioning, occupational, social and pressure care needs”, then an alternative seating system may not be necessary (ADV 2019 3872).

In an informal survey, TAB advisors have reported that another common justification for secondary seating system requests relates to the need for wheelchair users to be able to adopt a relaxed posture at times. This justification assumes there is a difference between a more rigid primary seating system and a more comfortable or relaxed secondary system. It also assumes, as above, that a primary seating system is not able to provide the opportunity for a relaxed posture.

4. Pressure care

A pressure injury (also pressure sore or pressure ulcer) is an area of localised tissue damage caused by unrelieved pressure, friction or shearing on any part of the body. Pressure injuries often occur in areas where there is minimal tissue covering the bone (Gillespie et al, 2020, p.1; Australian Commission on Safety and Quality in Health Care (ACSQHC), 2018, p.1). People are at risk of pressure injuries if they have limited mobility, limited activity and a high potential for friction and shear (European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance (EPUAP), 2019, p.14).

There are several strategies to reduce the risk of pressure injury for people who sit for prolonged periods. For example, ensuring skin is clean and dry, maintaining good posture and position, repositioning and weight shifting, scripting cushions and other pressure relieving devices, and ensuring proper nutrition and hydration (EPUAP, 2019; Shi et al, 2021; Gillespie et al, 2020; McInnes et al, 2015; Langer, Fink 2014).

[RES 214 – Rotating Beds](#) discusses how regular repositioning can reduce the risk of pressure injury during prolonged periods in bed. Standard practice has involved relieving pressure over key areas (sacrum, ischial tuberosities) for 5 minutes every 2 hours or 10 seconds every 10 minutes for periods of prolonged sitting (Kruger et al, 2013, p.574). More recent clinical guidelines do not recommend a particular repositioning protocol but instead suggest that

clinicians assess the person’s level of mobility and capacity to reposition themselves to determine an appropriate frequency (EPUAP, 2019; Gillespie et al, 2020, p.23). There is reason to believe that repositioning is effective in maintaining blood flow to affected areas. However, evidence is inconclusive regarding a particular optimum positioning protocol.

When a wheelchair user is not able to independently reposition or perform weight shifts, wheelchair positioning functions can reduce risk of pressure injuries. [RES 215 – The Benefits of Power Wheelchair Tilt, Recline and Leg Rests, Power Wheelchair Standing Systems, and Standing Frames for Power Wheelchair Users](#) (RES 215) discusses the impact on development of pressure sores of wheelchair functions including tilt, recline and standing. There is reason to believe that using tilt, recline and standing wheelchair functions reduces risk of pressure sores by redistributing the user’s weight in their chair. This is especially evident for wheelchair users with Spinal Cord Injury (refer to sections 3.1, 3.2 and 4.1 of RES 215). One study referred to in RES 215 notes that while there are reductions in pressure with the use of tilt and recline functions, the angle achieved can increase shear force. However, achieving an optimum angle of tilt (in this case 25°) can reduce shear to 0 (Springle, Maurer, Sorenblum, 2009, p.59-60). The same study refers to an early 1997 investigation on tilt and recline function which finds that some people may not be able to use a recline system for pressure relief because of increased spasticity during recline and because the recline may affect placement of postural supports (p.59).

There is some evidence that higher specification foam surfaces are more effective at preventing pressure injury than standard hospital mattresses (McInnes et al, 2015, p.19) and that reactive air surfaces are more effective at preventing pressure injury than foam surfaces (Gillespie et al, 2020, p.28). However, these results are mostly drawn from research on mattresses and mattress overlays. There is some evidence that certain types of seat surfaces are effective in reducing the risk of pressure injuries. However, according to McInnes et al, the research is inconsistent and there is insufficient clarity to draw a conclusion about the relative effectiveness of different seat cushions in preventing pressure sores (2015, p.17).

Of note, the Clinical Guideline on the Prevention and Treatment of Pressure Ulcers/Injuries jointly developed by European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance does not mention the use of a secondary or alternative seating system in any of their recommendations (EPUAP, 2019).

I was not able to locate any study that directly investigated the effect of sitting on multiple different surfaces or devices. Nor was there any available research focussing on utilising an alternative or secondary seating system on incidence or severity of pressure injury. Given the above research, we may assume that using an alternative seating device could have some benefit due to transferring out of the primary seating system and therefore relieving or redistributing pressure for the length of the transfer. However, I have not located any research to suggest that this would be more or less beneficial than having a properly scripted seating system with repositioning functions (tilt, recline, standing) or maintaining a repositioning protocol recommended by clinical specialists.

There may be circumstances in which a participant’s wheelchair seating system no longer meets their pressure care needs as their only seating system. In this case, a clinician might investigate whether using the wheelchair for a maximum duration and an alternative seating system for the remainder of time would be more cost effective than rescripting the wheelchair seating system.

5. Postural support

Postural control is “the ability to control the body’s position in space to obtain stability and orientation” (Chung, 2008, p.303; Babinec et al, 2013, p.2). This involves preventing some forms of movement which contribute to bad posture or increase risk of pressure injury while allowing or promoting functional movement (Babinec et al, 2013, p.8.).

Alternative seating systems aim to provide a seating position that is both comfortable and supportive ([Specialised paediatric equipment](#); [Adaptive Mall](#); Smith, [5 Expert Tips](#)). One element of comfort may be the ability to relax. Without a clinical definition of a ‘relaxed posture’, we can take this to describe a situation in which a person is able to allow a chair to take their weight and relieve the strain on their muscles required to maintain a good posture. Collins points out that it can be difficult to sit for long periods of time or independently maintain good posture due to “constant static muscle work in the trunk and spine in order to continually counteract the forces of gravity” (Collins, 2008, p.39). While seated, support is predominantly provided by the buttocks, thighs and feet. This means a smaller surface area is providing support compared to lying (Collins, 2002, p.15; Collins, 2008, p.40). When a smaller surface area is supporting the body, compensatory work is done by the muscles to maintain good posture (Collins, 2008, p.39). If it is possible to relieve the muscles and allow the chair to take some of the force, this can be more comfortable, less tiring, more relaxing.

We have already discussed above the benefits for skin integrity of being able to adopt a variety of postures throughout the day, including reclining. [RES 204 – 24 hour Postural Management Programmes](#) (RES 204) notes that poor body position and posture can also affect bodily functions such as digestion, breathing and sleep (refer to section 3.1). If a person’s wheelchair has a recline function then the need to adopt a reclining posture throughout the day can be met with their primary seating system.

RES 204 also notes that postural supports should aim to balance postural control and comfort. Some users are not able to tolerate recommended postural supports due to discomfort. RES 215 describes a study in which wheelchair users whose device has tilt and recline functions rate the chair more comfortable compared to those without the additional functions.

In circumstances where a person is not able to tolerate their seating system for the length of time they are in their chair, then the seating system may have to be re-examined to determine if adjustments can be made to improve comfort and sitting tolerance. If no adjustments can be made to the primary seating system, then it may be reasonable to investigate a secondary

seating system in which the balance of postural support and comfort leans more towards comfort.

Participants who can manage independent weight shifting or postural correction may fatigue more easily during long term chair use. This could form the basis of a clinical justification for an alternative seating system for participants with postural and pressure care needs. However, without direct evidence establishing the benefit of alternative seating systems, this remains speculative.

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7. Version control

Version	Amended by	Brief Description of Change	Status	Date
1.0	AHR908	Alternative seating systems for wheelchair users	Approved	21/01/2022

CPAP funding, management and use

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The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters.

Research question:

Are there publicly funded or subsidised CPAP services available in Australia?

What is the prevalence of CPAP use?

Where are the machines sourced and what is an average cost?

Are CPAP machines effective as a treatment for anxiety or depression?

Date: 14/02/2022

Requestor: Shannon 547F - personal privacy

Request endorsed by (EL1): n/a

Cleared by: Stephanie 547F - personal privacy

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2. Summary

CPAP is a commonly used device that is the first line treatment for moderate to severe obstructive sleep apnoea (OSA). There is no data for use of CPAP machines across Australia though moderate to severe OSA is quite common with adult prevalence ranging from 7% to 16%.

Online retailers based in Australia often offer trial and rental of CPAP devices. The most common brands of CPAP are generally above \$1000 though new machines can be found for as little as \$695.

There is strong evidence that CPAP use can treat symptoms of depression in people who meet criteria for clinical depression. Evidence suggests CPAP use does not have the same effect on symptoms of anxiety.

3. CPAP use in Australia

A CPAP machine is:

A type of positive airway pressure ventilator that applies continuous mild air pressure. It keeps the airways continuously open in people who are able to breathe spontaneously on their own, but need help keeping their airway unobstructed (AIHW, 2021, p.27).

CPAP therapy is used to treat OSA and is the usual first line treatment for moderate to severe OSA (Askland et al, 2020, p.12; Pinto & Sharma, 2021). It can also be used to treat respiratory distress syndrome in pre-term babies (Pinto & Sharma, 2021).

I am unable to accurately determine prevalence of CPAP use in Australia. According to a 2021 Australian Institute of Health and Welfare (AIHW) report, there is no prevalence data for use of CPAP in Australia (AIHW, 2021, p.23).

A 2017 systematic review estimated OSA prevalence across the general population. Prevalence of moderate to severe OSA in the adult population ranged from 6% to 17% with frequency increasing with age (Senaratna et al, 2017). This may give some indication of the percentage of adults who could benefit from CPAP therapy.

Another tool for approximating CPAP use across Australia is found in tracking Medicare Benefits Schedule item 12204. This is used when a clinician needs “to assess positive airway pressure. This study is performed overnight in a sleep study centre following diagnosis of a sleep disorder and the recommendation of CPAP therapy” (AIHW, p.27). According to the AIHW report, 16,631 patients received item 12204 in 2019.

3.1 Cost and retailers of CPAP machines in Australia

Refer to [7. Cost of CPAP machines in Australia](#) for a table of comparative costs. There are several Australia-based online CPAP retailers. The two most common brands of fixed pressure CPAP machine are ResMed and Fischer & Paykel. New machines in both common brands are generally over \$1000. DeViblis, BMC and SmartMed produce machines that generally retail for under \$1000. Parts and consumables such as tubes, masks, filters etc may come with purchase of the machine and then require replacement.

CPAP Australia offers trial or rental of the ResMed Airsense 10 Elite for \$35 / week (CPAP Australia, CPAP trials and rentals). CPAP Victoria offers trials for \$30/week for a minimum of 4 weeks (CPAP Victoria, Trials). CPAP Direct deducts the cost of the first month of machine hire from the purchase price (CPAP Direct, CPAP Machine Hire).

4. Public funding of CPAP machines

4.1 National

If a patient has a Commonwealth concession card, they may also be eligible for the Essential Medical Equipment Program through Services Australia. This program provides \$164 per year to assist with the electricity costs of essential medical equipment including CPAP machines (Services Australia, 2021).

4.2 Victoria

On 8th February I spoke to [s47F - personal pr] from State-Wide Equipment Service (SWEP). [s47F - persc] said that SWEP does not fund CPAP machines at all. [s47F - persc] transferred me to Empower Care Options, who assist NDIS participants and non-funded Victorians with equipment purchase and repair.

[s47F - personal] from Empower Care Options confirmed SWEP does not fund CPAP machines. [s47F - persc] said that Empower Care Options has a stock of 10 new ResMed Air Sense 10 Elite CPAP machines which they are selling to consumers at a reduced cost. The overall cost is \$900 plus \$20 delivery charge. This brand of CPAP machine retails for between \$998 and \$1374 ([7. Cost of CPAP machines in Australia](#)). [s47F - personal] also confirmed that they do not fund or subsidise the cost of repairs or maintenance to CPAP machines they have sold (refer to [5.1 State-wide equipment service](#)).

The Australian Sleep Association (ASA) conducted a brief inquiry into public funding of CPAP machines in 2019. The funding of CPAP machines in Victoria was found to be “fragmented and highly variable”. Individual public hospitals were able to offer CPAP machines to some patients depending on severity of sleep apnoea and financial difficulty. The criteria varied and were determined by individual hospitals (Australian Sleep Association, 2019).

[s47F - personal privacy], a sleep scientist from Box Hill Sleep Clinic confirmed in a phone conversation on 8th February that all hospitals have their own criteria for providing CPAP machines to patients. In a follow up email [s47F - personal privacy] confirmed that to be eligible for a CPAP machine funded by the hospital, patients need:

- a diagnosis of severe OSA
- either aged or disability pension
- to demonstrate compliance with treatment (at least 4hours/night over 4 weeks)
- to have purchased their own mask (refer to correspondence in [5.2 Eastern Health](#)).

In a phone conversation on 9th February, [s47F - personal privacy] Sleep Laboratory at Austin Health, described their process for funding CPAP machines for patients. A patient may be eligible for a subsidised CPAP machine if they have had their sleep study performed at the Austin and they can demonstrate a financial need. The latter is usually demonstrated by possession of a health care card but this is up to the discretion of the clinician. If a patient is eligible, they can pay \$50 for a 4-week trial of a CPAP machine. If trial is successful, they can pay an additional \$295 to have the machine permanently. This cost includes mask and tubes but does not include repairs or maintenance. The Austin will only subsidise one device for the patient.

I reached out to 3 other hospitals in Victoria but have not received any further responses.

The Victorian government offers a concession on power costs for people who have a concession card and use a life support machine which takes at least 1880 kilowatt hours per

year. They state, “[m]ost continuous positive airways pressure (CPAP) machines do not meet the 1,880-kilowatt hour threshold” (Department of Families, Fairness and Housing, 2021).

4.3 New South Wales

Enable NSW administers the Home Respiratory Program (HRP). To be eligible for support from Enable NSW, a person must:

- be residing in NSW or Lord Howe Island
- be enrolled with Medicare
- require the assistive technology to support a health need
- require the assistive technology to remain independent at home
- not be eligible for compensation or damages
- not be eligible to receive assistive technology through any other government-funded program.

In addition, to be eligible for HRP a person must have stopped smoking for at least 4 weeks. There are also other eligibility criteria specific to each respiratory device (EnableNSW, Home Respiratory Program). An adult must demonstrate **one** of the following criteria:

- Oxygen desaturation index (ODI) \geq 30/hr
- Apnoea Hypopnea Index (AHI) \geq 30/hr
- Apnoea Hypopnea Index (AHI) \geq 20/hr and a relevant comorbidity
- Hypoventilation/ daytime hypercapnia with one of the following:
 - transcutaneous carbon dioxide (TcCO₂) rising \geq 8 mmHg from baseline
 - awake partial pressure of carbon dioxide (PaCO₂) \geq 46 mmHg
 - a rise in PaCO₂ of \geq 8 mmHg (Enable NSW, 2021a).

A person under 18 years old must demonstrate **one** of the following criteria:

- Obstructive Apnoea Hypopnea Index (OAHI) \geq 15/hr
- OAHI \geq 10/hr or OAHI \geq 5/hr post adenoidectomy/tonsillectomy, and either:
 - minimum oxygen desaturation \leq 85%
 - CO₂ retention \geq 8 mmHg
 - TcCO₂ > 50mm Hg for 25% of the sleep study
 - documented evidence of significant cardiorespiratory co-morbidities (Enable NSW, 2021b).

Equipment through HRP is heavily subsidised. For adults on a pension or with a low income, or for children under 16 years old, there is a co-payment of \$100. For adults with higher

incomes, they will be responsible for 20% of the total cost of the equipment. The customer is responsible for the purchase of their own CPAP masks. Enable NSW is responsible for repairs (Enable NSW, Home Respiratory Program).

4.4 South Australia

The South Australian Department of Human Services administers the Equipment Program which provides some equipment to adults with chronic health conditions and palliative care patients (Department of Human Services, Equipment Program). [s47F - personal privacy](#) DHS Equipment Program confirmed in a phone call on 10th February that they do not fund or subsidise CPAP machines. According to the ASA's 2019 inquiry, South Australia does not have a state-wide system for funding CPAP machines. Further, as of 2019, the Southern and Central Adelaide Local Health Districts had limited budgets to provide CPAP machines for patients who have a concession card and meet certain OSA severity requirements (ASA, 2019).

4.5 Western Australia

The Community Aids and Equipment program (CAEP) may fund equipment for people living in WA who have a pension or concession card and who are not eligible for NDIS or other commonwealth programs. The equipment is offered as a long-term loan and should be returned when no longer required. CAEP judges requests on an individual basis but may fund equipment that is:

- essential for independent functioning and functional care at home
- the most basic model/type that meets the clinical need
- be for personal use only, that is not communal use
- required for use in the person's primary residence
- more than \$50
- required for safety and behavioural purposes where applicable.

The WA Sleep Disorders Research Institute is a CAEP specialist provider administering funding for all respiratory equipment including CPAP machines (Department of Communities, Community Aids and Equipment Program). ASA states the clinical criteria for CPAP funding in WA are:

- AHI >15/hr
- demonstrated satisfactory use (average at least 4 hours per night), at their own expense; and
- benefit (either a reduction in Epworth Sleepiness Scale or clinician indicating clinical benefit was obtained) during a CPAP trial (ASA, 2019).

I have not been able to confirm that these criteria are still current.

4.6 Tasmania

The state equipment provider TasEquip does not manage CPAP machine funding (Department of Health, Medical Aids and Equipment). I was unable to establish availability of other funding through local hospital districts.

4.7 Northern Territory

CPAP machines are not on the Approved Equipment list for the Territory Equipment Program (NT Health, Territory Equipment Program). ASA refers to a Respiratory Appliances Loan Scheme but this program appears to no longer operate (ASA, 2019). I was unable to establish availability of other funding through local hospital districts.

4.8 Australian Capital Territory

People who hold a commonwealth concession and meet ACT residency requirements may be eligible for a permanent loan of a CPAP machine from the Domiciliary Oxygen and Respiratory Support Service (DORSS). Patients must meet the following clinical criteria:

- be assessed and referred by an approved consultant
- have completed studies at a recognised sleep study unit within the last twelve months and successfully trialled the recommended unit for a minimum of 1 month.
- have a diagnosis of severe or moderately severe OSA confirmed by polysomnography as indicated below:
 - severe OSA is diagnosed where Respiratory Disturbance Index (RDI) > 30
 - moderately severe OSA is diagnosed where RDI > 20 and minimum overnight Oxygen Saturation < 90%
 - patients with an RDI > 10 accompanied by symptoms of excessive daytime sleepiness and documented cardiovascular diseases including hypertension, ischaemic heart disease or stroke.

There are no co-payments, though patients are responsible for purchasing replacement consumables (masks etc.). The CPAP machine remains the property of the ACT government. Repairs are conducted through ACT Government contract (Department of Health, ACT DORSS).

5. Effect of CPAP on anxiety and depression

Evidence of the effectiveness of CPAP use as a treatment for anxiety and depression in people with OSA is mixed though strongly suggests that it is effective on depressive symptoms.

A 2014 systematic review and meta-analysis found use of CPAP improves depressive symptoms. However, there was significant heterogeneity between trials and comparative effect of CPAP versus other treatments of depression was unclear (Povitz et al, 2014). This contrasts with a recent American Academy of Sleep Medicine systematic review of treatments for obstructive sleep apnoea. The researchers performed a meta-analysis of 5 studies measuring effects of CPAP use on mood. The meta-analysis revealed no clinically significant improvement in mood as measured by the Hospital Anxiety and Depression Scale. The studies included in the meta-analysis did not recruit participants who already presented with depression or anxiety (Patil et al, 2019, p.311). This is noteworthy as other studies have found that the effect of CPAP on depressive symptoms was larger in populations that met the criteria for depression (Povitz et al, 2014, p.3-4; Zheng et al, 2019, p.94).

A 2019 examination of 2687 subjects found a significant reduction in depressive symptoms but no clinically significant effect on anxiety symptoms (Zheng et al, 2019, pp.91-92). An associated systematic review and meta-analysis confirmed the effect on depression but not anxiety symptoms (p.94). Whether the subject was CPAP-adherent (defined as using the machine on average 4 or more hours each night) did not change the treatment effect (p.91). This is supported by a 2020 Cochrane review found that while certain interventions are shown to improve usage of CPAP machines, the current evidence does not demonstrate that increased usage improves functional or quality of life outcomes (Ackland et al, 2020).

6. Correspondence

6.1 State-wide equipment service

From: Empower Care Options <xxxxxxxxxxxxxxxxxxxxxx@xxx.xxx.xx>

Sent: Tuesday, 8 February 2022 3:31 PM

To: s47F - personal privacy Aaron <Aaron.s47F - personal privacy@ndis.gov.au>

Subject: RE: [External Email] CPAP machine inquiry [SEC=OFFICIAL]

I can confirm this is all correct.

Thank you

Kind Regards,

s47F - personal privacy |Administration Officer

Empower Care Options|Ballarat Health Services/Part of Grampians Health

P.O. Box 1993, Bakery Hill Vic 3354

P 1300 747 937 | E s47F - personal privacy@bhs.org.au | E xxxxxxxxxxxxxxxxxxxxx@xxx.xxx.xx



OFFICIAL

For Internal Use Only

Monday – Friday 8:30am – 5:00pm

--

From: [redacted] Aaron <Aaron.[redacted]@ndis.gov.au>

Sent: Tuesday, 8 February 2022 2:09 PM

To: Empower Care Options <xxxxxxxxxxxxxxxxxxxxxx@xxx.xxx.xx>

Subject: [External Email] CPAP machine inquiry [SEC=OFFICIAL]

Hi [redacted]

Thanks so much for your time this afternoon.

As per our discussion, can you please confirm:

- Victorian Aids and Equipment program / State-wide equipment program no longer funds or subsidises the purchase of CPAP machines
- Empower Care has a stock of 10 reduced cost RESMED AIRsense 10 Elite CPAP machines available for purchase at \$900 plus \$20 delivery
- you are not aware of any other equipment program in Victoria that funds or subsidises the purchase of CPAP machines
- neither Empower Care, VA&EP or SWEP will fund or subsidise repairs to CPAP machines.

Thanks again and all the best

Aaron [redacted]

Research Officer

National Disability Insurance Agency

Email [aaron.\[redacted\]@ndis.gov.au](mailto:aaron.[redacted]@ndis.gov.au)

6.2 Eastern Health

From: [redacted] <[redacted]@easternhealth.org.au>

Sent: Wednesday, 9 February 2022 10:45 AM

To: [redacted] Aaron <aaron.[redacted]@ndis.gov.au>

Subject: Hospital Funded CPAP - Eastern Health

Hi Aaron,

Further information after our conversation yesterday.



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All patients need to be referred from a sleep physician in the public outpatients and have a least one overnight sleep study at Box Hill Hospital.

Patient need:

Diagnosis of severe OSA

Either Aged or Disability Pension

Demonstrate compliance – at least 4hours/night over 4 weeks

Purchased their own mask

Hope that helps,

Kind regards,

s47F- personal privacy

Sleep Scientist

Box Hill Hospital

P: s47F- personal privacy | E: s47F- personal privacy@easternhealth.org.au

Part time: Monday - Thursday

5 Arnold St, Box Hill

7. Cost of CPAP machines in Australia

Machine	CPAP Australia (link)	CPAP Direct (link)	CPAP Victoria (link)	NSW CPAP (link)	The CPAP clinic (link)	CPAP club (link)	Sleepzone (link)
ResMed AirSense 10 Elite Fixed Pressure CPAP Machine	\$1315.00	\$1195.00	\$1374.00	\$1023.00	\$998.00	\$1250.00	
Fisher and Paykel SLEEPSTYLE CPAP Machine	\$1395.00	\$1195.00	\$1395.00	\$1330.00	\$850		
DeVilbiss Sleepcube Standard Plus CPAP Machine with Humidifier					\$695.00		
BMC G3 C20 Fixed Pressure CPAP Machine						\$895.00	\$900.00
SmartMed SmartMed iBreeze Fixed Machine		\$995.00					

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9. Version control

Version	Amended by	Brief Description of Change	Status	Date
1.0	AHR908	<p>Research paper representing the first instalment of a body of research on CPAP machines. This paper focuses on:</p> <ul style="list-style-type: none"> publicly funded or subsidised CPAP services in Victoria CPAP machines used as a treatment for anxiety or depression. 	Cleared	09/02/2022
2.0	AHR908	<p>Research paper expanded to include:</p> <ul style="list-style-type: none"> public funding available for CPAPs in Australia prevalence of CPAP use cost and retailers. 	Cleared	14/02/2022

Bariatric wheelchairs and transport safety

The content of this document is OFFICIAL.

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters, they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters

Research question/s:

What are the guidelines/ standards /laws for bariatric power wheelchair and crash testing?

Is there an evidence base that recommends how to clinically determine the safe working load for a participant?

How is a maximum safe working load of a power wheelchair determined?

If a power wheelchair has been crash tested to a maximum of 75kg what recommendations have been provided on how to best to safeguard people who are over the weight of 75kg should they be in a crash? Is this safe?

Date: 19/05/2022

Requestor: Brigid s47F - personal privacy

Endorsed by (EL1 or above): Yuemei s47F - pers

Researcher: Aaron s47F - personal privacy

Cleared by: Stephanie s47F - personal privacy

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2. Summary

I was not able to find any standards, guidelines or laws that pertain to bariatric power wheelchairs over and above what is required for standard power wheelchairs. There does not appear to be any legal requirement for wheelchairs to be crash-tested to the Australian standards, though this is to be preferred if available.

It is unclear how safe working load is determined for each model of wheelchair, though a variety of non-structural considerations are likely to apply including commercial factors. Australian standards do specify best practice for testing strength and stability of wheelchairs.

These conclusions are preliminary and further investigation may be useful. It may be especially useful to further investigate decision making frameworks for equipment that does not meet Australian standards but for which there is no alternative.

3. Relevant Australian Standards, legislation and guidelines

Australian standards describe minimum safety and quality requirements for products, systems and services. Some are formalised in state, territory or federal legislation. They can also be incorporated as conditions in private contracts (Standards Australia, n.d.).

There are at least 31 Australian Standards relating specifically to wheelchair design and use. Refer to [7. Australian wheelchair standards](#) for the full list.

There do not appear to be any specific requirements set out in Australian standards for bariatric power wheelchairs beyond what is required for standard power wheelchairs.

From my research it appears that no Australian standards related to wheelchair design and use has been endorsed in legislation. Discrimination laws apply when wheelchair users wish to travel on public transport and some regulations specific to wheelchair accessible taxis ensure that driver's assist the wheelchair user safely. There does not appear to be any legislated restrictions in any jurisdiction on the type of wheelchair that can be used on public transport.

Also, unless a specific exemption is sought, general transport and road safety laws still apply. For example, when traveling in a vehicle, wheelchair users should still wear a seat belt conforming to Vehicle Standard (Australian Design Rule 4/05 – Seatbelts) 2012.

The nationally applicable Disability Standards for Accessible Public Transport 2002 do not specify types of wheelchairs permitted on public transport. Paragraph 1.22 of the guidelines for this standard point out that the Disability Standard assumes that the wheelchair is stable enough to travel in a vehicle and that passengers will ensure their wheelchairs are safe to travel (Disability Standards for Accessible Public Transport Guidelines 2004, (Cth)).

The West Australian guidelines for wheelchair passengers state that a wheelchair user should:

- ensure their wheelchair is capable of being restrained correctly
- get their own advice about what type of wheelchair is most appropriate
- be familiar with the right way to secure their wheelchair and themselves (Department of Transport, 2022).

The NSW government's factsheet on travelling with a wheelchair notes that a wheelchair can be secure even if it does not have specific transit options in place. However, if the chair has these options, then they must be used (EnableNSW, 2016). This factsheet also specifies features that do not meet minimum standards for safe transport. These include wheelchairs with:

- low backs
- single pole seats
- insufficient base / frame to attach tie downs (if no other transit options in place)
- no headrest.

[RES 216 Safety of front versus second or third row vehicle conversion for wheelchairs](#), contains more general information on safely travelling with a wheelchair.

4. Safe working load

Safe working load can be defined as:

The steady or unsteady load against which a component or structure is designed for normal operation. It is lower than that which would cause failure by buckling, fracturing, or yielding, so as to accommodate uncertainty, possible fault or accident conditions (Escudier & Atkins, 2013, safe working load).

Safe working load may also be described as rated load, manufacturer's rated load or working load limit (Hanifan, 2014). In the context of wheelchair documentation, safe working load may be described in other ways depending on the wheelchair provider or manufacturer. Some providers or manufacturers might refer to [safe working load](#), [weight capacity](#), [weight limit](#), [maximum user weight](#), [maximum recommended user weight](#). Australian standards refer to safe working load (AS/NZS 3695.1), intended occupant mass (AS/NZS 3695.2) or maximum occupant mass (AS/NZS 7176.8). 3695.1 states that a manufacturer should label the wheelchair with the safe working load in kilograms. AS/NZS 3695.2 states that the manufacturer should provide documentation indicating characteristics of the intended occupant including their mass and functional capacity.

The Australian Standards describe methods for testing strength and stability of wheelchairs and wheelchair accessories such as restraints and fittings. AS/NZS 7176.8 specifies any anthropomorphic test device (ATD) used should equal the maximum occupant mass defined by the manufacturer. AS/NZS 3696.19 allows for an ATD to represent a range of weights when conducting a frontal impact test in a vehicle. For example, an ATD of 75 kg represents occupant weight range of 75 kg – 136 kg (more detail in [5. Crash Testing](#)). AS/NZS 3695.2 specifies that where a human test occupant is used for any test, they should equal the maximum occupant mass +/- 5kg. Tests for static strength of arm and foot supports also require maximum occupant mass to determine force applied in the test conditions.

There do not appear to be additional requirements for bariatric wheelchair testing beyond what is standard for all wheelchairs. However, several testing parameters specify using maximum mass values to calculate force. In the case of testing static strength of arm and foot supports, where the maximum occupant mass exceeds 125kg then AS/NZS 7176.8 still recommends using 125kg to calculate the force required for testing. Similarly, when testing for upward forces on arm and foot supports, the standard recommends using no more than 100 kg to calculate force even if the ATD (and therefore intended maximum occupant mass) exceeds 100 kg.

The Australian Standards assume that maximum occupant mass is specified by the manufacturer. I have not been able to find any guidelines describing how a wheelchair manufacturer initially determines the intended weight limit. However, correspondence with a provider suggests that several factors contribute to determining the intended weight limit including the intended user, the intended purpose of the wheelchair and other market considerations. From this advice it appears the provider determines the needed or desired occupant mass using non-structural decision and then confirms this is structurally appropriate for the design of the chair according to the appropriate standard (refer to [8. Correspondence](#)). If this is representative of other provider's practice, it means that the weight limit defined for a

particular model of wheelchair is the weight limit that the device was successfully tested to. The device might be safe to use under a greater weight but tests have not been completed to confirm it.

5. Crash testing

Crash testing is the way that manufacturers make sure that a wheelchair is likely safe for travel (SPOT, 2010). Three Australian standards cover requirements for crash testing of wheelchairs and restraint systems are: AS/NZS 3696.19-2009, AS/NZS 10542.1:2009 and AS/NZS 10542.2:2009.

AS/NZS 3696.19-2009 Wheelchairs - Part 19: Wheeled mobility devices for use as seats in motor vehicles describes methods of crash testing for wheelchairs intended for use as seats in vehicles. It is a modified version of International Standard ISO 7176-19:2008 Wheelchairs — Part 19: Wheeled mobility devices for use as seats in motor vehicles. This international standard has been superseded by ISO 7176-19:2022 - Wheelchairs — Part 19: Wheelchairs for use as seats in motor vehicles. However, AS/NZS 3696.19-2009 remains the endorsed Australian standard.

For frontal impact testing, AS/NZS 3696.19 specifies that an ATD should be selected based on the intended occupant weight according to the following table:

Table 1 ATD size and weight by intended occupant weight range. Source: AS/NZS 3696.19 Annex A, method for frontal impact test

Occupant weight range (kg)	ATD size	Approx. mass of ATD (kg)
18 - 27	6-year-old child	22.5
27 – 43	10-year-old child	35
43 – 57	Small adult female	47
57 – 75	Small adult female, weighted	59
75 – 136	Midsized adult male	76.3
Over 136	Large adult male	102

Note: where an ATD is weighted, this means additional weighting material are added to a figure to achieve the desired weight.

According to this table, for wheelchair users over 136 kg an ATD of 102 kg is sufficient to meet the conditions of the standard for frontal impact testing.

Where possible, wheelchairs should be selected to meet AS/NZS 3696.19-2009 (EnableNSW, 2016; SPOT, 2010). However, it is not always possible to ensure that a wheelchair has been

crash-tested. For example, in some cases there may be no wheelchair available that suits the user's height or weight. In these cases, AS/NZS 3696.19 notes failure to comply with the standard "cannot be used to limit access to, and availability of, motor vehicle transportation for wheelchair users" (p.v).

Guidelines note that crash testing is completed under specific test conditions and may not indicate that the wheelchair can withstand forces of a crash (EnableNSW, 2016; SPOT, 2010).

6. Reasonable and necessary

When determining whether a request for a wheelchair is reasonable and necessary, delegates need to have a good idea that the wheelchair is safe to use. NDIA's Assistive Technology guideline says:

We need to know that the assistive technology:

- is the right item for your needs
- is safe for you to use and meets Australia's safety standards, where this is possible
- will help you do all the things you need it to
- will work in all the places that you need to use it. ([Our Guidelines – Assistive Technology](#))

In some cases, it is not possible for wheelchairs to comply with the relevant Australian standards. The AT guidelines states that we will need to know that the piece of equipment meets Australian standards, where possible. However, it does not say how a delegate should make a decision if meeting Australian standards is not possible. This will likely depend on conditions specific to the participant and their context.

Moreover, AS/NZS 3696.19 indicates what to do if its own conditions are not met:

Transportation is only one of many daily activities that introduce unique circumstances and requirements that wheelchairs and wheelchair occupants may experience. Wheelchair products that comply with this part of ISO 7176 [or 3696 in Australia] will have additional features that provide increased levels of occupant security and safety whilst their occupants are riding in motor vehicles. However, a wheelchair's failure to comply with this part of ISO 7176 cannot be used to limit access to, and availability of, motor vehicle transportation for wheelchair users (p.v).

Wheelchairs that have been crash-tested to AS/NZS 3696.19 should be preferred with the understanding that in many cases it may not be possible to find an appropriate wheelchair that meets these standards. Moreover, even where these standards are met, this may not ensure safety in a crash. As was shown in [5. Crash Testing](#), frontal impact testing occurs with an ATD that represents a certain weight range. If a wheelchair manufacturer indicates that the wheelchair meets AS/NZS 3696.19 (or equivalent standard) this means it would have been

tested using one of the six typical ATD designs. If the manufacturer indicates a model has been crash tested to, for example, 135 kg, then this may mean it has been tested using an ATD of 76 kg.

Delegates should also keep in mind that transportation is only one activity that the wheelchair is used for and so crash testing according to AS/NZS 3696.19 is relevant to the wheelchair's use in specific activities. However, the safe working load is a relevant safety consideration during all activities.

7. Australian wheelchair standards

The following table lists Australian Standards relevant to specifications of wheelchair testing and use. Most are based on International Standards (ISO) and one is based on European Standards (EN). Most are applicable in both Australia and New Zealand (AS/NZS or SA/SNZ). One is applicable to South Australia and Tasmania only (SA TS).

This list may not be exhaustive. There may be other standards relevant to wheelchair testing and use.

If you would like further information on any specific document, please contact the Tactical Research Team.

Document Number	Title
AS/NZS 3695.1:2011	Wheelchairs, Part 1: Requirements and test methods for manual wheelchairs
AS 3695.2:2019	Wheelchairs, Part 2: Requirements and test methods for electrically powered wheelchairs (including mobility scooters)
SA TS 3695.3:2018	Wheelchairs, Part 3: Requirements for designation of powered wheelchairs and mobility scooters for public transport and/or road-related area use
AS 3696.5-1989	Wheelchairs, Part 5: Determination of overall dimensions, mass and turning space
AS 3696.6-1990	Wheelchairs, Part 6: Determination of maximum speed, acceleration and retardation of electric wheelchairs
AS 3696.13-1991	Wheelchairs, Part 13: Determination of coefficient of friction of test surfaces
AS/NZS 3696.19:2009	Wheelchairs, Part 19: Wheeled mobility devices for use as seats in motor vehicles (ISO 7176-19:2008, MOD)

Document Number	Title
AS/NZS 3696.21:2008	Wheelchairs, Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters
AS/NZS ISO 7176.1:2015	Wheelchairs, Part 1: Determination of static stability
AS/NZS ISO 7176.2:2020	Wheelchairs, Part 2: Determination of dynamic stability of electrically powered wheelchairs
AS/NZS ISO 7176.3:2015	Wheelchairs, Part 3: Determination of effectiveness of brakes
AS/NZS ISO 7176.4:2011	Wheelchairs, Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
AS/NZS ISO 7176.8:2015	Wheelchairs, Part 8: Requirements and test methods for static, impact and fatigue strengths
AS/NZS ISO 7176.9:2013	Wheelchairs, Part 9: Climatic tests for electric wheelchairs
AS/NZS ISO 7176.10:2011	Wheelchairs, Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
AS/NZS ISO 7176.11:2013	Wheelchairs, Part 11: Test dummies
AS/NZS ISO 7176.14:2013	Wheelchairs, Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
AS/NZS ISO 7176.16:2013	Wheelchairs, Part 16: Resistance to ignition of postural support devices
AS/NZS ISO 7176.22:2015	Wheelchairs, Part 22: Set-up procedures

Document Number	Title
AS/NZS ISO 7176.25:2014	Wheelchairs, Part 25: Batteries and chargers for powered wheelchairs
AS/NZS ISO 7176.26:2011	Wheelchairs, Part 26: Vocabulary
AS/NZS ISO 7176.28:2013	Wheelchairs, Part 28: Requirements and test methods for stair-climbing devices
AS/NZS 10542.1:2015	Technical systems and aids for people with disability - Wheelchair tiedown and occupant-restraint systems, Part 1: Requirements and test methods for all systems (ISO 10542-1:2012, MOD)
AS EN 12182:2015	Assistive products for persons with disability - General requirements and test methods
AS/NZS ISO 10865.1:2015	Wheelchair containment and occupant retention systems for accessible transport vehicles designed for use by both sitting and standing passengers, Part 1: Systems for rearward-facing wheelchair-seated passengers
AS/NZS ISO 16840.3:2015	Wheelchair seating, Part 3: Determination of static, impact and repetitive load strengths for postural support devices
AS/NZS ISO 16840.4:2014	Wheelchair seating, Part 4: Seating systems for use in motor vehicles
SA/SNZ TR ISO 16840.9:2015	Wheelchair seating, Part 9: Clinical interface pressure mapping guidelines for seating
AS/NZS ISO 16840.10:2015	Wheelchairs - Resistance to ignition of non-integrated seat and back support cushions, Part 10: Requirements and test methods



Document Number	Title
SA/SNZ TS ISO 16840.12:2015	Wheelchair seating, Part 12: Apparatus and method for cushion envelopment testing



8. Correspondence

From: Glide Support <xxxxxxx@xxxxx.xxx.xx>

Sent: Friday, 20 May 2022 1:44 PM

To: [s47F - personal privacy](#) Aaron <Aaron.[s47F - personal privacy](#)@ndis.gov.au>

Subject: RE: Determining safe working load for wheelchairs [SEC=OFFICIAL]

Good Morning Aaron

Hope you are well and thank you for your email below regarding determining safe working load of wheelchairs.

Please see answers below highlighted in red.

Please be advised new pricing effective from 1st February 2022

Kind Regards

[s47F - personal privacy](#)

PRODUCT SUPPORT OFFICER

NDIS Registered Provider

+[s47F - personal privacy](#) | www.glide.com.au

25 Ledger Road | Balcatta | Western Australia 6021

Office Hours | Monday to Friday | 8:30am to 4:30pm WST

From: [s47F - personal privacy](#) Aaron <Aaron.[s47F - personal privacy](#)@ndis.gov.au>

Sent: Wednesday, 18 May 2022 9:18 AM

To: Glide Support <xxxxxxx@xxxxx.xxx.xx>

Subject: Determining safe working load for wheelchairs [SEC=OFFICIAL]

Good morning

I am hoping you can assist with an inquiry regarding the safe working load for wheelchairs.

I am a researcher for the National Disability Insurance Agency. I've been asked to get a bit of information around how manufacturers determine the safe working load of their wheelchairs. I've hit a wall and was hoping that as an Australian wheelchair manufacturer you could assist. The information I'm after is for research purposes only. Any information you provide will not directly impact NDIA's relationship with any provider.

I have been reading through a handful of Australian Standards (in particular 7176.8, 7176.19, 3695.1 and 3695.2). These standards seem to assume that the manufacturer sets the maximum occupant mass before testing and they also state that the safe working load of a wheelchair needs to be made evident to customers.

So my questions are:

- How is the maximum occupant mass determined for a model of wheelchair? **There are a number of factors that are looked at in determining what user weight is set. We look at the market, the type of user and where it is to be used.**
- How is the safe working load determined for a model of wheelchair and does this differ from method for determining maximum occupant mass? **It does not differ. We then look at the standard and choose the weight that we think will match the information gleaned from the information researched. Remember that some chairs are tested to two different standards. AS3696.8 (strength and durability eg 175kg user weight) and AS3696.19 (crash testing up to a maximum if 159kg user weight – limited by the test dummy size at the test facility). So what this is saying is that the chair can be used for general use for user up to 175kg, however it is only compliant up to 159kg user weight when used as a seat in a vehicle.**
- Is the SWL determined by testing the completed product or by testing or calculating for each component? **It is done as a complete product**
- If each component is tested separately, how is safe working load for the piece of equipment as a whole determined from the individual components?

Thanks very much for your help and all the best

Aaron s47F - personal privacy

Research Officer

National Disability Insurance Agency

Phone s47F - personal privacy

Email aaron.s47F - personal privacy@ndis.gov.au

9. References

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Standards Australia. (2015). *Wheelchairs, Part 8: Requirements and test methods for static, impact and fatigue strengths (AS/NZS 7176.8)*.

Standards Australia. (2019). *Wheelchairs, Part 2: Requirements and test methods for electrically powered wheelchairs (including mobility scooters) (AS/NZS 3695.2)*.

Vehicle Standard (Australian Design Rule 4/05 – Seatbelts) 2012. (Cth).

<https://www.legislation.gov.au/Details/F2019C00042>

10. Version control

Version	Amended by	Brief Description of Change	Status	Date
0.1	Aaron <small>s47f - personal privacy</small>	Initial draft of research paper looking into standards, laws and guidelines for determining safe working load and crash testing / transport safety for bariatric wheelchairs.	Draft	19/05/2022
0.2	SJP131	Review	Draft	20.5.22
0.3				
1.0				

Entry level sports PWC

The content of this document is OFFICIAL.

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters, they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters

Research question: What options are available in the market for powered wheelchair users to participate in sport at an entry level?

Date: 07/06/2022

Requestor: Megan s47F - personal privacy

Endorsed by (EL1 or above): Nicole s47F - personal priv

Researcher: Aaron s47F - personal privacy

Cleared by: Aaron s47F - personal privacy

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2. Summary

Few sports are designed specifically for power wheelchair (PWC) users. The most popular such sports in Australia are powerchair soccer and powerchair hockey.

The standard specialised powerchair soccer PWC is the Strikeforce. There are other models of specialised powerchair soccer PWC but I have found no evidence that these retail in Australia. Beginning players may start in their own chairs with footguards attached. Powerchair Sports Victoria website states that some non-specialised PWCs “have the characteristics to be suitable as an introductory sports chair”. However, in the opinion of another professional, these non-specialised chairs are not safe or fit for purpose.

There are at least two models of PWC designed for powerchair hockey, the E-hockey and the TurboTwist. I have found no evidence that these retail in Australia. Most powerchair hockey players likely use their own or second hand PWCs. However, in the opinion of one professional, these non-specialised chairs are not safe or fit for purpose.

I have sought further information from other PWC sporting groups. I will update this research paper if further information is received.

Due to the minimal information available on safety and required technical specifications for entry level PWCs, I am unable to say with confidence whether there are other suitable entry level alternatives to the Strikeforce.

3. Power wheelchairs in sport

Many sports are adapted for play by wheelchair users. Wheelchair basketball, rugby, and goalball are well known examples. Fewer have been adapted for play by PWC users (Duvall et al, 2020). Sports designed to be played by users of PWCs include power soccer and power hockey (Powerchair football, n.d; Powerchair hockey, n.d). Wheelchair tennis allows users of PWCs in the quadriplegic division (International Tennis Federation, 2022). The World Para Dance Sport Technical Committee of the International Paralympic Committee began an unofficial online competition in 2021 including events for PWCs (Picasso, 2021). Some wheelchair sports can be played regardless of the kind of wheelchair you have. Duvall et al. (2020) note that of the 28 activities included in the Paralympics, only Boccia, Archery, Shooting and Curling could be played in a PWC. Of these 4 activities, only Boccia specifies that a powerchair can be used. The other 3 do not state what type of device can be used.

Cybathlon is a competition designed to showcase developments in assistive technology and includes a PWC race (Wheelchair Race, n.d).

While some sports require the wheelchair to remain stationary and therefore do not depend on the device specifications, sports that require the chair to move during play often require specific modified or customised wheelchairs (Duvall et al, 2020). The largest PWC sports in Australia are powerchair soccer and powerchair hockey.

4. Powerchair soccer

4.1 Power wheelchair requirements

A Powerchair soccer player needs a PWC with a lap belt and footguard. The footguard is a cage that extends around the front of the wheelchair which the player uses to kick the football (FIPFA, 2020a).

The FIPFA rules for PWCs are:

- Powerchairs must have 4 or more wheels.
- 3 or 4-wheeled scooters or similar equipment are not permitted.
- The maximum speed allowable during the match for powerchairs is 10 km/h, forwards and reverse.
- Backpacks, bags, etc. are not allowed to be attached to power chairs during play (essential equipment accepted e.g. Oxygen / feeds / ventilators etc).
- Chairs must not have any sharp surfaces or items that might become entangled with other powerchairs (inc. essential equipment).
- Lateral side supports (armrests) must be in place on both sides of the powerchair.
- Appropriate additional restraints are required equipment for those athletes who need them, these may include restraints for chest, shoulder, head, arm or leg.
- No part of the chair shall be constructed so as to be able to trap or hold the ball.
- Additional protection must be added to the powerchair which will prevent the ball from becoming trapped or the wheels riding over the ball.
- Rear protection can be added to a chair to protect the motors and minimise possible entrapment of the ball (FIPFA, 2020b, p.13).

There appear to be standard characteristics which are useful for play beyond what is specified in the rules. Duvall et al. (2020) note that PWCs designed for soccer have a low centre of gravity and use rear wheel drive: “The low centre of gravity aides in stability while permitting high speed and acceleration. The rear wheel drive allows more power to be transferred to the ball through the cage by swinging the front end of the chair” (Duvall et al, 2020, p.2).

4.2 Suitable models of power wheelchair

In the opinion of the president of the Western Electric Sporting Association, there is no safe, entry level alternative to the [Strikeforce](#) for powerchair soccer ([6.1 Western Electric Sporting Association](#)). The Strikeforce is a PWC specifically designed for powerchair soccer. It is manufactured in the USA and price starts in Australia at \$16,335, though it may be considerably more with required personal customisation (STRIKE FORCE, n.d). The website for the South Melbourne powerchair soccer club says that the Strikeforce is the international standard for powerchair soccer devices. They also note:

Players will start playing powerchair football using their day chair. Powerchair Sports Victoria can assist new players [to get started] including providing guards which can be attached to their day chair. Those players interested in participating in powerchair sport may look to invest in a sports chair. Some day chairs have the characteristics to be suitable as a introductory sports chair (Powerchair Sports Victoria, 2021).

On the Melbourne City club website, their list of players notes that while most use Strikeforce, one player uses a [Magic Mobility](#) chair, and another uses a [Quantum Rehab](#) chair. The specific model of chair is not stated (Powerchair Sports Victoria, n.d a, n. d b).

Other specially designed soccer chairs include:

- **Equaliser** by [Power Sports](#) in UK
- **DB Bullet** by [DB Bullet](#) in UK
- **Invacare TDX2 Sprint**, a variation on a standard TDX2 model by [Invacare UK](#)
- **TTS3 PowerSoccer**, by [Degonda Rehab](#) in Switzerland

I have not found evidence that any of these products retail in Australia. DB Bullet also note that they can transfer existing control gear and seating onto the DB Bullet chassis. They also sell a footguard which they market as “a universal attachment to suit most electric day chairs” (Products, n.d).

5. Powerchair hockey

5.1 Power wheelchair requirements

According to the 2021 International Powerchair Hockey Rulebook, requirements for PWCs used in powerchair hockey are:

- wheelchair must have 4 – 6 wheels, with a maximum of 2 safety wheels
- wheels must be fitted with tyres that do not mark the playing field
- wheels with 2 wheels on 1 axle count as 1 wheel
- wheelchair can have no sharp or protruding parts

- except the wheels, all parts of the wheelchair must be high enough for a regulation ball to pass under (that is, over 73mm)
- guards to protect the wheelchair from damage are permitted provided that the guards:
 - are rounded and have no sharp or protruding parts
 - allow the ball can pass underneath
 - do not extend beyond 5cm from the further edges of the wheelchair. (IWAS, 2021)
- wheelchair must not accelerate beyond 15.5 km/h (IWAS, n.d).

As with powerchair soccer, powerchair hockey chairs may have characteristics which are useful or even required for play beyond what is specified in the rules. Duvall et al. (2020) note that powerchair hockey chairs are compact and highly manoeuvrable. The sport is faster play than powerchair soccer, reflected in the maximum permitted speed on the field (15km/h for hockey, 10km/h for soccer). The chairs also sit higher than powerchair soccer chairs, allowing for better control of the stick. They generally have mid-wheel drive.

5.2 Suitable models of power wheelchair

In the opinion of the Western Electric Sporting association president, [s47F- personal privacy](#), there are no safe alternatives to the E-hockey made by [Wolturnus](#) in Denmark or the Turbo Twist made by [Degonda Rehab](#) in Switzerland. All indications are that these models of PWC are not yet available for purchase in Australia. However, [s47F- personal privacy](#) suggests that retailers would import them if they thought the powerchairs would be funded by NDIS ([6.1 Western Electric Sporting Association](#)).

[s47F- personal privacy](#) also suggests that while playing powerchair hockey with day chairs is possible, it can often lead to safety risks including tipping and may cause injury ([6.1 Western Electric Sporting Association](#)).

A history of powerchair hockey from the International Wheelchair and Amputee Sports Federation (IWAS) states:

In the seventies, Powerchair Hockey was born. Back then it was still called Electric Wheelchair Hockey. There were no sports chairs yet, so everybody played in their own electric wheelchair. Players began adding protection to their wheelchairs to protect them from getting damaged. Since the nineties, wheelchair manufacturers have been making electric wheelchairs that are also suitable to play Powerchair Hockey with. Nowadays, there are also sports wheelchairs that only get used to play this sport with. Those wheelchairs are very light, maneuverable, fast and have protection around them. This isn't a contact sport, but collisions happen (IWAS, n.d.).

6. Correspondence

To source information on wheelchair models available in Australia, I sought comment from professional sporting associations around Australia. I contacted:

- Disability Sports Australia
- Australian Powerchair Football Association
- Western Electric Sporting Association
- Powerchair Sports Victoria
- Queensland Powerchair Football Association
- NSW Powerchair Football Association
- Australian Powerchair Hockey Association NSW

At present, I have only received responses from s47F - personal privacy Western Electric Sporting Association and Sales Administrator for NDIS provider Wild West Wheelchairs.

6.1 Western Electric Sporting Association

From: s47F - personal privacy Aaron
Sent: Monday, 6 June 2022 9:04 AM
To: s47F - personal privacy <support@wildwestwheelchairs.com>
Subject: RE: Wheelchairs for powerchair soccer and hockey [SEC=OFFICIAL]

Hi s47F - persona

Thanks so much for the info. It'll be really helpful.

I'll get in touch if I have any further questions.

All the best

Aaron s47F - personal privacy
Research Officer
National Disability Insurance Agency
Email [s47F - personal privacy@ndis.gov.au">aaron.s47F - personal privacy@ndis.gov.au](mailto:aaron.<span style=)

Work days: Monday – Thursday

From: s47F - personal privacy <xxxxxxx@xxxxxxxxxxxxxxxxxxxxxxx.xxx>
Sent: Thursday, 2 June 2022 5:43 PM

To: ^{s47F - personal privacy} Aaron <^{s47F - personal privacy} Aaron.^{s47F - personal privacy}@ndis.gov.au>

Subject: Re: Wheelchairs for powerchair soccer and hockey [SEC=OFFICIAL]

Hi Aaron,

Thanks for your email. I will just clarify some of your points:

- There are a few 2nd hand hockey chairs around Australia, which may be available to rent for competitions, but there are not enough to go around

The 2nd hand hockey chairs are privately owned, only 4 exist in Australia, and owners are generally reluctant to loan them, although they may be loaned during inter-state competitions. For local- entry level - competition, day chairs are able to be used, however they are not suitable for safety reasons - regardless of modifications - as discussed.

- A couple of European companies, Wolturnus and Degonda make hockey chairs but there are no retailers in Australia that stock them.

Australian Disability Equipment suppliers in WA, NSW and South Australia have been looking to stock Wolturnus and Degonda, chairs, but the NDIS has so far declined all applications for both Wolturnus and Degonda hockey chairs.

I have attached FIPFA Official rules and regulations to this email, and you can find rules on playing equipment in Section 4 (p.13). The FIPFA Document was published in 2010, and the Strikeforce Powerchair for Soccer has been introduced to the market since the publication of this document.

For Powerchair Hockey, as per the website of the international governing body:

In the seventies, Powerchair Hockey was born. Back then it was still called Electric Wheelchair Hockey. There were no sports chairs yet, so everybody played in their own electric wheelchair.

Players began adding protection to their wheelchairs to protect them from getting damaged. Since the nineties, wheelchair manufacturers have been making electric wheelchairs that are also suitable to play Powerchair Hockey with. Nowadays, there are also sports wheelchairs that only get used to play this sport with. Those wheelchairs are very light, maneuverable, fast and have protection around them. This isn't a contact sport, but collisions happen.

Players can drive on the playing field with a maximum speed of 15km/h. This is the international standard, but in some national leagues there is no speed limit. At the moment, sports chairs can drive about 18km/h.

Since 2012, there is speed control on EC's and WC's. Before the tournament starts, all wheelchairs are inspected. The wheelchairs will only get approved for the tournament if they don't drive faster than 15,5km/h. The official limit is 15km/h, but a deviation of 0,5km/h is allowed.



I have attached the instructions for checking player equipment which specifies the minimum requirements of a Power Hockey chair, as well as the IPCH Game Rules. Rules about powerchairs can also be found in section 5 of this document.

Whilst none of the documents stipulate a specific model of chair required for both sports, the Strikeforce, Turbo Twist and Wolturnus E-Hockey chair are the standard for Powerchair Soccer and Powerchair Hockey respectively. There is no safe entry-level alternative to these chairs.

Please get in touch if you have any more questions - I'd really like to assist!

Regards,

s47F - personal privacy

Sales Administrator

Wild West Wheelchairs

s47F - personal privacy

Unit 6, 16 Stanford Way

Malaga, WA 6090

From: s47F - personal privacy Aaron

Sent: Thursday, 2 June 2022 5:01 PM

To: support@wildwestwheelchairs.com

Subject: Wheelchairs for powerchair soccer and hockey [SEC=OFFICIAL]

Hi s47F - personal privacy

Thanks heaps for your time this afternoon.

Just to confirm what we talked about:

- Soccer and hockey chairs have different requirements and can't easily be repurposed for the other sport.
- Day chairs are generally too heavy and tip too easily to be used for soccer or hockey.
- Its possible to make some modifications to day chairs (eg. install footbars) but the chairs will still be unsafe.
- Strikeforce is so far the only brand of soccer chair you've seen in Australia.
- There are a few 2nd hand hockey chairs around Australia, which may be available to rent for competitions, but there are not enough to go around.

- A couple of European companies, Wolturnus and Degonda make hockey chairs but there are no retailers in Australia that stock them.

Does that about cover it?

As far as technical specifications, I am interested in what makes a suitable chair for both hockey and soccer. What are minimum requirements in terms of speed (forward and reverse), turning speed, rear wheel/mid wheel drive, weight, height etc.?

Thanks again for your help.

All the best

Aaron s47F - personal privacy

Research Officer

National Disability Insurance Agency

Email s47F - personal privacy aaron.s47F@ndis.gov.au

Work days: Monday – Thursday

7. References

Duvall, J., Satpute, S., Cooper, R., & Cooper, R. A. (2020). A review of adaptive sport opportunities for PWC users. *Disability and Rehabilitation. Assistive Technology*, (preprint online), 1 - 7. <https://doi.org/10.1080/17483107.2020.1767220>

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8. Version control

Version	Amended by	Brief Description of Change	Status	Date
1.0	Aaron <small>S47F - personal privacy</small>	Research paper investigating PWC options for sport.	Cleared	07/06/2022
0.2				
0.3				
1.0				

Outcome comparison of catheter model and technique

The content of this document is OFFICIAL.

Please note:

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The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters

Research question:

Date: 02/03/2022

Requestor: Nicola s47F - personal priv

Endorsed by: Charika s47F - personal privacy

Researcher: Aaron s47F - personal privacy

Cleared by: Aaron s47F - personal privacy

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2. Summary

Different catheter types and different methods of use, cleaning and management may affect the comfort, usability and potential risks of catheter use. Due to inconsistency in the literature, firm conclusions are not possible regarding the effect of different catheter types or methods on risk of UTI and other health complications. No conclusions can be drawn to suggest hydrophilic catheters, closed system catheter sets, or ‘no touch’ catheters lower risk of health complications.

Catheter types and management strategies can vary widely in cost. Reusable non-coated catheters are the least expensive catheter type by unit cost. The most expensive is likely single-use, closed-system, hydrophilic catheters. However, when associated costs such as health-care and employment are included, the overall costs may be different.

Most cost-effectiveness studies from the last 7 years find that hydrophilic catheters are more cost-effective over a lifetime compared to single-use uncoated catheters. An Australian study calculates a lifetime saving of \$298,450 in favour of hydrophilic catheters. All cost-effectiveness analyses reviewed are limited by assumptions and inferences that may not be supported by current evidence. Therefore, it is not possible to say with confidence that the hydrophilic catheter is more cost-effective than lower cost options.

Risk of urinary tract infection (UTI) and associated health-care costs are a key feature of cost-effectiveness analyses. Most cost-effectiveness studies fix an incidence rate for UTI for different types of catheter. The studies finding that hydrophilic catheters are more cost-effective generally infer a reduced risk of UTI for hydrophilic compared to other types of catheter. However, this conclusion may not be supported by current evidence.

While there are a number of reviews and meta-analyses which favour hydrophilic catheters for reducing risk of UTI and other health complications, the evidence is not firm. Several studies find no difference between catheter types. There is moderate level evidence that hydrophilic catheters may even increase the risk of urethral trauma.

There are also some notable limitations in the literature. There is significant heterogeneity especially around the definition of UTI. Studies are often not generalisable due to non-representative samples and attrition bias.

3. Catheter types and methods

In-dwelling catheterisation involves leaving the catheter in place for a period of time. This is not the preferred option for most people requiring catheterisation but is still used by around one third of people with a spinal cord injury (Wu et al, 2022). Intermittent catheterisation involves

inserting and removing a catheter multiple times a day. Catheters used in intermittent catheterisation may be used once and discarded (single-use) or used multiple times (reusable). Reusable catheters may be used for one day or for longer periods. They usually require washing between uses (Wu et al, 2022; Ye et al, 2021; Health Quality Ontario, 2019).

Single-use catheters can be used with either a sterile technique (sterile catheter, gloves, in a sterile environment as far as possible) or a clean technique (clean hands or gloves). Reusable catheters can only be used with a clean technique (Prieto et al, 2021; Ye et al, 2021; Health Quality Ontario, 2019).

Some catheters require the user or carer to add lubricant before insertion. They are referred to as non-coated catheters to distinguish them from hydrophilic-coated catheters which have a polymer coating that acts as a lubricant when it interacts with water. Hydrophilic catheters may also come in sterile packaging with saline solution, which means the user does not need to add water before insertion. These are called pre-activated hydrophilic catheters. Non-coated catheters may also come in a sterile package pre-lubricated. Catheters may be purchased by themselves or with a urine collection bag already attached (Ye et al, 2021; Health Quality Ontario, 2019).

4. Outcomes

Research on outcomes associated with catheter use focusses on:

- incidence of UTIs
- other adverse events (like haematuria, urethral trauma, bladder stones etc.)
- preference or satisfaction with different types or methods.

Most contemporary research focusses on comparisons of different intermittent catheterisation techniques using hydrophilic or non-coated catheters. Despite this being a well-researched area, few firm conclusions are possible. Many systematic reviews and meta-analyses show inconsistent results.

Due to the quantity of research material available, we have prioritised:

- evidence published in the last 7 years (2017-2023)
- review articles and cost-effectiveness studies
- evidence related to an Australian context where possible.

The following discussion of catheter type and method outcomes is based on 17 systematic reviews conducted between 2017 and 2023.

4.1 Risk of urinary tract infections

Low level evidence suggests that intermittent catheterisation is associated with fewer UTIs than in-dwelling catheterisation (Wu et al, 2022; Kinnear et al, 2020).

There is significant disagreement in the literature as to whether hydrophilic catheters are associated with lower risk of developing a UTI. Some meta-analyses have found a significantly reduced risk of UTI for people using hydrophilic catheters (Plata et al, 2023; Gauhur et al 2022; Ye et al, 2021; Feng et al, 2020; Rognoni & Taraconi, 2017). However, the results are not straight-forward. Feng et al (2020) found a 54% reduction in frequency of UTI associated with use of hydrophilic catheters. Rognoni & Taraconi (2017) found a lower risk of UTI associated with hydrophilic catheter compared to single-use non-coated catheter. This contrasts with Plata et al (2023), who found a reduction in frequency of UTIs overall, but not if the comparison is limited to single-use hydrophilic versus single-use non-coated. They found a significantly lower risk in adult hydrophilic catheter users but not the paediatric group. Gauhur et al (2022) found hydrophilic catheters are associated with a statistically significant reduction in UTIs only if the sub-group is limited to long term catheter users. When comparing all subjects, there was no significant difference in UTI frequency. Ye et al (2021) found a significant reduction in UTIs for both hydrophilic and gel-lubricated catheters when compared to non-coated catheters, but no significant difference between hydrophilic and pre-lubricated models. There is some low-very low certainty evidence favouring pre-lubricated catheters presented in other reviews (Health Quality Ontario, 2019; Shamout et al, 2017). A report from Health Quality Ontario (2019) did not find significantly different levels of risk in the development of UTI for any catheter type. Prieto et al (2021) note that both higher risk of UTI and lower risk of UTI are possible considering the margin of error.

This inconsistency is reflected in reviews that did not complete a meta-analysis. Shamout et al (2017) found only one out of 6 papers reviewed found a significant reduction in risk of UTI associated with use of hydrophilic catheter. Barken & Vaabengaard (2022) in contrast, found 8 out of 10 studies supported the use of hydrophilic catheters to reduce UTI frequency.

Prieto et al (2021) suggest that the most impactful question regarding risk of UTI is whether risk is affected by single-use or multiple-use catheter practice. The authors found no compelling evidence that single- or multiple-use was associated with different rates of UTI. This is echoed in the Health Quality Ontario report (2019).

Furthermore, there is some emerging evidence that other strategies such as catheter cleaning techniques or education programs for nurses or carers can decrease risk of UTI for long term catheter users (Alex et al, 2022; Mitchell et al, 2021; Shamout et al, 2017). However, evidence is not sufficient to draw a conclusion regarding these interventions (Prieto et al, 2021; Mangal et al, 2021; Sheperd et al, 2017).

Due to inconsistency of results, firm conclusions are not possible regarding the effect of different catheter types or methods on risk of UTI. Some limitations are pervasive in the literature. Reviewers often refer to differences in the definition of UTI to explain the

inconsistency of results (Plata et al, 2023; Barken & Vaabengaard, 2022; Prieto et al, 2021; Rognoni & Taraconi, 2017). Many studies included in systematic reviews and meta-analyses have disproportionate levels of male participants and high drop-out rates, especially for hydrophilic treatment groups (Plata et al, 2023; Ye et al, 2021; Rognoni & Taraconi, 2017).

4.2 Other adverse events

Prieto et al (2021) found moderate certainty evidence that non-coated catheters slightly reduce the risk of urethral trauma and bleeding compared with hydrophilic catheters. Whereas Feng et al (2020) found a 55% reduction in risk of urethral trauma associated with hydrophilic catheters. Liao et al (2022) found a significant reduction in microscopic haematuria with hydrophilic catheters compared to non-coated catheters, but no statistically significant difference for gross haematuria. Health Quality Ontario (2019) and Plata et al (2023) found a similar result. Rognoni & Taraconi (2017) found a higher, but non-significant risk of haematuria for hydrophilic catheters.

4.3 User preference

Most studies that track user preference favour hydrophilic catheters (Barken & Vaabengaard 2022; Feng et al, 2020; Shamout et al, 2017). Ye et al (2021) found a stronger preference for pre-activated hydrophilic catheters followed by reusable non-coated, non-preactivated hydrophilic, pre-lubricated and single-use non-coated. However the differences between these groups were not significant. Health Quality Ontario (2019) found a stronger preference for pre-lubricated single use catheters. Prieto et al (2021) found no reliable evidence of difference in preference between catheter models.

5. Cost-effectiveness

Cost-effectiveness studies have been completed for Australia (Couchman et al, 2022), Japan (Watanabe et al, 2017), Italy (Rognoni & Tarricone, 2017), United Kingdom (Baker et al, 2023), Brazil (Truzzi et al, 2018), Canada (Health Quality Ontario, 2019; Welk et al, 2018) and United States (Hutton et al, 2018). Multiple systematic reviews consider cost-effectiveness of different catheter models or techniques (Barken & Vaabengaard 2022; Prieto et al 2021; Feng et al 2020; Shamout et al, 2017) but only one was found for which cost-effectiveness was the main focus (Xi et al, 2021).

Most cost-effectiveness analyses have focussed on costs and outcomes for people with spinal cord injury (Couchman et al, 2022; Xi et al, 2021; Truzzi et al, 2018; Welk et al, 2018; Watanabe et al, 2017; Rognoni & Tarricone, 2017). Baker et al (2023) included patients with either spinal cord injury or multiple sclerosis. Hutton et al (2018) included patients with indwelling catheters residing in nursing homes. The study from Health Quality Ontario (2019) focussed on participants with chronic urinary retention.

The international studies from Japan, Canada, UK, USA, Brazil and Italy all suggest that the single use hydrophilic catheter is a cost-effective option in their respective contexts. This is

primarily due to costs of treatment of UTIs and other complications of UTIs. The exception is one study from Ontario, Canada, which found multiple-use non-coated catheters were the most cost-effective option:

Given the marginal differences in total QALYs across catheter types, the lowest-cost intervention—multiple-use noncoated catheters (one per week)—had the highest probability of being cost-effective when compared with multiple-use noncoated (one per day), single-use noncoated, and single-use hydrophilic catheters. Where it may not be feasible for some patients to clean and reuse catheters, single-use noncoated catheters have the highest probability of being cost-effective (Health Quality Ontario, 2019, pp.79-80).

This conclusion likely differs from most other cost-effectiveness analyses due to:

- limited horizon of 5 years compared with lifetime horizon of other studies
- a very high estimate of the difference in cost between hydrophilic and non-coated catheters relative to other studies
- the authors' assessment that there is a low level of evidence for significantly different outcomes for hydrophilic, non-coated catheters and for single or multiple-use catheters.

Regarding the 5 year horizon, the authors justify this based on limited evidence for the long term incidence of complications for different catheter types and lack of data on the associated costs of complications. Other studies either: i) make cost and incidence predictions based on inferences from related data, or ii) assume costs and risk are constant over a lifetime.

Regarding the high cost estimate, the authors based monthly and unit costs on information providers made available online. They calculated a minimum of \$800 per month for single use hydrophilic catheters based on a unit cost of \$7.02 and a minimum of \$135 per month for single use non-coated catheters based on a unit cost of \$1.09 (all prices in Canadian dollars). In contrast, the other Canadian based cost-effectiveness analysis set prices at \$3.77 hydrophilic catheters and \$1.07 for non-coated catheters (Welk et al, 2018). The hydrophilic catheter unit cost is almost double from one study to the next, which is bound to make a significant difference to the final analysis.

It is important to note that all of these international studies are limited in terms of generalisability. Conclusions may not transfer to other contexts or service systems. As with the two Canadian studies, Xi et al (2021) note that the stated difference in costs between hydrophilic and non-hydrophilic catheters varied considerably between the studies they reviewed (from \$2.49 USD to \$24.24 USD per day). Few of the cost-effectiveness studies reviewed considered other types of catheters, for example, gel-lubricated non-hydrophilic catheters. All these studies also make assumptions inferences or about the benefits of hydrophilic catheters which may not be supported by the current evidence. And most recognise that either important data points are missing or the quality of the included clinical

evidence is low. As such, its not clear if long term costs of either product are under- or over-estimated.

One study looked at the cost-effectiveness of hydrophilic catheters for people with spinal cord injury in an Australian context. Couchman et al (2022) found hydrophilic catheters have higher unit cost, but ultimately provide a more cost-effective option due to reduction in UTIs, quality of life, life years gained and productivity. Including unit cost and societal costs such as productivity loss, hospital admissions and treatment for UTIs and other complications, the authors calculate a lifetime saving of \$298,450 in favour of hydrophilic catheters.

This study has some limitations. The authors were not able to source Australian data on UTI frequency for people with spinal cord injury living in the community or for costs associated with some UTI complications. They inferred a UTI frequency based on in-hospital incidence and clinical judgement. Outcomes for hydrophilic catheters (e.g reduction in UTIs) were based on only meta-analyses which showed a positive effect on UTI frequency in favour of hydrophilic catheters. A few of those meta-analyses were published over 25 years ago. Furthermore, the authors note that a longitudinal cost-effective analysis based on real-world cost and health outcome information would be more reliable.

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Research Request – Phrenic nerve pacing

Brief

Investigate and develop summary of available literature published including the below too:

- Information about the total phrenic nerve pacing support ‘package’ including equipment and interventions (hospitalisation, surgery etc) required to implement support, maintenance or replacement of equipment etc
 - Any clinical guidelines available outlining potential risks and benefits of the Phrenic nerve pacing option, recommendations around the medical assessment/monitoring supports,
 - What would be other support options considered/required instead of phrenic nerve pacing support? what alternative respiratory support options look like
-

Date: 12/06/2020

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Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters

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1. Summary

Phrenic nerve stimulation is not a new concept and has been around for decades.

- The quality of evidence investigating phrenic nerve pacing is rated as low due to small sample sizes, lack of comparison groups and high potential for bias.
 - This is due to the low number of patients who meet the strict criteria for surgery. For example, a report from the UK has estimated that only 4-5 patients per year would be deemed suitable. Data from the Avery Biomedical (first FDA approved device in 1987) shows that as of 2018 only 973 devices have been implanted globally. This means that the procedure is also relatively uncommon in other countries other than Australia (no MBS code for the procedure or any mention in Insurance/compensation schemes).
 - Although evidence is weak. The overall clinical consensus is that the procedure is safe (low adverse events and no deaths linked to the procedure) and there is long-term follow up data that shows many patients have continued to pace for over 10 years.
 - No data which investigates whether the device increases life expectancy
 - Improved comfort level, improved speech, reduced anxiety and embarrassment, and reduced hospitalisation due to respiratory infections are the several benefits of the device
- Cost effectiveness: no studies undertake a complete cost effectiveness analysis, however, a UK report provide a basic 10 year comparison which found that mechanical ventilation is slightly cheaper than phrenic nerve pacing. Those using phrenic never pacing report greater quality of life and reduced hospitalisation from respiratory tract infections which would likely offset these costs.
 - Refer to section 5.6 and 5.7 for information on product warranty and device failure of each component.
- Mechanical ventilation (invasive) is still the most common form of respiratory support. Refer to section 6 for an overview of other respiratory supports.

2. What is the phrenic nerve?

The body has two phrenic nerves, a left and a right one. Each originates in the neck and passes down between the lung and heart to reach the diaphragm. These nerves play a pivotal part in breathing – passing motor information to the diaphragm while receiving sensory information.

3. What is phrenic nerve stimulation?

Phrenic nerve stimulation, also known as diaphragmatic pacing, is an alternative to standard mechanical ventilation. The application of repetitive stimulus patterns to the phrenic nerves causes smooth, rhythmic contractions of the diaphragm, which result in the inhalation of air into the lungs.

There are 3 commercially available devices that can stimulate the diaphragm. The Mark IV Breathing Pacemaker, made by Avery Biomedical Devices; the Atrotech OY's Atrostim; and the Synapse Biomedical NeuRx [1]. The Avery and the Synapse devices are available in the United States, and the Atrotech device is available only in Europe. The Synapse NeuRx device received FDA approval in 2011 for humanitarian use in patients 21 years or older with amyotrophic lateral sclerosis (ALS). The Avery Mark IV Breathing Pacemaker received full premarket approval by the FDA in 1987 and is reimbursed by Medicaid and Medicare services in the USA. A key difference between the devices is that the Mark IV Breathing Pacemaker and Atrotech OY's Atrostim stimulate the phrenic nerve and the NeuRx DPS is an intramuscular diaphragm stimulator. This is a newer approach which uses an abdominal laparoscopic approach has been proposed instead, in an effort to reduce the risk of phrenic nerve injury [2, 3].

The benefits of intra muscular diaphragm stimulators (NeuRx) for long-term use following spinal cord injury are questionable [4, 5].

4. Intra-muscular diaphragm stimulation

The aim of intramuscular diaphragm stimulation is to make the diaphragm contract, strengthening it and allowing full or partial weaning from mechanical ventilation [5]. This procedure needs intact phrenic nerve function, and avoids the need to access the phrenic nerve through the neck or thorax, as well as reducing the risk of phrenic nerve damage [5].

The procedure is done laparoscopically with the patient under general anaesthesia. A special probe is used to identify areas of the diaphragm where minimal electrical stimulation causes maximal diaphragm contraction (known as the 'motor points') [5]. Two intramuscular electrodes are implanted on the abdominal surface of each hemi-diaphragm at the motor points. The electrode leads are tunneled subcutaneously to an exit site in the chest where they are connected to an external battery-powered pulse generator [5]. A reference electrode (anode) is also implanted and the leads tunneled with the other electrodes. Intraoperative stimulation and voltage calibration tests are carried out to confirm adequate contraction of the diaphragm. After implantation the patient has a diaphragm conditioning programme, which involves progressive use of the system for increasing periods of time with gradual weaning from the ventilator [5].

4.1 Literature Review

A systematic review [6] of 148 patients with traumatic high cervical spinal injuries and ventilator-dependent respiratory failure (from 12 studies), intramuscular diaphragm stimulation systems were implanted successfully in all patients except one. This was because of a false positive preoperative phrenic nerve conduction test in this patient.

Half of the patients (range 40% to 72%) could be weaned from ventilators after the procedure and most could use the stimulator instead of a ventilator for several hours per day. One study [7] reported that more than 50% were using diaphragm pacing 24 hours per day and up to 96% were able to use pacing for 4 hours continuously.

Current evidence on intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure caused by high spinal cord injuries shows that there are serious but well-recognised safety concerns [4, 5] (see Table 1 for list of safety concerns). NICE guidelines [4, 5] report anecdotal evidence of increased mortality and decompensated respiratory failure and breathlessness related to diaphragm pacing. Evidence on efficacy is limited in quantity and quality. Therefore, the NICE recommends that this procedure should only be used in the context of research.

In comparison to standard phrenic nerve pacing devices, the intramuscular diaphragm pacing machines do not have long term follow up/safety data (only 12 years compared to 45 for original phrenic nerve pacing devices), additional risk of infection due to protruding wires, only a single point system failure meaning there is no backup if the system fails [4, 5, 8].

4.2 Experimental use in the treatment of amyotrophic lateral sclerosis

The Synapse Biomedical NeuRx has humanitarian approval for use in those with amyotrophic lateral sclerosis (ALS) [2, 3]. Randomised controlled trials have shown increased mortality in groups treated with NeuRx, although the reasons for this were unclear [5]. Safety issues arising from studies included increased adverse and serious adverse events, respiratory failure, capnothorax, venous thromboembolism, gastrostomy tube placement, infection at the stimulation cable entry point was noted in 22%, and wire failure was reported in 14% [4, 5].

NICE guidelines conclude that intra-muscular diaphragm stimulation for motor neurone disease poses serious long-term safety concerns. Evidence on efficacy is limited and therefore, this procedure should not be used to treat this condition. The peer reviewed literature referenced in the NICE guidelines has not been summarised in this document but can be found at <https://www.nice.org.uk/Guidance/IPG593>

At this time, there are no studies comparing phrenic nerve stimulation and intramuscular diaphragm stimulation.

5. Phrenic nerve pacing via direct stimulation

5.1 Indications

A phrenic nerve pacer is indicated in persons who require chronic ventilator support because of upper motor neuron respiratory muscle paralysis (RMP) or because of central alveolar hypoventilation (CAH) and whose remaining phrenic nerve, lung and diaphragm function is sufficient to accommodate electrical stimulation [9]. All ventilator dependent

people with high spinal cord injury (C0-C4) with intact phrenic nuclei should be considered for this procedure, regardless of age or gender [10].

Candidates for diaphragm pacing include, but are not limited to, patients who have [9]:

- Central alveolar hypoventilation
- Decreased day or night ventilatory drive (i.e. sleep apnoea, Ondine's curse)
- Brain stem injury or disease
- Spinal cord injury or disease

5.2 Patient selection

Diaphragm pacing is generally indicated in prospective candidates who have [9, 10]:

- Functional lungs and diaphragm muscle
- Intact or repaired phrenic nerves
- Absence of infection
- A clear and adequate upper airway (including nasopharynx, pharynx and larynx)
- Adequate physical caregiver quality and availability including nursing, family support and medical care

5.3 Benefits of phrenic nerve pacing [11]

Subjective sense of more normal breathing

Improved comfort level

- Elimination of ventilator tubing
- Easier transport outside the home
- Easier transfer to and from bed
- Increased mobility

Improved speech

Restoration of olfactory sensation

Reduced anxiety and embarrassment

- Elimination of ventilator noise
- Elimination of ventilator tubing and fear of ventilator disconnection
- Daytime closure of tracheostomy

Reduced overall costs

- Reduction or elimination of ventilator supplies
 - Reduced level of caregiver support
-

5.4 Surgical Information

The phrenic nerve pacing system consists of 'implanted components' (phrenic nerve electrodes, implanted connector and radiofrequency receiver) and 'exterior components' (antenna and stimulus transmitted) which can be seen in Figure 1 [11].

A surgical procedure is necessary to implant the electrode under the phrenic nerve and the receiver just under the surface of the skin [8]. This procedure can take place at the neck (cervically) or in the chest (thoracically). Usually patients receive two sets of implants, one on each side, unless their condition is limited to only one side [8, 11].

The procedure averages 2-4 hours in length [8, 10]. Depending on the procedure selected, it can be performed on an outpatient basis [8]. The decision as to which approach is appropriate is determined by the surgeon performing the procedure [8, 10, 11].

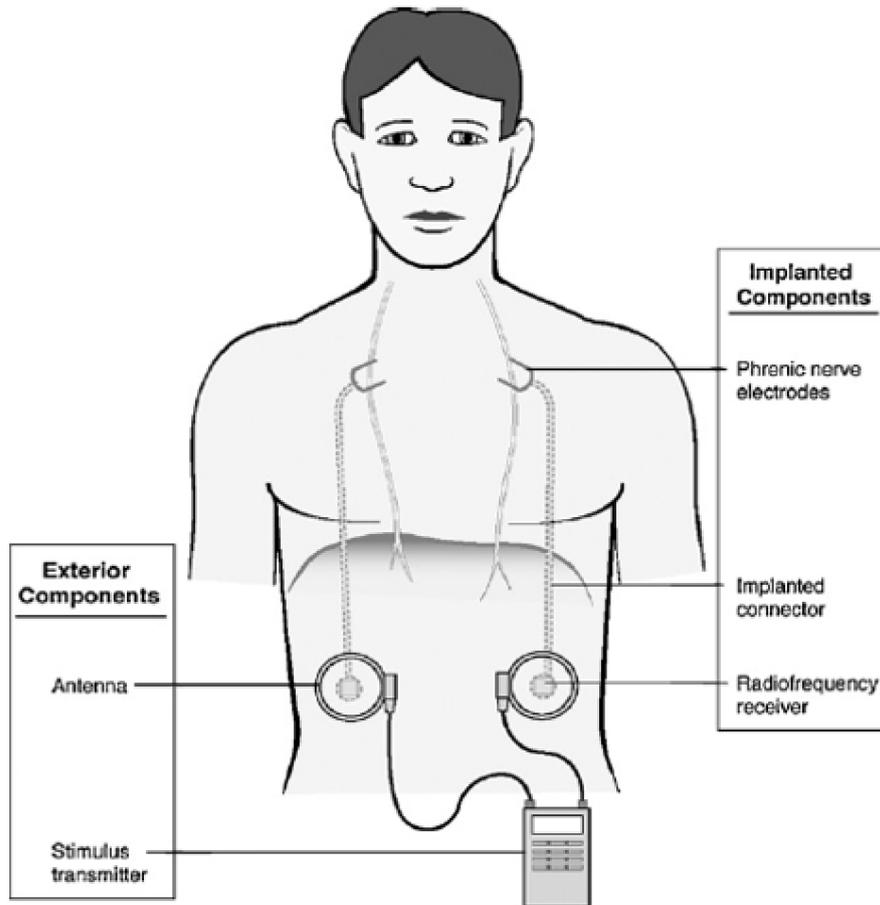


Figure 1. Basic design of commercially available phrenic nerve pacing systems. The internal components (right side of image) consist of a single electrode implanted on each phrenic nerve in the thorax; each electrode is connected by wires to subcutaneously implanted radio-frequency receivers. The external components consist of a stimulus transmitter and attach rubberised antennae which must be positioned over the radio-frequency receivers. The receiver converts them to electrical signals from the transmitter and converts them to electrical signals which stimulates the phrenic nerves to activate the diaphragm.

5.4.1 Thoracic approach

The thoracic approach involves a small (5-7 cm) incision made between a pair of ribs so that the phrenic nerve can be isolated alongside the heart. The surgeon places the electrode under or near the phrenic nerve and sutures it in place. The receiver is then placed just under the skin, usually from within the same incision [8, 10].

The thoracic approach can be performed in a minimally invasive manner by using video-assisted thoracic surgery techniques. Since a small camera is used to provide visualization of the operative site, the incision can be significantly smaller [8, 10].

The thoracic approach can also be performed thoracoscopically and involves the use of multiple small (5-10 mm) incisions instead of one primary incision. Through these incisions, a camera and specially designed instruments are used to visualize the nerve and place the electrode. Thoracoscopic procedures can be performed with standard endoscopic instruments or by use of a surgical robot [8, 10].

This approach is commonly chosen for the youngest paediatric patients since the anatomy of the neck is not sufficiently developed in these cases. It is also a common approach for patients who are suspected of having nerve damage so that the stimulation can occur below the presumed injury [8, 10].

5.4.2 Cervical approach

The cervical approach is also considered minimally invasive since it does not require a thoracotomy, or chest procedure [8, 10].

It uses a small (3-5 cm) incision made in the area where the neck meets the torso. The phrenic nerve is isolated where it is most superficial. The surgeon places the electrode under the phrenic nerve and sutures it in place. The receiver is then placed just under the skin, usually within a small pocket made on the upper part of the chest [8, 10].

This approach is commonly chosen for older paediatric patients and adult patients who are known to have good phrenic nerve conduction. In addition to avoiding a thoracotomy, this approach has the advantage that it can be performed on an outpatient basis for some patients [8, 10].

5.5 Post-operative care

A report by the NHS [10] has suggested that 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 to 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 spinal cord injury 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.

Immediate postoperative care should include:

- Maintenance of usual, chronic ventilatory support and/or pacing on an unaffected side
- Continuation of intraoperative antibiotics for a reasonable period
- Use of a short postoperative course of steroids to diminish the incidence of perineural oedema.
- Meticulous wound care to decrease infection
- The patient's CO₂ level should be in the mid to upper 30's prior to pacing. If necessary this level should be gradually adjusted during the **10-14 day waiting period** [8, 10].

5.6 Product warranty

All warranty and information on device failure is taken from the Avery Biomedical website [8].

Transmitter: 3 years

The expected service life of the Mark IV transmitter (Avery Biomedical) is 10 years. There is no calibration, preventative or scheduled maintenance during the lifetime of the transmitter.

Antenna: 90 days

It is recommended that they are replaced every 6 months (expected service life). Proper care and gentle handling will make them last longer but they will eventually wear out.

Receivers: 5 years

Receivers have an expected service life of 10 years. Replacement can be done under local anaesthetic on an outpatient basis.

Electrodes: 5 years

Most electrodes will serve the patient for their entire life. In rare instances electrodes have been damaged or destroyed through stretching because of growth of the patient.

In cases of receiver replacement, with undisturbed electrodes, pacing can begin immediately. With newly implanted electrodes, diaphragmatic pacing should be deferred in the immediate postoperative period. Surgical trauma causes local perineural oedema and oedema of the subcutaneous tissues. Healing, with fibrosis and accommodation gradually occur and pacing can safely begin at about **10-14 days postoperatively**. However, some doctors may choose to wait longer depending upon patient status.

Depending on patient status, discharge from the hospital following recovery from surgery is suggested. The patient may then be brought back to the hospital or clinic for initiation of pacing or may initiate pacing at home. Regardless of patient diagnosis, determination of each hemidiaphragm threshold is required prior to the start of effective bilateral diaphragm pacing. Threshold is the lowest transmitter amplitude setting that starts muscular contraction.

5.7 Device Failure/backup

Failure of the diaphragm pacing system can occur due to battery failure, broken battery connector wire, or intermittent antenna cable or connector, or component failure in the receiver, electrode wire, or external transmitter. Avery Biomedical diaphragm pacing systems are designed with bilateral redundancy for superior safety. Each diaphragm is paced by its own receiver, electrode, and external transmitter output. This independence provides an extra level of safety as there is no single failure point which could cause the entire system to stop working. These devices have also been subject to rigorous environmental and electromagnetic testing by independent laboratories to ensure safety and efficacy.

A device for providing artificial ventilation by mask, mouth piece or tracheal tube should be available for those patients who are continually dependent on the phrenic pacemaker as an alternative to mechanical ventilation.

5.8 Number of implanted devices and long-term follow up data

The UK national incidence and prevalence figures for spinal cord injury would indicate 40 newly injured patients per annum would require mechanical ventilation support [10]. Using data from the single implant centre in the UK as a reference, 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 [10].

Recent data from Avery Biomedical [8] shows that a total of 973 (since 1970's) active, deceased, and inactive patients have been implanted with a phrenic nerve pacing device. 331 patients were implanted using the cervical approach, 630 using the thoracic approach, and 12 using cervical for one side and thoracic on the other.

The majority (50%) of patients with a phrenic nerve pacer had a diagnosis of spinal cord injury (Figure 2).

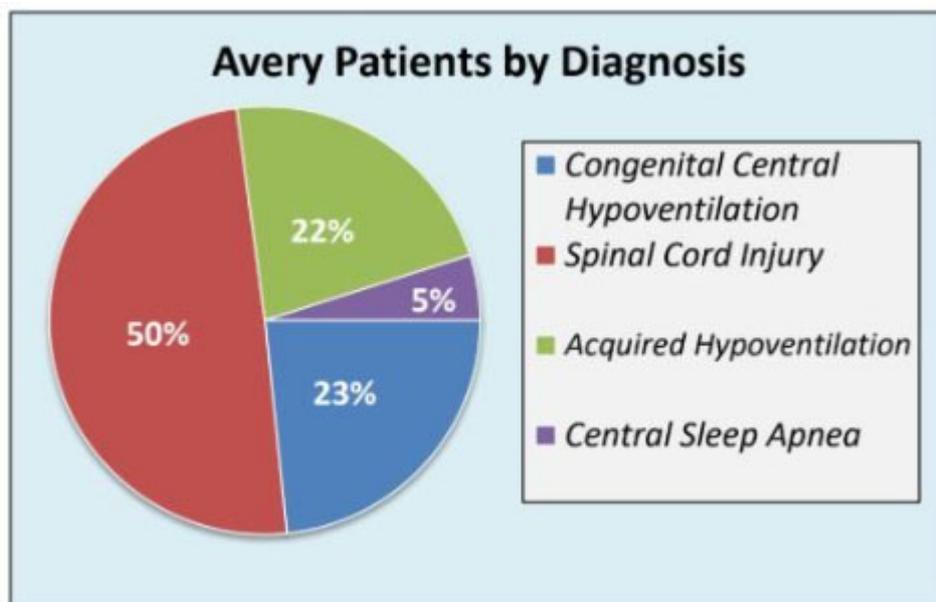


Figure 2. Graph of patients implanted per year separated by surgical approach.

Two patients have been pacing for 40 years. A total of 68 active patients have been using the Avery Diaphragm pacer for over 30 years with an additional 9 patients who paced for over 30 years before death. The average amount of time in between revisions for this group

of patients was 15.1 years. Approximately 8% of patients (3 total) in this category required no revisions since their original implantation (Figure 3) [8].

195 revision surgeries were identified in the company database [8]. 37 of 331 patients who were initially implanted cervically and 78 of 630 patients initially implanted thoracically required one or more revision surgeries. Of the 64 cervical implant revisions, 52 had no change of electrode location and 12 had the electrodes moved into the thoracic region. Of the 131 thoracic implant revisions, 126 had no change in the location of their electrode and 5 were moved into the cervical region [8].

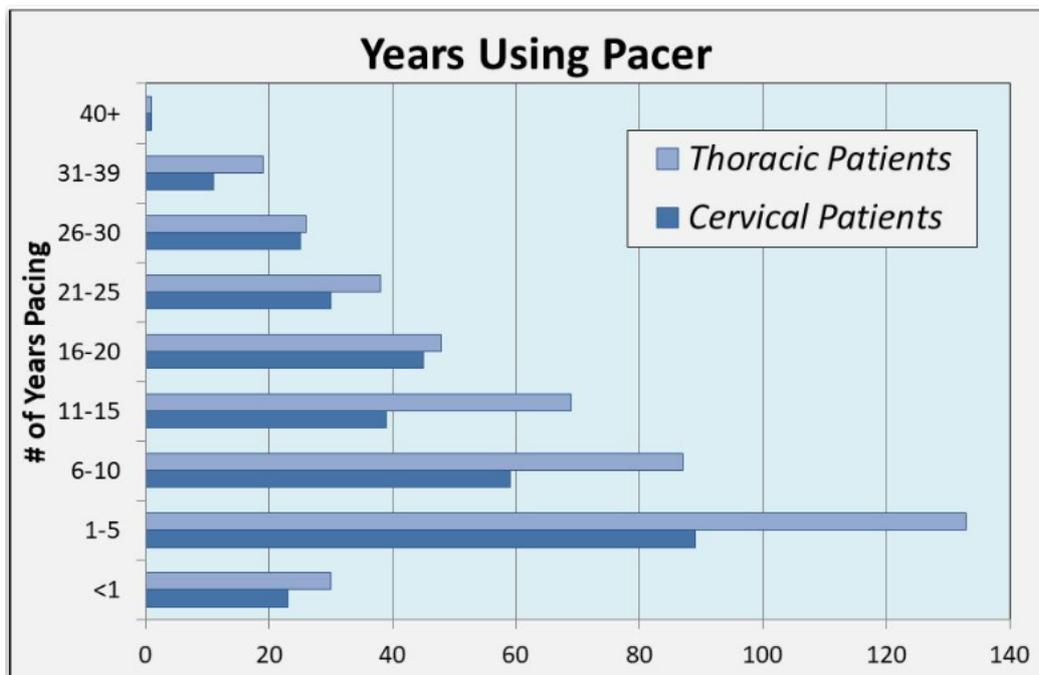


Figure 3. Number of years spent using the Diaphragm Pacer as of November 2018.

5.9 Outcomes and Quality of Life

The main outcomes considered in the only published systematic review [12] on phrenic nerve pacing 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 trial of 64 patients (32 managed by mechanical ventilation and 32 including phrenic nerve stimulation) [13]. There was a trend towards improved survival with phrenic nerve stimulation, however, those treated with phrenic nerve stimulation were younger, more likely to be male and the difference was not statistically significant.

There was a 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 [13]. 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 [13].

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 may be clinically important and statistically significant, though the phrenic nerve stimulation group was younger [13]. *It is not possible from the evidence published to determine if phrenic nerve stimulation impacts on life expectancy* [10, 13].

Self-reporting of symptoms by patient questionnaire and assessment by clinicians indicated an improvement in quality of life and speech. Likely due to lower postoperative respiratory infections in the group treated with phrenic nerve stimulation compared to the mechanically ventilated group [10, 13].

Long-term outcomes are reported in case series from France [14] and Australia [15]. 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.

5.10 Cost Effectiveness

Hirschfield, et al. 2008 [13] in a controlled study reported 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 aim of phrenic pacing is for 24 hours ventilator-free breathing, however, Avery Biomedical reports that only 17% of patients pace for 24 hours per day [8]. Therefore, there is still a considerable cost associated with nursing care of patients with phrenic nerve pacing devices. No other publications were identified that reported on the costs or cost effectiveness of this device.

Khong, Lazzaro et al. 2010, [15] reported a number of device failures that required revision surgery. These costs would need to be included in any cost effectiveness evaluations. 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 the device.

The difference in equipment costs for establishing a person at home on 24 hour ventilation, or 24 hour phrenic nerve pacing has been costed in an NHS report [10]. The initial outlay and 10 year consumable costs are summarised below (converted to AUD from Pounds).

*Note, these prices are from 2014 and are likely to have increased.

5.11 Initial set up costs

Phrenic pacing (plus back-up ventilator): \$96,754.88

Ventilator dependent patient: \$18,704.22

10 year equipment and consumable costs;

Phrenic pacing \$16,878.72

Ventilator dependent patient %72004.42

Price differential over 10 years (per annum); \$2,292.49

The additional cost for establishing a person on a phrenic pacing system is therefore \$2,292.49, but the impact on patient-reported quality of life and increased life expectancy would perhaps outweigh this slightly increased cost. The greatest cost saving relates to the

impact of phrenic pacing on reducing respiratory infection. The Hirschfeld et al. [13] 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 [10, 13].

In Australia, there are no specific MBS items for implantation of a phrenic nerve pacing system. Possible item codes for surgery include dual chamber permanent trans venous electrodes (MBS item 38356 [\$837.35]) and anaesthesia, (20540 [\$261.50]). Operating theatre costs and in-patient admission to intensive care would need to be accounted for.

Unable to obtain any information about whether phrenic nerve pacing would be funded by a compensation scheme. Because it isn't an MBS item for the procedure it would likely need to be a special request.

6. Comparative respiratory treatment options

Various types of ventilation exist to assist patients who have difficulty breathing independently. They can be invasive or non-invasive, and can be further categorised into positive or negative pressure ventilation. 1) Positive pressure ventilation: pushes air into the lungs, 2) negative pressure ventilation: sucks the air into the lungs by making the chest expand and contract. Negative pressure ventilators are rarely in use.

6.1 Positive pressure ventilation

6.1.1 Invasive ventilation (also known as mechanical ventilation)

Invasive ventilation is and has been the standard treatment for respiratory device dependent spinal cord injury patients. Air is forced into the lungs to enable lung function, however, mechanical ventilation can impair the ability to cough and can limit speech [16].

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 [16].

- Endotracheal intubation: the tube is inserted into the patient's airway (trachea) through the mouth or nose.
- Tracheostomy: is a tube inserted below the larynx to enable a patient to breathe when there is an obstruction above the larynx.

6.1.2 Non-invasive ventilation

Non-invasive alternatives to mechanical ventilation, which may be used in some patients to provide periods of time off mechanical ventilation. Non-invasive mechanical ventilators come with masks and can be used at home. The two kinds are [17, 18]:

- Continuous positive airway pressure (CPAP): CPAP treatment uses a positive air pressure to hold the airway open during sleep. The positive air pressure is generated by a pump called a CPAP machine, and is applied through a small mask which fits over the nose, or the nose and mouth and delivers constant and steady air pressure.
- -Auto-titrating (adjustable) positive airway pressure (APAP): occurs in a continuous positive airway pressure (CPAP) machine when the machine's sensor and internal algorithm adjust air pressure on a breath by breath basis.
- Bi-level positive airway pressure (BiPAP): BiPAP is an adaptation of CPAP and delivers two levels of positive airway pressure, an inhale pressure and an exhale pressure.

6.2 Negative pressure ventilators

During negative pressure ventilation, the airway opening is free, unlike in positive pressure ventilation, and consequently, performing bronchial aspiration or bronchoscopy to remove excessive airway secretions is easy. The major advantage of negative pressure ventilation is the avoidance of invasive endotracheal intubation and its related complications. However, limitations include lack of upper airway protection, possibility of obstruction in unconscious patients and neurologic disorders, and many patients are restricted to the supine position [19].

- **Portalung/Tank ventilator:** is a rigid chamber in which the body of the person is subjected to phasic negative and neutral pressure changes in order to cause lung inflation and deflation. The person's head is excluded from the chamber. (This technique of artificial ventilation was formerly used in the treatment of victims of poliomyelitis and was commonly known as an "iron lung" – because the chamber was constructed of metal).
- **Jacket Ventilator (Pulmo-Wrap, Poncho-Wrap):** This ventilator is a windproof, water-permeable nylon parka suspended over a rigid grid that includes the rib cage and abdomen. It allows the application of negative pressure over the anterior portion of the chest wall. Airtight seals around the neck, arms, and hips are required to prevent air leakage.
- **Cuirass:** This consists of a rigid shell fitting firmly over the anterior portion of the chest. It applies negative pressure over a smaller surface area than either the iron lung or jacket and is the least efficient NPV. Its efficiency improves if the anterior abdominal wall is enclosed in the device and movement of the lateral aspect of the upper rib cage is not restrained.

6.3 Additional respiratory supports

* Air humidifier – is a machine that increases the humidity (moisture) in the air and is commonly used to maintain respiratory comfort.

* Portable suction machine (i.e. aspirator) – suction machines are used to remove unwanted fluids such as saliva, mucus or blood, from a person's airway to facilitate breathing.

* Cough assist machine – is a device that mimics an effective cough. The machine pushes a deep breath in the person's lungs and then rapidly pulls that breathe out, mimicking a cough, to ensure removal of airway secretions.

* Oxygen concentrator – is a floor standing, electronically driven device that draws in air through a fine filter. It removes nitrogen and allows only oxygen to pass through the outlet

* Oxygen cylinders – portable oxygen cylinders are used when the patient leaves the home. Used if there is a power failure.

Table 1: Peer reviewed literature relating to diaphragm pacing

Author (year) and country	Study aim	Methods/inclusion criteria/ participant characteristics	Outcome/summary	Quality of evidence High/Moderate/ Low/Very Low
Garara et al. (2016) [6] Phrenic nerve not directly stimulated	To systematically review the safety and effectiveness of intramuscular diaphragmatic stimulators in the treatment of patients with traumatic high cervical injuries resulting in long-term ventilator dependence, with particular emphasis on the effect of timing of insertion of such stimulators.	<p>Systematic Review</p> <p>(1) Reported on adult patients with traumatic high cervical injury, who were ventilator-dependant,</p> <p>(2) Patients underwent intramuscular diaphragmatic stimulation, and</p> <p>(3) Commented on safety and/or effectiveness.</p> <p>Studies published between 2000-2015</p> <p>12 eligible articles were selected</p> <ul style="list-style-type: none"> -Two multicentre retrospective studies -Eight case series -Two case reports <p>Unclear how many participants included – approx. 148. Some studies may have included the same participants across multiple publications</p>	<p>National Institute for Health and Care Excellence (NICE) recommend that this procedure only be used in the context of research due to safety concerns and limited evidence on efficacy.</p> <p>Safety</p> <ul style="list-style-type: none"> -Capnothorax (CO2 related pneumothorax) post-operatively in up to 42% of cases -Asymptomatic pneumothorax (n = 1) -Two cases of post-operative infection -Superficial wound infection along tunnelled wires (which resolved with oral antibiotics, shortening and terminating electrodes) (n = 2) -The diaphragm pacing stimulator interacted with a pre-existing cardiac pacemaker (n = 1) -One patient described intermitted aspiration of food during meals that was attributed to contraction of the diaphragm causing large negative airway pressure - interaction with a pre-existing cardiac pacemaker was reported in 1 patient -Right shoulder pain during maximum stimulation of a single electrode -Progressive pacing failure <p>Effectiveness</p> <ul style="list-style-type: none"> -Only one failed procedure was reported -40% and 72.7% of patients were completely free of ventilator support after conditioning 	<p>Low</p> <p>None of the studies used an unbiased assessment of the end point or provided a prospective calculation of the study size. Studies were variable in terms of demographics, technique, post-operative weaning programme and outcome data reported.</p>

			<p>-Larger studies reported it took on average 10 days to become ventilator free</p> <p>Delay of insertion</p> <p>-mean delay in insertion of diaphragmatic pacing wires ranged from 40 days to 9.7 years</p> <p>-No safety issues were reported.</p>	
Sieg et al. (2016) [12]	To examine the strength of evidence relating to phrenic nerve pacing in patients with high SCI, brain stem injury or congenital central hypoventilation.	<p>Systematic Review</p> <p>18 eligible studies included</p> <p>-All rated class IV evidence</p> <p>Studies from 2005 onwards</p> <p>Unable to perform meta-analysis due to poor quality of include studies.</p>	<p>-Review found prolonged survival in the phrenic nerve stimulation group and a higher quality of life score in the area of social functioning</p> <p>-One study reported a nearly 17,000 euro increase in cost per patient per year with mechanical ventilation versus phrenic nerve stimulation</p> <p>-Of patients that passed away during the follow up period, a high percentage died of respiratory tract infections in the mechanical ventilation group compared to phrenic nerve stimulation ($p < 0.05$)</p>	<p>Low</p> <p>Phrenic nerve stimulation is a potentially viable alternative to mechanical ventilation, although the body of evidence was low due to potential for bias, indirectness, and publication bias</p>
Khong et al. (2010) [15]	This paper reviews the available data on the 19 patients treated with phrenic nerve stimulation in Australia to date	<p>Retrospective case review</p> <p>Implanted with Avery Biomedical Devices</p> <p>19 patients in total (first performed in 1977)</p>	<p>-11 of the pacers are known to be actively implanted</p> <p>-Total pacing duration ranging from 1 to 21 years (mean 13 years)</p> <p>-Eight of the 19 patients had revision surgeries. Four of these were to replace the original 107 system (which had a 3–5-year life expectancy) with the current I-110 system, which is expected to perform electrically for the patient's lifetime</p> <p>-Three patients had revisions due to mechanical failure. The remaining patients' notes were incomplete.</p>	<p>Low</p> <p>Absence of a control group. Small sample size</p>

			These data suggest that phrenic nerve stimulation can be used instead of mechanical ventilators for long-term ongoing respiratory support.	
Le Pimpec-Barthes (2011) [14]	Evaluated results of phrenic pacing performed by video-assisted thoracic surgery (VATS)	<p>Retrospective case review</p> <p>Quadripolar phrenic pacing system from Atrotech (Jukka, Atrotech; Tampere, Finland)</p> <p>2 components: internal (the permanently implanted device) and external antenna taped to the skin and connected to the transmitter)</p> <p>20 included participants between 1997-2007</p> <p>Diaphragm reconditioning began 2 weeks after the surgical procedure.</p> <p>reconditioning procedure was considered complete when the patients could spend 8 hours under stimulation without any significant drop in tidal volume</p> <p>Follow up 6 months after implantation and then 2-yearly</p>	<p>No significant intraoperative complications were observed</p> <p>No nerve injury occurred</p> <p>No early postoperative mortality or major morbidity. 2 cases of pneumonia with partial atelectasis that regressed with bronchial aspiration and intravenous antibiotic therapy</p> <p>-All patients were able to withstand stimulation 24 hours a day. Nevertheless, 8/18 refused to renounce nocturnal mechanical ventilation.</p> <p>All the patients weaned from mechanical ventilation reported improved comfort and quality of life.</p> <p>Seven of the 18 patients who had been weaned from their ventilator died 6 to 74 months after implantation. Causes of death included septic shock of extra pulmonary origin (n=2), digestive haemorrhage (n=1), pneumonia (n=2), intracerebral haemorrhage (n=1), and intra cerebral abscess (n=1). No deaths were directly attributable to phrenic stimulation.</p>	<p>Low</p> <p>Absence of a control group. Small sample size</p>
Hirschfeld et al. (2008) [13]	To compare mechanical ventilation (MV) with phrenic nerve stimulation (PNS) for treatment of respiratory device-dependent (RDD)	<p>Prospective Clinical Trial (non-randomised)</p> <p>patients treated in the special unit for respiratory device dependency with spinal cord injury</p> <p>1987-2006</p> <p>Atrotech stimulator devices</p>	<p>-Incidence of respiratory infections (RIs per 100 days) prior to use of final respiratory device was equal in both groups, that is (median (interquartile range)) 1.43 (0.05–3.92) with PNS and 1.33 (0.89–2.21) with MV (P= 0.888)</p> <p>-With final device in our institution it was 0 (0–0.92) with PNS and 2.07 (1.49–4.19) with MV (Po0.001) at final location it was 0 (0–0.02) with PNS and 0.14 (0–0.31) with MV (Po0.001).</p>	<p>Moderate</p> <p>Comparison group. Long follow up and moderate sample size.</p>

	<p>spinal cord-injured (SCI) patients.</p>	<p>All patients were seen for a check-up once a year.</p> <p>64 patients treated (32 in the phrenic nerve group)</p>	<p>In summary compared to MV, respiratory treatment with PNS significantly reduces frequency of RI.</p> <p>Quality of speech is significantly better with PNS.</p> <p>Nine patients with PNS, but only two with MV, were employed or learned after rehabilitation (P=0.093).</p> <p>Median participation time in the study until death or 31 Dec 2006 was 3.4 years (range, 0.6–15.9) with PNS and 3.6 (0.1–10.7) years with MV.</p> <p>Total 12 patients on PNS and 14 on MV died during the observation period (P=0.1023); of these, 3 with PNS and 10 with MV died of RI (P=0.0472).</p> <p>The primary investment in the respiratory device is higher with PNS, but it can be paid off in our setting within 1 year because of the reduced amount of single use equipment, easier nursing and fewer RIs compared to MV.</p>	
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Research Request – Botox, Splinting and Serial Casting

Brief	Research into Botox and splinting i.e. who can provide, what level of professional needs and in what setting. Purpose is to assist planning practice guidance development.
Date	14 August 2019
Requester	Kate <small>s47F - person's</small>
Researcher	Aanika <small>s47F - personal pr</small>

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Note: The information in this document has been collated from various websites (mostly copy and pasted information). Where possible, journal articles and Australian based credible clinical sources have been used in the first instance, however provider websites have been used to fill in gaps.

Below each subheading in this document a summary of issues that may need to be considered in the development of planning guidance is included (purple table format as this one).

Key issue

The key NDIS planning issue with post-Botox therapies such as splinting and serial casting, is whether under NDIS legislation these health interventions should be reasonably considered to be a maintenance and therapy support **OR** a time-limited rehabilitation intervention.

What is Botox, splinting and serial casting?

Botox injections are used in conjunction with multiple types of rehabilitation therapies, splinting and serial casting are the ones that have received reasonable and necessary requests and have been raised by states and territories, particularly NSW.

➤ Clinical use of botulinum toxin

Botulinum neurotoxin type A inhibits the release of acetylcholine from cholinergic motor and autonomic nerves. Intramuscular injection leads to muscle relaxation, and intradermal injection reduces sweat gland secretion. Repeat doses are usually required as the effect of the toxin wears off after 3-4 months. Therapy including stretching, splinting and strengthening may prolong the effect of muscle relaxation.¹

Clinical indications

Considering whether to start a patient on botulinum toxin depends on balancing the risks of treatment against the potential improvements in active and passive function, level of pain, secondary effects of unwanted muscle over activity and quality of life. In Australia, specialist medical practitioners such as ophthalmologists, neurologists, surgeons, rehabilitation specialists and paediatricians may access the government's Section 100 scheme. This provides reimbursement for the cost of botulinum toxin type A for the following conditions:

- blepharospasm
- spasmodic torticollis
- dynamic equinus foot deformity associated with cerebral palsy in children two years or over
- spasticity following stroke.

Botox is also approved for the treatment of strabismus in children and adults, focal spasticity of the limbs, primary hyperhidrosis of the axillae, and spasmodic dysphonia².

Note: Information about all of these conditions can be found on the footnoted website – information about focal spasticity is included below as this is likely to be the most common support request in the NDIS context.

Focal spasticity

¹ A Scheinberg, 'Clinical use of botulinum toxin', *NPS Medicine Wise*, 1 April 2019, <<https://www.nps.org.au/australian-prescriber/articles/clinical-use-of-botulinum-toxin>> accessed 15 August 2019.

² Ibid.

Spasticity is one component of the upper motor neurone syndrome and is defined as a velocity dependent increase in muscle tone. Botulinum toxin type A is often used for managing hypertonicity in conjunction with other treatments such as splinting, stretching and strengthening antagonist muscles³.

Maximise gains of Botulinum Toxin-A (BoNT-A) with therapy

If there is enough clinical evidence to provide BoNT-A in the first place then there are gains to be made for the client and these should be maximised by therapeutic intervention - preferably a combination of OT and PT to ensure gains are made in muscle length, muscle strength, movement patterns, splinting is provided and as well as placing this into functional movement patterns and translated into task performance⁴.

Note: A 2015 study by Cusick et al. into 'Upper limb spasticity management for patients who have received Botulinum Toxin A injection: Australian therapy practice', found that there were significant issues with the lack of nationally consistent clinical guidance around Botox use and associated therapy access.

The report found that (1) shared care between the physician and therapist was not occurring, (2) post-injection therapy was not available to some patients, (3) therapist numbers were inadequate for demand and coordinated goal directed care was not being implemented⁵.

This highlights the need for a clear handover/delegation from the physician to the therapist providing the post-Botox splinting or casting.

○ Focal Spasticity Treatment – Difference between Adults and Children

Focal spasticity is just one condition, but it highlight's the difference between therapy support needs for children and adults.

Children

Ideally, children receiving treatment should have access to a multidisciplinary clinic where other interventions for spasticity can be considered. The largest group of children receiving botulinum toxin type A for spasticity are those with cerebral palsy.

Treatment has been shown to be effective in reducing equinus gait pattern in these children (injections to calf, hamstring and hip flexor muscles), improving upper limb function (injections to shoulder, elbow, wrist and finger flexor muscles), reducing pain (injections to hip adductors) and reducing the need for orthopaedic surgery.

Children with dystonia may also improve with botulinum toxin type A treatment, although muscle selection and dosing is clinically challenging.

Children with spasticity and minimal contracture, who have functional or care goals, may benefit from treatment as early as 12–18 months. In general, botulinum toxin type A is less effective, particularly in the lower limbs, beyond the first decade.

Adults

Spasticity in adults is seen most commonly after acquired brain injury, stroke, multiple sclerosis and spinal cord injury.

³ Ibid.

⁴ A Cusick, N Lannin & N.Z Kinnear, *Upper limb spasticity management for patients who have received Botulinum Toxin A injection: Australian therapy practice*, Australian Occupational Therapy Journal, 2015, 62 (1), 27-40, Table 3 - 'Issues related the therapy access', <https://ro.uow.edu.au/cgi/viewcontent.cgi?referer=&httpsredir=1&article=2360&context=sspapers> accessed 14 August 2019,.

⁵ Ibid.

Setting goals before treatment, along with the pattern of affected muscle groups and the tone abnormality, determines muscle selection. Early treatment with botulinum toxin type A after stroke has been shown to reduce disability and carer burden⁶.

○ Botox neurotoxin - Medicare Benefits Schedule

Botox neurotoxin type A injections are covered under 'Therapeutic Procedures' under the Medicare Benefits Schedule.

There are approximately 18 MBS item numbers for different types of Botox injection therapeutic procedures.

Items for the administration of botulinum toxin can only be claimed by a medical practitioner who is recognised as an eligible medical practitioner for the relevant indication under the arrangements under Section 100 of the *National Health Act 1953* (the Act) relating to the use and supply of botulinum toxin⁷.

➤ Serial casting

Note: Research indicates that serial casting is a more common therapy that accompanies the use of Botox than splinting.

Serial casting is a common procedure used to stretch and lengthen muscles. Children may have shortened muscles due to limited movement, muscle tightness or muscle stiffness called spasticity. Casting is a common treatment for the management of children who walk on their toes. For children with spasticity, serial casting may be used after Botulinum Toxin injections. The prolonged stretch provided by the cast may:

- increase the length of the muscle
- reduce the spasticity in the muscle
- improve your child's walking pattern
- improve tolerance of ankle foot orthoses⁸

Serial casting is the application of plaster and/or synthetic casting materials, with cast changes until the desired length of muscle is achieved. The period of casting will depend on the child's response and the outcome required. Most casting is completed within 3 weeks⁹.

Serial casting is an evidence based intervention for children with CP, to increase passive ankle range and the changes, while often small, are deemed clinically meaningful for children that require more dorsiflexion to walk. Botulin toxin injections are also clinically indicated for children with CP to help manage spasticity in the lower limbs¹⁰.

It is not uncommon for serial casting to follow Botox injections as evidence shows it can lead to a better result than Botox or serial casting alone when treating spasticity with muscle shortening.

The reduction in lower limb spasticity and improved ankle range of movement in children with CP is likely to lead to better functional outcomes when part of a multimodal intervention¹¹.

The role of Botox in serial casting

Botulinum toxin, or Botox®, injections into the tight muscle can provide relaxation of the contractile tissue of the muscle and make serial casting more successful. This medication will block the release

⁶ Sheinberg, loc cit.

⁷ Medicare Benefits Schedule, Category 3 – Therapeutic Procedures – botulinum toxin injections, <<http://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=18360&qt=item>>, accessed 14 August 2019.

⁸ Children's Health Queensland Hospital and Health Service, 'Serial Casting – lower limb', <<https://www.childrens.health.qld.gov.au/fact-sheet-serial-casting-lower-limb/>>, accessed 16 August 2019.

⁹ Ibid.

¹⁰ I Novak, et al, 'A systematic review of interventions for children with cerebral palsy: state of the evidence', *Developmental Medicine & Child Neurology*, Cerebral Palsy Alliance Research Institute, 2013, p.

¹¹ Clinical practice Guidelines – Cerebral palsy, The Royal Children's Hospital Melbourne, <https://www.rch.org.au/clinicalguide/guideline_index/Cerebral_palsy/>, accessed 14 August 2019.

of acetylcholine, a neurotransmitter, at the neuromuscular junction, which results in weakness or paralysis in the muscle (Cincinnati Children's Hospital, 2009) and a reduction in spasticity. This effect usually takes 10 to 14 days, and it is best to wait until the injection is fully effective before putting on the cast. Serial casting is much more comfortable for a patient when the muscle is weakened and stretched out versus a muscle that is still fully contracting. This will increase the tolerance and the outcome when incorporated with the serial casting¹².

➤ Splinting

It was difficult to find academic information on splinting.

This information is from an OT provider:

Botox treatment is not permanent because nerve endings usually grow new connections to muscles that have not been exposed to Botox. In order to maximise the benefits of the Botox injections, Southern OT occupational therapists work with the clients treating Medical Consultant to fabricate a customised splint and provide rehabilitation. Rehabilitation focuses on retraining of the muscles around the site of the Botox injections and then retraining of the muscles injected as the effects of Botox wears off¹³.

Who can administer Botox, splinting and serial casting?

Only a physician can administer Botox injections. Injection therapy with botulinum toxin type A is only available on prescription from a doctor. It should always be given by a trained medical professional who is familiar with the correct technique. Your doctor will be able to let you know whether this treatment is suitable for you¹⁴.

The follow up therapy will be provided usually by a Physiotherapist or Occupational Therapist.

A NDIS / Rehabilitation provider has the following information on their website:

In Australia, Botox injections for spasticity are only given by Doctors¹⁵. They will usually either do so in private rooms or as part of a hospital spasticity clinic.

Prior to injection there should be a comprehensive assessment of the level of spasticity and what the goals of injection would be. An example of some goals may include weakening a muscle such as the calf to enable the opposite muscle an opportunity to strengthen, such as the dorsiflexors; weakening inappropriate muscle contractions to prevent contracture and tissue shortening, often seen at the biceps or weakening a muscle to prevent damage to skin integrity and maintain hygiene, often seen in the tight fists.

Goal planning is often best done in consultation with your physiotherapist. Once you have had the injection it takes around 4-7 days to take effect. You can then expect it to last around 3-4 months. Due to this, the minimum time you can have between injections is 3 months.

When your injection has started to take effect you should visit your physiotherapist to start on a program achieve your goals.

Physiotherapists and Occupational Therapists will work with you to get the most out of your injection by formulating a comprehensive treatment plan including a home exercise program. It is important to remember that this home program is a crucial part of your therapy, as the

¹² Rainbow Rehabilitation Centers, Serial Casting, 'Therapy News', <http://www.rainbowrehab.com/RainbowVisions/article_downloads/articles/art-fa12-therapy_serialcasting.pdf>, accessed 14 August 2019.

¹³ Southern OT, Post Botox Splinting and Rehabilitation, 2015, <<http://www.southernot.com.au/post-botox-splinting-rehabilitation.html>>, accessed 14 August 2019.

¹⁴ MyDR.com.au [website], 'Botox Injections', <<https://www.mydr.com.au/skin-hair/botox-injections>>, accessed 14 August 2019.

¹⁵ Advanced Rehab Centre, 'Physiotherapy and Botulinum Toxin', Feature article Multiple Sclerosis, 3 July 2013, <<https://www.archhealth.com.au/2013/07/03/physiotherapy-and-botulinum-toxin/>>, accessed 16 August 2019.

limited visits with your therapist can never make up for the hours you can spend practicing and exercising at home.

The following are some different forms of therapy that may be used following Botox injection:

- Splinting – used to provide a prolonged stretch to a muscle by wearing the splint for a designated period of time each day.
- Orthotics – may be used to assist your walking by correcting foot position.
- Stretching – a manual stretching program may be given if splinting is not appropriate.
- Strengthening – now that a particular muscle group is more relaxed, it may be possible to strengthen another group of muscles that you previously couldn't
- Electrical Stimulation – may be used in conjunction with a strengthening program to stimulate a particular muscle group.
- Functional Task Training – this can help you steer your therapy in the direction of your functional goals.

The important thing to remember is that the therapy after the injection is as important as the injection itself if you want to make any lasting meaningful change. The injection will relax the muscles, but the therapy associated with this will help you achieve your goals and improve your function. If you are thinking about having, or your doctor has mentioned, a Botox injection, then talk to your therapist now to enable you to get the most out of it¹⁶.

The Royal Children's Hospital website says that:

Physiotherapists from the community and the physiotherapy department fill an important role in the early interventions and assessment for CP and play an important role in the ongoing assessment of treatment of children throughout their development.

Botulinum toxin (Botox) is sometimes indicated as an aid to dealing with spastic muscle disease. In some cases its use delays and prevents the need for surgical intervention. It is sometimes also used as an adjunct to surgery¹⁷.

This makes it clear that the actual administration of the Botox and the consumable is well within the health space and helps to delineate the responsibilities.

A physician will administer the Botox and create a treatment plan based on the person's health needs. The follow up therapy aspect of this may then be provided by an NDIS funded OT or Physio.

It really highlights the need for a handover of health information.

Gaps in guidelines

At present Australian therapists must practice in the **absence of national BoNT-A spasticity management guidelines** and without therapy-specific guidelines in particular¹⁸.

¹⁶ Ibid.

¹⁷ Royal Children's Hospital, 'Cerebral Palsy and related conditions', <https://www.rch.org.au/ortho/departments_sections/Cerebral_Palsy_and_related_conditions/>, accessed 15 August 2019.

¹⁸ Cusick et al, 2015, p.9.

In the 2015 study by Cusick et al, one research participant's comment illustrates current gaps:

Most adult patients I have had experience with rarely see a therapist pre-injection. They also rarely receive post-injection therapy. If patients do have access to therapy services it is extremely uncommon that the therapist has the required skills to provide appropriate interventions such as casting, splinting and movement based interventions. The most significant issue is related to the model of service delivery for adults with a disability. Patient follow-up and monitoring over time is completely inadequate and patients are given their immediate post injection therapy and discharged. This is not appropriate for this patient population as their complex impairments need ongoing review and intervention.

The research concluded that:

Australian guidelines for BoNT-spasticity management and therapy specific guidelines are urgently required. Guidelines will provide a national benchmark for local practice improvement. Meanwhile therapists can improve their own process of care through professional development and consider implementing quality improvement activities to enhance local organization of care¹⁹.

Where does it need to be administered?

Botox must be administered in a clinical setting.

In Australia, therapeutic Botox injections for spasticity are only given by Doctors²⁰. They will usually either do so in private rooms or as part of a hospital spasticity clinic.

Commonly linked health conditions and impairments

Botulinum toxin type A injections can be used to treat several medical conditions. Muscular conditions that can be treated include:

- blepharospasm (twitching or spasm of the eyelid);
- cervical dystonia, or spasmodic torticollis (a type of muscle spasm in the neck);
- facial or other localised muscle spasms;
- **muscle spasticity due to cerebral palsy; and**
- strabismus (a condition where the eyes are not properly aligned)²¹.

Can splinting or serial casting be delegated?

No. Splinting, serial casting and other rehabilitation therapies must be performed by an appropriately trained allied health professional.

NDIS documents to inform this position:

To inform the practice guidance development on splinting, Botox and serial casting there are key sections of documents or legislation that need to be considered.

- Board Paper &
- Attachment A
- Plain English guide
- COAG APTOS

¹⁹ Ibid.

²⁰ Advanced Rehab Centre, loc cit.

²¹ MyDR.com.au [website], loc cit.

- Supports for Participant Rules 2013
- NDIS Act

➤ Key sections of Board Paper

Exceptions

- 1.1. Exceptions would be items and services which require delivery or are provided in a hospital and/or clinical or clinical-like setting.

The clinical or community setting aspect of the post-Botox therapy is a key issue in this policy as many providers are now saying that the serial casting/splinting can be done in the home. This does not change the actual nature of the therapy though.

➤ Key section of Attachment A

The Attachment A document states that:

Support Type 8: Botox and Splinting	
<p>Clinical intervention:</p> <ul style="list-style-type: none"> • Therapeutic Botox (Administration) • Splinting and rehabilitation after Botox <p>Botox is required for the rehabilitation or treatment of a health condition. The treatment provides short term relief from muscle spasticity and is clinical in nature.</p>	<p>NDIS Responsibility</p> <p>Unlikely to be funded by the NDIS given clinical use. However, funding assessed on a case by case and may be provided when it is a regular part of the participant’s daily life and results from the participant’s disability. PBS impacts will need to be considered.</p> <p>Health System Responsibility</p> <p>All supports provided in a hospital setting or when not a regular part of the participant’s daily life or resulting from the participant’s disability.</p>
<p>Consumable:</p> <ul style="list-style-type: none"> • Botox neurotoxin type A <p>Botox neurotoxin type A is a pharmaceutical which is covered under the Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS).</p>	<p>NDIS Responsibility</p> <p>Nil.</p> <p>Health System Responsibility</p> <p>The Health System via PBS is the most appropriate provider for pharmaceuticals.</p>

The clinical rehabilitation versus maintenance therapy support question is still not answered with this information.

It simply notes that for some participants, in rare circumstances, splinting and serial casting will be a regular part of the participant’s daily life and result from the participant’s disability, and for others it will be related to the time-limited rehabilitative treatment of a health related condition.

➤ Key sections from Plain English Guide

How to determine if a support is related to a participant's disability

In determining whether a health support is related to the participant's disability, use the following determination:

- “The participant would not require this health support BUT FOR his/her disability”.
 - If answered ‘yes’ the health support IS RELATED to the disability and the support is NDIS funded provided it is required on a regular basis.
 - If answered ‘no’ the health support is NOT RELATED to the disability and the support is not NDIS funded.

What health supports will we not fund?

NDIS will not fund disability-related health supports

- provided in a clinical setting such as a hospital, health care centre, hospital-in-the-home or General Practitioner Practice
 - Although there may be times when supports are provided in a health setting but still provided by the NDIS
 - For example, in a rural, remote, or regional setting where the supports might be provided in a health centre due to thin markets or ease of delivery.
- that do not relate to a participant's disability
- that are not required on a regular basis.

Again this information about supports related to disability does not clarify the Botox/splinting/serial casting support queries.

Splinting or serial casting may be related to the participant's disability, but it is **not** necessarily required on a regular basis.

Botox and Splinting: *caring for participants suffering from muscle spasticity*

NDIS will only fund Botox/splinting supports OUTSIDE of a hospital or clinical environment

-
- Administration of therapeutic Botox
 - NDIS will fund the administration of Botox outside of a clinical setting where it is required as a direct result of the participant's disability and needed on a regular basis
 - this is to be assessed on a case-by-case basis
 - the likelihood of Botox being administered outside of a clinical setting is rare
 - Administration of splinting and rehabilitation after Botox
 - NDIS will fund the administration of splinting (and rehabilitation after Botox) outside of a clinical setting where it is required as a direct result of the participant's disability and needed on a regular basis
 - this is to be assessed on a case-by-case basis

- the likelihood of splinting being administered outside of a clinical setting is rare
- Purchase of Botox neurotoxin type A
 - NDIS will not fund the purchase of Botox neurotoxin type A
 - Botox neurotoxin type A is covered under the Medicare benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS)

This policy basically states that NDIS funding can be used to fund post-Botox therapy:

- If it is in a home or community setting
 - *(which was not usually the practice, however we are seeing providers now saying it can be done in these settings to get funding)*
- It is related to the disability
 - *(which will be argued for every NDIS participant case)*
- Is needed on a regular basis
 - *(this is a point of contention because while it is a time-limited therapy, it is often provided in intervals e.g. every 3-4 months. If someone has a physician saying that a participant requires this periodic therapy as maintenance for an extended period of time it would meet R & N.*
 - *If it is a one off treatment, it would be rehabilitation as per the COAG APTOS passages below).*

➤ Key COAG APTOS passages

- Health systems are responsible for funding time limited, recovery-oriented services and therapies (rehabilitation) aimed primarily at restoring the person's health and improving the person's functioning after a recent medical or surgical treatment intervention. This includes where treatment and rehabilitation is required episodically.
- The NDIS will be responsible for supports required due to the impact of a person's impairment/s on their functional capacity and their ability to undertake activities of daily living. This includes "maintenance" supports delivered or supervised by clinically trained or qualified health professionals (where the person has reached a point of stability in regard to functional capacity, prior to hospital discharge (or equivalent for other healthcare settings) and integrally linked to the care and support a person requires to live in the community and participate in education and employment.
- NDIS: Allied health and other therapy directly related to maintaining or managing a person's functional capacity including occupational therapy, speech pathology, physiotherapy, podiatry, and specialist behaviour interventions. This includes long term therapy/support directly related to the impact of a person's impairment/s on their functional capacity required to achieve incremental gains or to prevent functional decline. Also includes allied health therapies through early intervention for children aimed at enhancing functioning.
- Health: Rehabilitative health services where the purpose is to restore or increase functioning through time limited, recovery oriented episodes of care, evidence based supports and interim prosthetics, following either medical treatment or the acquisition of a disability (excluding early interventions). When a participant is receiving time limited rehabilitation services through the health system, the NDIS will continue to fund any ongoing 'maintenance' allied health or other therapies the person requires and that are unrelated to the health system's program of rehabilitation.
- Joint: Provision of specialist allied health, rehabilitation and other therapy, to facilitate enhanced functioning and community re-integration of people with recently acquired severe conditions such as newly acquired spinal cord and severe acquired brain injury.

➤ Key Legislative passages

NDIS Supports for Participant Rules

- 2.3 In relation to both general supports to be provided and reasonable and necessary supports to be funded, the CEO also needs to be satisfied of a number of matters, including the following:
- (a) the support will assist the participant to pursue the goals, objectives and aspirations included in the participant's statement of goals and aspirations;
 - (b) the support will assist the participant to undertake activities, so as to facilitate the participant's social or economic participation;
 - (c) the support represents value for money in that the costs of the support are reasonable, relative to both the benefits achieved and the cost of alternative support;
 - (d) the support will be, or is likely to be, effective and beneficial for the participant, having regard to current good practice;
 - (e) the funding or provision of the support takes account of what it is reasonable to expect families, carers, informal networks and the community to provide;
 - (f) the support is most appropriately funded or provided through the NDIS, and is not more appropriately funded or provided through other service systems (**service systems** is defined in paragraph 6.4).

6.4 In these Rules:

service systems means general systems of service delivery or support services offered by a person, agency or body, or systems of service delivery or support services offered:

- (a) as part of a universal service obligation; or
- (b) in accordance with reasonable adjustments required under a law dealing with discrimination on the basis of disability.

Health (excluding mental health)

7.4 The NDIS will be responsible for supports related to a person's ongoing functional impairment and that enable the person to undertake activities of daily living, including maintenance supports delivered or supervised by clinically trained or qualified health practitioners where these are directly related to a functional impairment and integrally linked to the care and support a person requires to live in the community and participate in education and employment.

7.5 The NDIS will not be responsible for:

- (a) the diagnosis and clinical treatment of health conditions, including ongoing or chronic health conditions; or
- (b) other activities that aim to improve the health status of Australians, including general practitioner services, medical specialist services, dental care, nursing, allied health services (including acute and post-acute services), preventive health, care in public and private hospitals and pharmaceuticals or other universal entitlements; or
- (c) funding time-limited, goal-oriented services and therapies:
 - (i) where the predominant purpose is treatment directly related to the person's health status; or
 - (ii) provided after a recent medical or surgical event, with the aim of improving the person's functional status, including rehabilitation or post-acute care; or

NDIS Act 2013

34 Reasonable and necessary supports

- (1) For the purposes of specifying, in a statement of participant supports, the general supports that will be provided, and the reasonable and necessary supports that will be funded, the CEO must be satisfied of all of the following in relation to the funding or provision of each such support:
- (a) the support will assist the participant to pursue the goals, objectives and aspirations included in the participant's statement of goals and aspirations;
 - (b) the support will assist the participant to undertake activities, so as to facilitate the participant's social and economic participation;
 - (c) the support represents value for money in that the costs of the support are reasonable, relative to both the benefits achieved and the cost of alternative support;
 - (d) the support will be, or is likely to be, effective and beneficial for the participant, having regard to current good practice;
 - (e) the funding or provision of the support takes account of what it is reasonable to expect families, carers, informal networks and the community to provide;
 - (f) the support is most appropriately funded or provided through the National Disability Insurance Scheme, and is not more appropriately funded or provided through other general systems of service delivery or support services offered by a person, agency or body, or systems of service delivery or support services offered:
 - (i) as part of a universal service obligation; or
 - (ii) in accordance with reasonable adjustments required under a law dealing with discrimination on the basis of disability.
- (2) The National Disability Insurance Scheme rules may prescribe methods or criteria to be applied, or matters to which the CEO is to have regard, in deciding whether or not he or she is satisfied as mentioned in any of paragraphs (1)(a) to (f).

External NSW Health paper

A collaborative position paper on serial casting for children with physical disabilities put together by Cerebral Palsy alliance, Hunter New England Local Health District, Sydney Children's Hospital Network and the Benevolent Society concludes that funding of this intervention rests with the NDIS as the therapy is

- a. Directly related to maintaining or managing a child's functional capacity
- b. Directly related to the impact of a child's impairment/s on their functional capacity and required to achieve incremental gains or to prevent functional decline
- c. Required to achieve incremental gains or to prevent functional decline
- d. It may also be part of early intervention for children aimed at enhancing functioning.

The paper states that Serial casting for children with physical disabilities is the application of plaster and/or synthetic casting materials to upper and/or lower limbs for the purpose of providing a prolonged stretch to the muscles over time. Serial casting for children with disabilities is a routine part of managing the impact of abnormal growth in children who have difficulty maintaining muscle length and joint range due to their underlying condition.

Serial casting is used for the management of muscle and joint contracture acquired through impairments associated with spasticity and muscle weakness in children with physical disabilities. Serial casting is not an intervention related to recovery from illness or injury. It is directly related to addressing functional goals by managing a common feature of an individual's disability and the impact of growth and/or progression of the condition on function.

Serial casting is only one intervention that can contribute to the maintenance of muscle length/joint range of movement and the achievement of functional goals related to the child's underlying condition.

Several of the TAT advisors have had visibility of this collaborative position paper.

It should be noted that the NDIS did not have input into this position paper. It should also be noted that the Benevolent Society has been chosen to operate the NSW government's specialist disability support services so has a vested interest in transitioning disability services to community settings²²

While points a-d in the paper are all valid, TAT's opinion is that elements of the paper are misleading, or do not provide the full picture of serial casting. For example:

- The position paper states that serial casting is the **only** disability related intervention for muscle length management, which has been deemed not the responsibility of NDIS (emphasis added). While, surgery is sometimes considered appropriate in managing contracture/deformity for children with CP.
- The paper also states that health services should remain responsible for acute and sub-acute casting such as required post-surgery or for acute intervention for fracture management, neglecting medical management. Whereas, later in the paper serial casting is noted to be an important part of the intervention post-Botox to help support the effectiveness of the botulinum toxin therapy.

Recommendations

The intent of the new disability related health support policy direction is to fund supports that are regular and ongoing health supports related to the participant's disability.

While serial casting and splinting therapies are not realistically going to be a permanent part of someone's 'daily life' for their entire life, these therapies may be an intervention that is regularly provided at intervals for the participant's foreseeable future e.g. every 3-4 months for a few years with the aim of reducing further need for supports.

²² L Caneva, 'Benevolent Society to Take over NSW Govt Disability Support Services', *Probono Australia*, 2 March 2017, <<https://probonoaustralia.com.au/news/2017/03/benevolent-society-take-nsw-govt-disability-support-services/>>, accessed 15 August 2019.

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Research – Feasibility of NDIS providing insulin pumps as a way to reduce expensive nursing supports as well as optimising the independence of participants

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Research Brief

Research into the suitability of insulin pumps for NDIS participants.

The participants that might benefit from this technology would be insulin dependent diabetic participants who require nursing support for daily checking of BGL's and insulin administration who have the cognitive ability to access this technology (e.g. amputees)

I would like to investigate the feasibility of NDIS providing insulin pumps possibly as a way to reduce the expensive nursing supports as well as optimising the independence of participants.

Cost of pumps, types of pumps, do they differ and what features do they offer?

What is the anticipated lifespan of pumps, do they require ongoing review and intervention to keep running – who is the likely person/party to do this?

Is there other technology which is required to use the device – i.e. do you need a smart phone or watch to use the device? Cost of consumables – how does this compare to administration via needles?

Do any other systems fund consumables with pumps? What is the estimated annual cost of consumables?

Other notes from requester:

- Many of our participants require assistance with checking BGL's and administering insulin.
- Currently we receive multiple requests for nurses to help manage diabetes (BGL checking and insulin administration. These seem to average 1 -2 hours per day. These are very expensive supports, often costing in the 10s of \$1000's for what is a relatively simple procedure.
- Technology has improved (e.g. these devices can now communicate with remote devices) however the price of these devices has remained around the \$5000 - \$7000 mark.
- I personally believe that these devices, matched to the right participant will not only save money but will provide more independence and freedom (i.e. not having to be in the same place every day waiting for a nurse).
- It is a relatively simple procedure to insert the catheter...the device sits on the belt like a pager with a subcutaneous catheter in the abdomen.
- Insulin pumps have been shown to offer increased flexibility, improved glucose levels and improved quality of life.
- I also accept that insulin pumps are not suitable for all of our participants who require assistance, as they require cognitive input and a little motivation.

- Insulin pumps have been particularly effective in the following situations:
 - hypoglycaemia unawareness (inability to detect 'hypos')
 - severe and frequent hypoglycaemia
 - frequent night time hypoglycaemia
 - gastroparesis (delayed emptying of the stomach)
 - an unpredictable lifestyle or daily routine (e.g. working nightshifts)
 - extreme insulin sensitivity
 - dawn phenomenon (rising blood glucose early in the morning)
 - planning for, and during, pregnancy.

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters.

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2 Summary

- Insulin pumps are more cost effective than providing nursing supports. However, the participant's functional capacity to use an insulin pump would need to be assessed.
- If a participant who would normally require 2 daily support visits for insulin administration (Multiple Daily Injections (MDI)), were to use an automated insulin pump with continuous glucose monitoring, over a 12 month period a saving of \$47,703 can be achieved if an enrolled nurse was initially used for the MDI, or a saving of \$28,627 if a support worker was initially used for the MDI.
- Advantages of insulin pumps as opposed to multiple daily injections (MDI) appear to outweigh the disadvantages.
- There are a variety of insulin pumps by different manufacturers available on the market. All pumps work in the same basic manner but vary in specific functions and features.
- Continuous Glucose Monitoring Systems (CGMS) which measure glucose levels continuously, can be worn as a separate device to the pump, or may be combined within the pump as a single device unit.
- Both insulin pumps and CGMS require consumables.
- Insulin pumps and CGMS may require other technology and equipment for their use, such as a mobile phone and internet access.
- Insulin pumps may not be suitable for those with cognitive or visual impairments.
- For diabetes type 1, evidence-based guidelines recommend the use of insulin pumps rather than MDI, automated pumps rather than non-automated pumps, and CGMS rather than self-monitoring of blood glucose levels (BGL).
- Evidence-based guidelines suggest choice of technology type is highly dependent on personal preference and users should discuss suitability with their health professional.
- Insulin pumps are covered by gold tier private health insurance. The Australian Government's Insulin Pump Program offers subsidies to children with type 1 diabetes from low income families.
- Consumables for insulin pumps are subsidised by the National Diabetes Services Scheme (NDSS) at around 91% of cost to the user.
- Lifespan of insulin pump devices and CGMS could not be determined. Warranty periods for insulin pumps by all TGA approved devices is four years. Insulin pumps and CGMS appear to

not require servicing and maintenance is covered under warranties.

- Cost of insulin pumps range from \$8950 to \$9500 depending on the type and brand.

3 What is an Insulin Pump

3.1 Overview

Insulin pump therapy is also known as continuous subcutaneous insulin infusion (CSII) therapy [1]. In Australia, insulin pumps are almost entirely used for the management of people with type 1 diabetes. In the USA, in addition to those with type 1 diabetes, there are a significant number of people with type 2 diabetes who use insulin pumps [2].

An insulin pump is a small battery-operated electronic device that holds a reservoir of insulin. It is about the size of a mobile phone and is worn 24 hours a day. The pump is programmed to deliver insulin into the body through thin plastic tubing known as the infusion set or giving set. The pump is worn outside the body, in a pouch or on a belt. The infusion set has a fine needle or flexible cannula that is inserted just below the skin where it stays in place for two to three days [3].

3.2 How they work

3.2.1 Overview

- Only fast acting insulin is used in the pump such as [NovoRapid®](#) and [Humalog®](#), therefore replacing the need for long-acting insulin such as [Lantus®](#), [Levemir®](#) or [Protophane®](#) [4].
- Whenever food is eaten the pump is programmed to deliver a surge of insulin into the body, similar to the way the pancreas functions in people without diabetes [3].
- Between meals a small and steady rate of insulin is delivered [3].
- The pump delivers insulin continuously (basal) and on demand (bolus) to account for carbohydrates in meals or high BGLs [4].
- A small motor inside the pump controls the delivery of insulin. Insulin is delivered from the reservoir/cartridge through flexible tubing fitted with a small Teflon® (or metal) cannula that is inserted subcutaneously (under the skin) and held in place with special adhesive tape [4].
- Together, the tubing and cannula are called an infusion set. The cannula is easily inserted and removed by the user; it is not surgically implanted [4].
- An introducer needle allows the cannula to be inserted under the skin. The needle is then removed leaving behind the cannula only [4].
- For users who do not want to insert the needles manually, there are disposable and reusable devices to assist with cannula insertion [4].
- The cannula must be changed every two to three days. Metal cannulas may need to be changed every one to two days [4].
- The most common site to place infusion sets is in the abdomen (easy to access) but they can also be placed in the upper buttock, upper outer thigh, hip or upper arm [4].

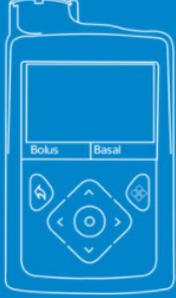
The image below shows how the MiniMed 770G Insulin Pump provides insulin to the body [5].



COMPONENTS OF INSULIN PUMP THERAPY

1. INSULIN PUMP

A small, durable electronic device to program your insulin and show you how you are tracking. The device includes a reservoir compartment.



2. INFUSION SET

An infusion set includes a thin cannula that goes from the reservoir to the infusion site on your body. The cannula is inserted into the site - similar to where you would give insulin injections. The infusion set is changed every two to three days.



3. RESERVOIR

A plastic cartridge that holds the insulin and is locked into the insulin pump. A reservoir can hold up to 300 units of insulin and is changed every two to three days.



3.2.2 Automatic Insulin Pumps / Smart Pumps [4]

- Most pumps will calculate the insulin dose for each meal or snack based on the insulin to carbohydrate ratio programmed into the pump.
- This ratio is calculated with the user's diabetes educator or endocrinologist.
- The user needs to know the carbohydrate content of the meal or snack they intend to eat so that you can enter the amount of carbohydrate into the pump.
- The pump will calculate the insulin dose required for the meal. 'Smart pumps' can also add a correctional bolus of insulin at this time if user's pre-meal BGL is out of the target range.
- Although it is possible to rely on a 'smart pump' to calculate the insulin dose required, it is important that the pump user understands the basis of the calculation so that the dose recommended by the pump can be verified.

4 Advantages and disadvantages of Insulin Pumps as opposed to multiple daily injections

4.1 Advantages

- Unlike insulin pens or injections, data can be uploaded from most insulin pumps via web-based software. The data relating to glucose concentrations and insulin delivery can be

reviewed by the health professional in conjunction with the patient [2].

- Meta-analyses and randomised controlled trials have reported improvements in glycaemic control using insulin pump therapy compared to multiple daily injections [2, 6]. These include reductions in blood glucose, reduced hypoglycaemia (both frequency and severity), lower glycated haemoglobin (HbA1c), lower insulin requirements, and improved quality of life [2].
- Provides insulin delivery that better mimics normal pancreatic function [2].
- Uses rapid-acting insulin only and minimises glucose peaks and absorption-related variability [2].
- Built-in bolus algorithms to suggest bolus doses based on user-estimated carbohydrate content and blood glucose [2].
- Increased flexibility with day-to-day activities e.g. exercise, mealtimes, travel, shift work [2].
- Can be integrated with continuous glucose monitoring to provide real-time glucose information [2].
- Potential for advanced features e.g. low-glucose suspend, predictive low-glucose suspend [2].

4.2 Disadvantages

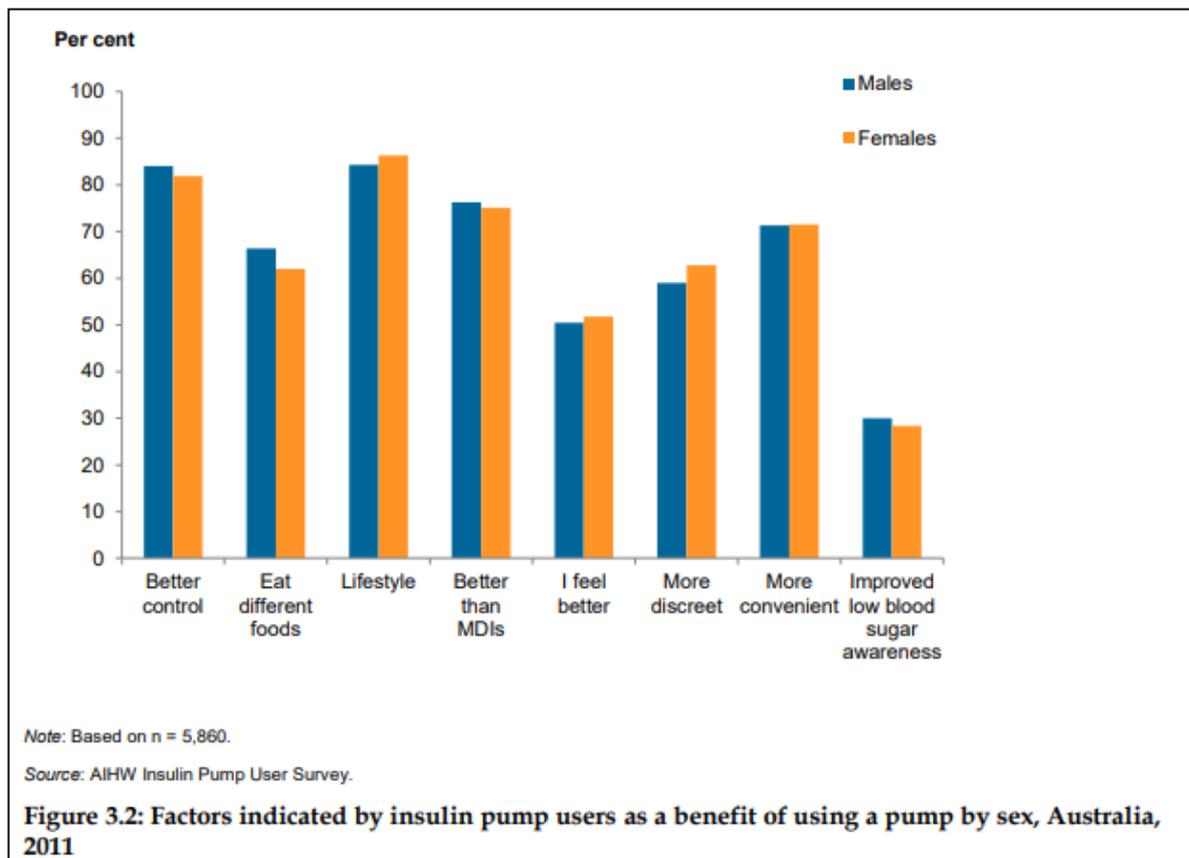
- External device attached to the body 24 hours a day [2].
- Potential for mechanical malfunction such as blockage or kinking in the infusion set which can lead to diabetic ketoacidosis [2].
- Potential for insertion site problems such as skin infections or local irritation [2].
- Need to learn how to carbohydrate count prior to using a pump [7].
- May require a full day of training to use the pump [7].
- High cost and limited access for uninsured patients [2].
- Patients have to be willing and able to manage the technology [2].
- Requires motivation, regular blood glucose checking, and the willingness to keep in regular contact with diabetes educator or endocrinologist for review and adjustment of pump rates [3].

4.3 Australian Insulin Pump User Data

The most recent information regarding the number and characteristics of people using insulin pumps in Australia, is a 2011 report by the Australian Institute of Health and Welfare (AIHW) examining the use of insulin pumps by people with Type 1 diabetes. Findings were based on administrative data supplied by Diabetes Australia and data from the Insulin Pump User Survey, conducted by the AIHW [1].

The AIHW survey resulted in the **advantages** indicated by respondents as follows. Further details of the survey are in the table below [1].

- 86% indicated that it fitted in with their lifestyle.
- The other important benefits were the achievement of better diabetes control (83%).
- Relocating a cannula was better than having several daily injections (76%).
- It was convenient (71%).
- 29% of respondents considered that they had benefited through a greater awareness of their low blood sugar levels.

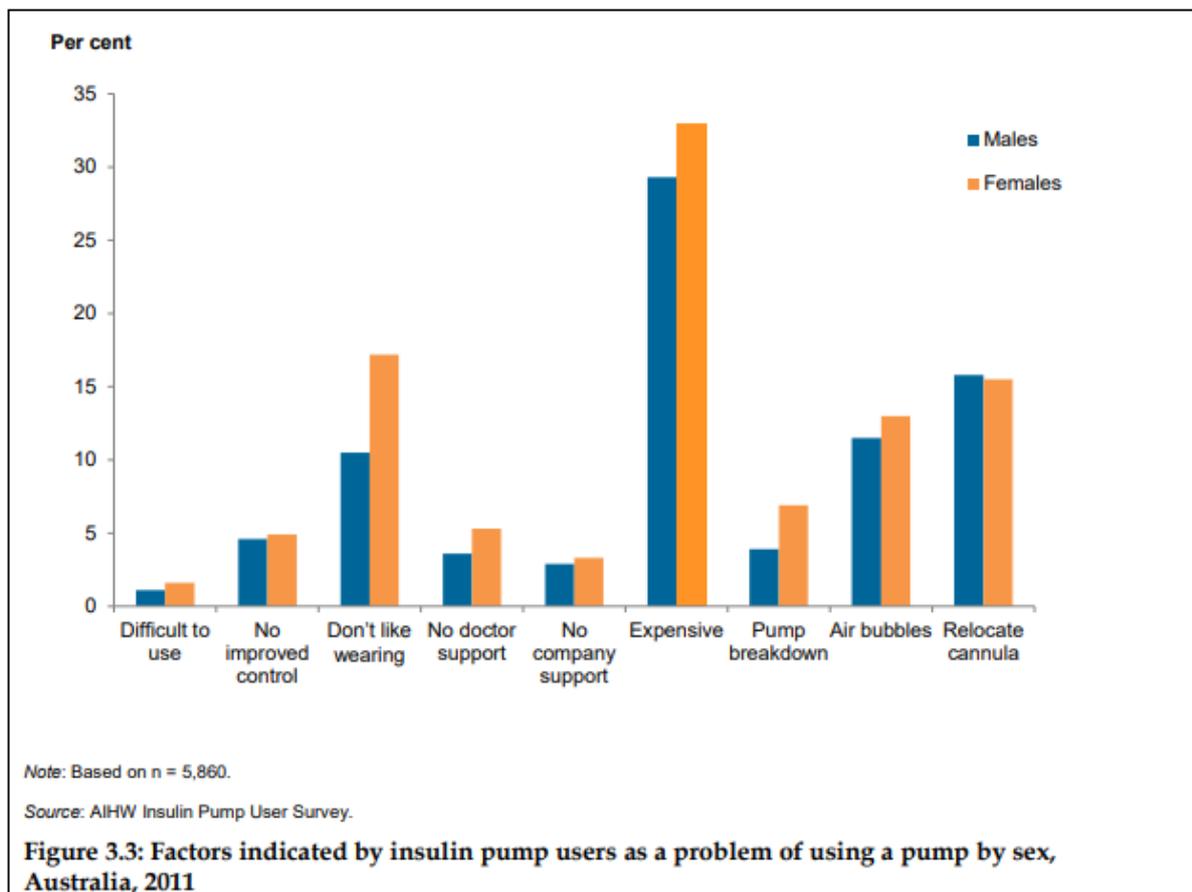


The AIHW survey resulted in the **disadvantages** indicated by respondents as follows. Further details of the survey are in the table below [1].

On the whole, survey respondents did not consider they had many problems with their insulin pumps, with an average of one problem selected by each respondent. When compared with the

average of five beneficial factors indicated by each respondent, this figure emphasises the level of satisfaction of most insulin pump users [1].

- The biggest issue for insulin pump users was the cost of the pump with 32% of respondents indicating that they were too expensive.
- 16% had problems with relocating the cannula or tubing.
- 15% did not like wearing an insulin pump.
- Pump breakdown was considered a problem for 6% of respondents.



5 Types and Features of Insulin Pumps

5.1 Types

There are two types of pump devices [8]:

1. Traditional Insulin pumps have an insulin reservoir (or container) and pumping mechanism, and attach to the body with tubing and an infusion set. The pump body contains buttons which allow the user to program insulin delivery for meals, specific types of basal rates, or suspend the insulin infusion, if necessary.

2. Insulin patch pumps are worn directly on the body and have a reservoir, pumping mechanism, and infusion set inside a small case. Patch pumps are controlled wirelessly by a separate device that allows programming of insulin delivery for meals from the patch.

Many pumps connect wirelessly with **blood glucose meters**, which measure blood sugar levels using a drop of blood from your fingertip. Some pumps connect wirelessly with **continuous glucose monitoring devices**, which are inserted under the skin and monitor blood sugar levels all day long [8].

5.2 Features

There are a variety of insulin pumps by different manufacturers on the market. All pumps work in the same basic manner but will vary in their specific functions and features. Following is a summary of functions and features available on insulin pumps [4]:

Calculating insulin

Pumps calculate the amount of insulin required to cover the carbohydrate eaten (using rates set by your diabetes educator or endocrinologist). Pumps also calculate the insulin dose required to correct any high BGL entered in the pump that is outside the users target range.

Tracking active insulin

Pumps have a feature that prevents the user from 'stacking' or giving too much insulin. When the user enters their BGL and carbohydrate intake, the pump will calculate the dose required after considering the insulin still active or 'on board' from a previous bolus. This may assist with avoiding hypos.

Bolus types

Pumps can be programmed to deliver a meal bolus in different ways. A meal bolus may be delivered, for example, over a period of two hours rather than all at once. These different bolus types can make eating a variety of foods and eating out much easier.

Insulin delivery

Pumps vary in the increments of the basal rate and bolus dose that can be delivered. If the user has a very small total daily dose of insulin or is very insulin sensitive (e.g. small children) then small delivery doses will be important.

Insulin reservoir/cartridge size

The reservoir/cartridge size varies between pumps, so depending on the user's daily dose of insulin some pumps will be more suitable than others.

Infusion sets

Not all infusion sets are suitable for everybody. Some people with very little subcutaneous fat will need a different type of infusion set to those with more. Some people have skin sensitivities so will require a set with little tape in contact with the skin.

Insertion devices

Some infusion sets have an insertion device that assists the user to insert the cannula with its introducer needle. This can make infusion set changes much easier, especially for children.

Computer software

All pumps have software that allows the user to upload pump activity into a program that can analyse the data. The program can save the data in a format that makes it suitable for sharing electronically with diabetes health professionals.

Food database

Pumps with a food database allows the user to store the carbohydrate content of a large range of foods that they commonly eat for easy reference.

Water resistance

Some pumps are splash resistant and others are waterproof to certain depth specifications.

Continuous glucose monitoring systems

Some pumps are continuous glucose monitoring system (CGMS) ready, and can display real-time glucose information on the monitor. Some can automatically halt insulin delivery for a couple of hours if the system detects that the user's glucose level has fallen below a pre-set threshold and they do not respond. CGM can be useful especially at night when the user is asleep.

5.3 Insulin Pump products available in Australia

As of December 2020, the following six pumps could be purchased through private health insurance in Australia [9]. A regularly updated list of TGA approved pumps can be found on the [department of health prosthesis list](#) [10] .

- [Accu-Chek Combo](#)
- [Accu-Chek Solo](#)
- [Tandem t:slim X2](#)
- [YpsoPump](#)
- [Medtronic 670G](#), [Medtronic 770G](#)

There are also older model pumps still available for purchase [9]:

- [Medtronic 640G](#)
- [Medtronic Paradigm and Veo](#)
- [DANA R and RS](#)

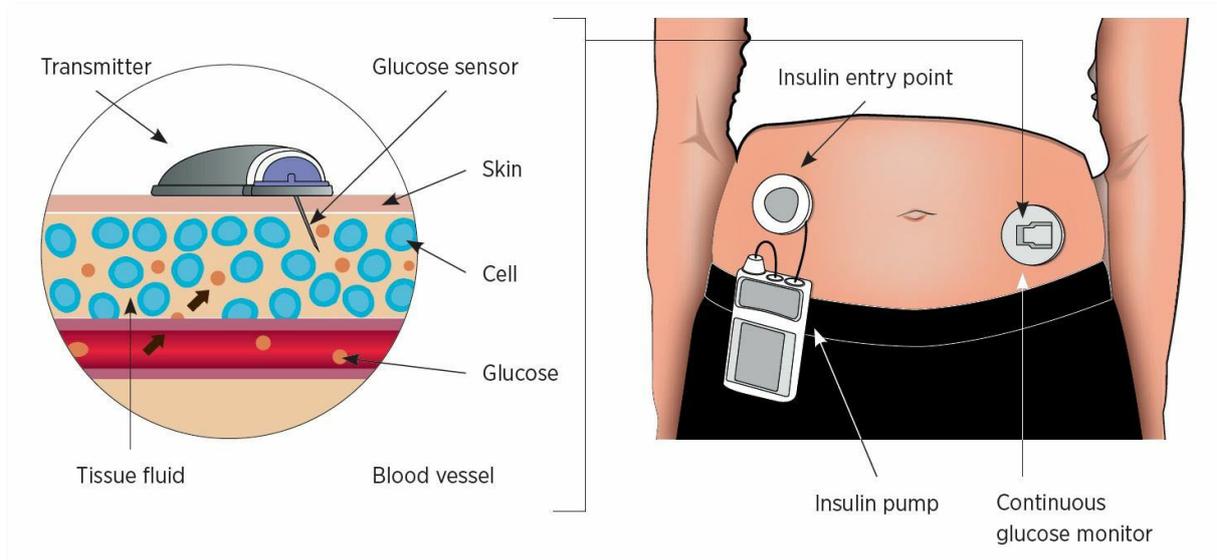
6 Continuous Glucose Monitoring Systems and Insulin pumps

6.1 Overview

CGMS is a means of measuring glucose levels continuously in order to gain insight into patterns and

trends in glucose levels throughout the day and night. A CGMS sensor is worn separately to the pump, inserted under the skin, and measures the level of glucose in the interstitial fluid (fluid in the tissue). The sensor is disposable and changed according to manufacturer recommendations [4].

The image below shows the CGMS used in conjunction with the insulin pump [2].



6.2 Types of continuous glucose monitoring systems

Currently there are two types of CGMS products available in Australia [4]:

1. One type of CGMS product includes a sensor and a separate unit of similar appearance to a normal blood glucose meter (worn separately in a similar fashion to a pump). This type does not communicate with the pump and, therefore, can be used by people who do not have an insulin pump (those on multiple daily injections) or who use an insulin pump that does not include continuous sensing.
2. The other type of CGMS product combines CGMS with an insulin pump. A sensor and an attached transmitter are worn separately to the pump and transmit glucose levels to the insulin pump (not a separate unit) via radio frequency.

More recent advances in technology have allowed for insulin pumps to automatically shut off insulin delivery for two hours in the event of hypoglycaemia ('low-glucose suspend') or predicted hypoglycaemia ('predictive low-glucose suspend') [2].

6.3 Continuous glucose monitoring system products available in Australia

Diabetes Australia suggest that there are several continuous glucose monitoring systems available in Australia [11]. These include:

- [Dexcom G5](#)
- [MiniMed 640G](#)

- [Medtronic 670G](#)
- [Guardian Connect CGM](#)

7 Other technology and equipment required to use an insulin pump or continuous glucose monitoring systems

Internet connection

Depending on the type of insulin pump an internet connection is required. The pump will have connectivity via a mobile phone app which will alert the use of their BGL via mobile phone notifications.

Mobile Phone and phone application

Depending on the type of insulin pump, and the need to alert BGL to the user, the user will require a mobile phone with internet connectivity, with a mobile phone application installed.

Computer and Software

To view and monitor the progress of the users pump therapy, a software application will need to be installed on the user's computer which will need an internet connection. The user will attach a USB type device into the computer to upload the data to produce reports which can be accessed by the user and the user's health professional [12-14].

Consumables

Various consumables are required for the pump and CGMS. For pumps these include: sertes, insulin reservoir cartridges and infusion sets [15]. For CGMS these include: sensors, transmitter and sertes [16].

Accessories

There are various optional accessories available from manufactures including mini storage charging units, equipment cases, silicone pump case, bra pouches, waste pouches, and waist bands [17].

8 Evidence-Based Clinical Guidelines for Diabetes and Insulin Pumps

For type 1 diabetes, the [Australian Evidence-Based Clinical Guidelines for Diabetes](#) (V1.2 published 27/11/20) [18] recommends:

- Insulin pumps over the use of MDI for children, adolescence and adults.
- Automated insulin pumps rather than non-automated pumps to optimise glycaemia for children, adolescents and adults.

- CGM devices rather than self-monitoring of blood glucose alone for all adults treated with multiple daily injections.

The guidelines were generated as a result of collaboration between the Australian Diabetes Society, the Australian Diabetes Educators Association, the Australasian Paediatric Endocrine Group and Diabetes Australia, with representation from the Royal Australian College of General Practitioners, the Australian Government Department of Health and Cochrane Australia (the Australian Living Evidence Consortium) [18].

The purpose of the guidelines are to provide an up-to-date, evidence-based resource that health professionals and people living with diabetes can use to guide shared decision making in the treatment of diabetes [18].

When addressing medical device technology for the management of type 1 diabetes, the guidelines addressed the following clinical questions [18]:

- Should you use continuous glucose monitoring (CGM) with/without alerts or self-monitored blood glucose (SMBG) alone in conjunction with MDI in adults?
- Should you use CSII pumps (with or without continuous glucose monitoring) or MDI (with or without continuous glucose monitoring) in children, adolescents and adults?
- Should you use non-automated CSII pumps with CGM (including low-glucose insulin suspend systems), or automated CSII pumps with closed-loop systems in children, adolescents and adults?

Below is a table with a brief summary of the recommendations contained in the guidelines. The guidelines gave “Conditional Recommendations” for all of the clinical questions. A conditional recommendation is given when it is considered that the benefits of the intervention are greater than the disadvantages, or the available evidence cannot rule out a significant benefit of the intervention while assessing that the adverse effects are few or absent. This recommendation is also used when people with diabetes' preferences vary [18].

With reference to the recommendations, the guidelines comment that:

- The choice of what technology type to use is highly dependent on personal preference.
- Health professional discussions with people with type 1 diabetes should include:
 - The use and potential benefits of the technology type and considerations of personal preferences.
 - The value of the different options, available resources, and the importance of high level engagement with the technology and health services.

Treatment	Conditional Recommendation	Remark
Insulin Pumps - Children and Adolescent	We suggest CSII or MDI treatment for <i>children and adolescents</i> with	CSII improves glycaemia (lowers HbA1c) which could ultimately lead to decreased microvascular complications. However, there is a paucity of studies examining the long term impact of CSII on

Treatment	Conditional Recommendation	Remark
(CSII)	type 1 diabetes based on the preference of the person with diabetes (and carer).	microvascular complications, diabetic ketoacidosis, mortality and quality of life. There is also little current evidence to demonstrate that CSII decreases weight. Variation in preference for CSII is anticipated in light of the higher treatment intensity required and costs associated with its use to manage type 1 diabetes.
Insulin Pumps - Adults (CSII)	We suggest CSII rather than MDI treatment for adults with type 1 diabetes based on the preference of the person with diabetes.	CSII improves glycaemia (lowers HbA1c) which could ultimately lead to decreased microvascular complications. However, there is little current evidence examining the impact of CSII on microvascular complications, diabetic ketoacidosis, and mortality. There is also little current evidence to demonstrate CSII decreases severe hypoglycaemia and weight gain or improves quality of life. Variation in preference for CSII is anticipated in light of the higher treatment intensity required and costs associated with its use to manage type 1 diabetes.
Insulin Pumps - Automated (Automated continuous subcutaneous insulin infusion (AutoCSII))	We suggest AutoCSII treatment rather than non-automated CSII treatment to optimise glycaemia for children, adolescents and adults with type 1 diabetes	AutoCSII technologies are relatively new, with the first randomised clinical trial being reported in 2014, and are distinct to previous nonautomated CSII systems which function solely using manual insulin pump settings with or without suspension of basal insulin in response to actual or predicted low glucose (also known as '(Predictive) Low Glucose Suspend' systems). Use of AutoCSII results in further improvements to glycaemia compared to non-automated CSII. It was not possible to evaluate the age groups separately as most trials incorporated people across both paediatric and adult age ranges. The generalisability of benefits from AutoCSII to children under six years old is limited given the lack of evidence in this young group. It is anticipated that future AutoCSII systems may use more refined automated insulin delivery algorithms (including automatic bolus delivery in addition to automatic basal delivery) and potentially dual hormone treatment (e.g. insulin and glucagon).
CGMS	We suggest CGM rather than self-monitoring of blood glucose alone for all adults with type 1 diabetes treated with multiple daily injections.	CGM devices provide a large amount of real-time data and summary glycaemic data (e.g. modal day reports) which can be highly valuable for both the person with diabetes and their healthcare providers. Higher proportions of time spent actively using and responding to CGM data are consistently associated with glycaemic improvements such as lower HbA1c concentrations and increased time within an appropriate glucose range (3.9-10.0 mmol/L). A conditional recommendation for use of CGM in type 1 diabetes was based on low-moderate certainty of evidence for favourable outcomes.

9 Cohorts suitable for insulin pump use

9.1 Overview

Diabetes Australia suggest that pump therapy "is not a cure for people who require insulin to manage their diabetes but a way of delivering insulin", and that the therapy is not suitable for everyone, and its use should be first discussed with a doctor or credentialed diabetes educator [3]. The Australian Evidence-Based Clinical Guidelines for Diabetes stresses that health professional discussions with people with type 1 diabetes should include the importance of high level engagement with the technology and health services with regard to the use of insulin pumps [18].

Diabetes Australia suggests that insulin pump therapy is not recommended for people who [4]:

- Are not performing or are not willing to perform frequent blood glucose checks.
- Are not willing or able to calculate the amount of carbohydrate in meals and snacks.
- Are not able to detect air bubbles in the infusion line (vision impaired).
- Are not able to hear the alarms (hearing impaired), although most modern pumps have a vibration alarm as well as an audible alarm.
- Are not able to press the buttons on a pump (e.g. severe arthritis).
- Are not able to manage possible problems which may arise, including site infections and blocked lines.
- Are not willing or able to keep in regular contact with their diabetes educator or have regular reviews by their endocrinologist.
- Are in any way unable to manage the pump functions.

9.2 Cognitive, Visual and Hearing Impairments

Literature sourced suggests that those with cognitive, visual or hearing impairments may have difficulty using insulin pump technology.

- Cognitive impairment is a common, underdiagnosed complication of diabetes that can interfere with the ability to adequately perform required daily self-management behaviours [19].
- Insulin pumps may be appropriate for these cohorts if the caregiver is available and well educated in its use [19].
- A system that stresses a user's visual and cognitive abilities can generate use-related errors which have a negative impact on usability. For example, programming a standard bolus into the pump to deliver insulin in anticipation of an impending consumption of carbohydrates through food intake should consist of a task sequence that can easily be learned and remembered. In insulin pump therapy, it is a task that precedes several daily events that require a user to calculate the amount of carbohydrates to be consumed. The amount then needs to be entered into the programming interface to prompt the system to deliver additional insulin to equalize blood glucose to a pre-set normal level. Any system constraint during such a common procedure can lead to use-related errors that affect the accuracy of insulin therapy for a patient [20, 21].
- Users with vision problems have trouble with unlocking the pump, and should have a good support system to help them manage the pump [20].
- Insulin pumps may not be suitable for those not able to hear the alarms (hearing impaired), although most modern pumps have a vibration alarm as well as an audible alarm [4].
- Pump users need to be able to "read" the measurement results. For visually impaired patients pump systems should have a sufficiently large display with good backlight - there should be a good contrast of the number on the display, allowing good readability even under less than optimal lighting conditions or under strong light [22].
- When handling insulin pumps it is important for visually impaired or blind patients that the pumps can guide the user through the various menus and so on with suitable tones [22].

9.3 Prescription of Insulin Pumps and Continuous Glucose Monitoring Systems

No published guidelines could be sourced with regard to professionals most suitable to prescribe insulin pumps or CGMS.

For eligibility of the NDSS CGM scheme, the person will need to be assessed by an authorised health professional to determine whether they meet specific eligibility criteria and to ensure that they know how to best use CGM or Flash GM in the management of their diabetes.

The NDSS suggests that only the following health professionals can perform these assessments and are authorised to certify eligibility to access the CGM scheme [23]:

- Endocrinologists
- Credentialed diabetes educators
- Other health professionals specialising in diabetes (physicians, paediatricians or nurse practitioners).

10 Funding schemes for Insulin Pumps, Continuous Glucose Monitoring Systems and Consumables

10.1 Insulin Pumps

10.1.1 Australian Government's Insulin Pump Program

The Australian Government's Insulin Pump Program [24]:

- Offers subsidies to low income families who have children with type 1 diabetes.
- Aims to improve access and affordability of insulin pumps for limited income families who have children (up to 18 years of age) with type 1 diabetes, and do not have access to other means of reimbursement, such as private health insurance.
- Offers families with a combined annual income of up to \$109,610 eligibility to apply for a pump subsidy under the program, subject to meeting the program criteria.

As of 1 July 2017, the following pumps are available under the Insulin Pump Program [3]:

- [Accu-Check Spirit Combo](#)
- [MiniMed 640G](#)
- [Paradigm Veo](#)

10.1.2 Health Insurance

Gold Tier private health insurance policies cover insulin pumps [3].

Under the Private Health Insurance Act 2007, private health insurers can cover the cost of insulin pumps under their Hospital or General Treatment policies. If an insulin pump is provided as part of an episode of hospital treatment and the patient has an appropriate hospital policy, private health insurers are required to pay benefits towards the cost of the pump, as well as the hospital accommodation fees and the doctor's fee [25].

10.1.3 Medtronic Bridging the Gap Program

Insulin pump product manufacturer Medtronic offers a pump loan arrangement for users under their Bridging the Gap program where successful applicants will have access to a Medtronic insulin pump for the remainder of their health fund waiting period (a maximum of 12 months) [26]. To be eligible the applicant must:

- Have private health cover.
- Be in the interim 12-month waiting period for private health cover benefits.
- Have been diagnosed with Insulin Dependent diabetes.
- Meet the NDSS criteria for insulin pump consumables (for details, visit NDSS).
- Be under supervision from healthcare professionals, including a diabetes educator and endocrinologist or paediatrician, for insulin pump therapy.

10.2 Continuous Glucose Monitoring System

10.2.1 National Diabetes Services Scheme (NDSS)

The Australian Government provides access for eligible people to fully subsidised CGM and Flash GM products through the CGM Initiative as part of the NDSS to assist users with type 1 and 2 diabetes [23].

Eligibility [27]:

- Live in Australia or are visiting from a country with which Australia has a Reciprocal Health Care Agreement on an applicable visa.
- Have been diagnosed with any type of diabetes by your doctor; or have other eligible conditions requiring regular monitoring of blood glucose levels.
- Hold (or are eligible to hold) a Medicare card or Department of Veterans' Affairs card.

Users are not eligible to register if they have impaired glucose tolerance or impaired fasting glycaemia, sometimes referred to as pre-diabetes.

Non Eligibility [27]:

- Users with impaired glucose tolerance or impaired fasting glycaemia, sometimes referred to as pre-diabetes.

The following devices are available under the scheme:

- [Dexcom G4 Platinum](#)
- [Dexcom G5 Mobile](#)
- [Dexcom G6](#)

10.3 Consumables

10.3.1 National Diabetes Services Scheme

People with type 1 diabetes registered with the NDSS can gain access to insulin pump consumables.

The cost of an insulin reservoir/cartridge is about \$1 per unit. Batteries and other pump accessories are not subsidised by the scheme [4].

In certain circumstances, people who have been diagnosed with 'other diabetes' and 'hard to manage' type 2 diabetes can request special consideration from the Department of Health to access consumables through the NDSS [28].

10.3.2 Medtronic Pump Consumables Grant

For type 2 diabetes pump users, Medtronic offer a consumables grant with savings of up to 90% on RRP consumables [29].

- Number of grants are limited to 250
- Applicants must have a suitable level of hospital cover with a private health insurance fund.

11 Lifespan, warranty, maintenance, upgrade and service of Insulin Pumps

11.1 Lifespan

The lifespan of an insulin pump or CGMS could not be precisely determined. There are many variables which can impact the lifespan of a device, and they can be broadly placed into two areas:

- Usage environment
- Usage patterns and treatment
- Engineering/product design.

11.2 Warranty

Warranty information for TGA approved pumps referenced above is in the table below, where the warranty period for all products is four years. Information for **Medtronic** products [30] and the

Tandem t:slim X2 [31] is available on the manufacturer's websites, and **YpsoPump** [32] and **Accu-Chek** [33] information was sourced via phone calls to the manufacturer/distributor. Note that guarantees for products are protected under Australian Consumer Law [34].

During a warranty period the manufacturer will usually repair or replace the device when there are defects in materials and workmanship. Replacement may include either a new or recertified device. In such cases warranties will not be extended but will continue from the date of the initial warranty period.

NOTE: The TAB Research Team is currently working on research surrounding the potential need to replace out of warranty assistive technology which is currently well functioning, to reduce the risk of catastrophic failure and potential harm to participants and responsibility risk to the agency.

Product	Warranty Period	Date Period Commences
Medtronic Insulin Pump	Pump - 4 years Remote control - 2 years	Date of purchase
Medtronic Guardian™ Connect Continuous Glucose Monitoring System	Transmitter - 1 year	Date of purchase
Medtronic Infusion Sets/Reservoirs	3 days	Date of package opening, provided product was shipped to end-user less than 6 months beforehand
Medtronic MiniLink™ Transmitter	1 year	Date of purchase
Medtronic CareLink™ iPro™2 System	Monitor - 1 year Dock - 1 year	Date of purchase
Medtronic CareLink™ USB	6 months	Date of purchase
NOTE: The Medtronic Warranty does not apply to batteries, glucose sensors and accessories, and is additional to the rights of the consumer under Australian Consumer Law [30].		
AMSL Diabetes Tandem t:slim X2	4 years	Once product leaves warehouse
mylife DiabetesCare YpsoPump	4 years	Time of sale
Accu-Chek	4 years – pumps 2 years - Metres	Time of sale

11.3 Maintenance, Upgrade and Service

According to Diabetes Australia, some people upgrade their pumps after a number of years (usually four or five years) to a new pump, and each private health insurer has specific criteria to qualify for

a pump upgrade [4]. Health funds will not upgrade the pump because a newer model is available. The pump must be out of warranty and faulty [4].

Manufacturer's warranties generally state that they will either repair or replace any defective products or part thereof at no charge to the purchaser for parts or labour during the warranty period. Warranties will generally exclude wear and tear and cosmetic damage [30, 31].

It appears insulin pumps do not require periodic servicing. No information could be sourced on this topic.

12 Insulin Pump Users and Health Professional Support and Training

Although insulin pumps are user-friendly in terms of programming and daily use, they still require a certain level of skill to program and make changes to basal rates, set bolus doses, alarms etc. The user also needs to learn to change cartridges and infusion sets [4].

Pump users will need at least one intensive training session with their diabetes educator when they are first fitted with a pump. There is also a lot of 'on-the-job training' as the user gets to know their pump in the first few weeks [4], and they will need to keep in regular contact with their diabetes educator or endocrinologist for review and adjustment of pump rates [3].

Users in remote and regional areas may also have insufficient access to training and support for optimal implementation of insulin pump therapy [18].

13 Costs of Insulin Pumps and Continuous Glucose Monitoring Systems

13.1 Insulin Pumps and consumables

The cost of insulin pumps are not promoted on the product manufacturer or distributor's websites, and manufacturers and distributors were not contacted to determine costs.

Diabetes Australia suggests the **cost of an insulin pump** can range from \$8950 to \$9500, depending on the brand [4].

The cost of consumables for insulin pumps is around \$270 per month (\$3,240 per year) as suggested by Diabetes Australia [4].

13.2 Continuous Glucose Monitoring Systems and consumables

According to Diabetes Australia the cost of CGMS including consumables (sensors) is around \$5,000 per year [11].

14 Cost Effectiveness of Insulin Pumps as opposed to Multiple Daily Injections

Australian evidence-based clinical guidelines for diabetes, suggest that CSII may be cost-effective particularly among those who gain significant improvement in glycaemic blood glucose management and quality of life [18].

There is a significant expense associated with the use of insulin pumps [18, 35]. The purchase price for individual pumps range from \$8950 to \$9500 [4], with consumables purchased through the NDSS costing the consumer an average of over \$340 per year above the 91% Government subsidy provided through NDSS. The annual cost of insulin varies based on requirements. Individuals who administer insulin via MDI are required to pay the costs of insulin only, as syringes and pen needles are provided at no cost through the NDSS [18].

From a government funding perspective, review of international economic evaluations found that CSII with SMBG may be cost-effective in comparison to MDI particularly among those who gain significant improvement in blood glucose management and quality of life [18].

In more detail, cost-effectiveness analyses aim to assess the differences between costs of therapy balanced against the differences in health outcomes. Incremental cost-effectiveness ratios are used in cost effectiveness analyses and represent the difference in costs of treatments and outcomes between two interventions divided by the difference in quality adjusted life years over a predefined period of time, or time horizon. While the acquisition costs of CSII therapy are significantly larger than SMBG for example, economic evaluations assess whether fewer complications of diabetes due to glycaemic improvement from CSII might offset these costs. The evidence-based guidelines found nine economic evaluations that compared CSII and SMBG therapy against MDI and SMBG [18]. Five studies concluded CSII was cost-effective while the other four did not [18].

15 Cost of nursing supports in providing daily insulin administration and checks

15.1 Multiple Daily Injections by Nurse or Support Worker? - NDIS Practice

As per the NDIS Practice Guide – Diabetic Management Supports (V2.0 2020-07-02) [36], MDI can be administered by **a nurse or support worker** under delegated care, depending on the complexity of the participants needs.

- **Skilled Personnel:** Insulin administration is a procedure that is required to be performed by skilled personnel that are trained appropriately. The personnel can be a **registered nurse, enrolled nurse or attendant carer**. Maintenance procedures can be delivered by non-skilled personnel to NDIS participants who have reached a point of stability and require routine maintenance (i.e. considered to be part of the usual daily personal care routine). This can include some aspects of the day-to-day care related to subcutaneous injections such as insulin for an insulin dependent diabetic. **Registered nurses and local medical officers** would be responsible for overseeing the medication management and health of the participant

[36].

- **Funding of Training:** The NDIS would be responsible for funding the provision of care, training and supervision of a delegated worker to deliver these maintenance supports which are integral to a person's ongoing care and support to live in the community, participate in education and employment as well as social and recreational activities [36]. When required the NDIS would fund a suitable number of hours as per delegation of care for a **support worker** to attend training that is [36]:
 - Provided by the health treatment team or a registered nurse responsible for development of the Diabetes management plan and funded by NDIS.
 - Specific to the implementation of the participant's management plan.
 - Required to ensure that the support worker is able to perform day-to-day maintenance and care.
- **Complex Support:** For participants with complex health and disability care needs, a **registered nurse** may be required to administer insulin. However, usually a **support worker** with appropriate competency would provide assistance with the administration of routine, non-complex insulin. (Documentation needs to be provided to the NDIS that clearly explains why this task cannot be delegated such as evidence that the participant has unstable diabetes with a registered nurse required to assess and determine the level of insulin to be administered) [36]. Note: certified training of support workers does not include insulin management as part of the curriculum [37].

15.2 Approximate cost per annum for support - Nurse

Costing nursing supports depends on the support frequency of a nurse or support worker required by the participant's condition being either complex or routine non-complex. The calculations below are based on a support period of 12 months where a participant with Acquired Brain Injury requires:

- 2 visits per day by an **Enrolled Nurse** (EN)
- 4 visits per year for assessment by a Registered Nurse (RN)
- Travel within metropolitan area

Costings are per the current NDIS Price Guide and Support Catalogue 2020-21 [38].

Support Item/Line Number	Time	Visits	Rate (\$)	TOTAL (\$)
Assessment Weekly Daytime – RN 01_606_0114_1_1	1 Hour	4	107.25	429.00
Weekday Daytime – EN 01_600_0114_1_1	30 minutes	502	41.31	21,741.62
Saturday – EN 01_602_0114_1_1	30 minutes	104	61.79	6,426.16

Support Item/Line Number	Time	Visits	Rate (s)	TOTAL (\$)
Sunday – EN 01_603_0114_1_1	30 minutes	104	71.03	7,378.12
Public Holiday – EN 01_604_0114_1_1	30 minutes	20	80.26	1,605.20
Travel - Rate1 - Weekday – RN 01_606_0114_1_1	15 minutes	4	26.81	107.24
Travel - Rate1 - Metro Weekday Daytime – EN 01_600_0114_1_1	15 minutes	502	21.66	10,873.32
Travel - Rate1 - Metro Saturday Daytime – EN 01_602_0114_1_1	15 minutes	104	30.89	3,212.56
Travel - Rate1 - Metro Sunday Daytime – EN 01_603_0114_1_1	15 minutes	104	35.51	3,693.04
Travel - Rate1 - Metro Public Holiday – EN 01_603_0114_1_1	15 minutes	20	40.13	802.60
Consumables (NDSS or PBS funded)	N/A	N/A	N/A	N/A
TOTAL				56,277.86

15.3 Approximate cost per annum for support – Support Worker

Using the same participant example as the above, the calculations below are based on a support period of 12 months where a participant with ABI requires:

- 2 visits per day by a **Support Worker** (SW).
- 4 visits per year for assessment by a RN.
- Travel within metropolitan area.

Costing are as per the current NDIS Price Guide and Support Catalogue 2020-21 [38], where it has been determined that a **level 1 support worker** has the capacity to provide Assistance With Self-Care Activities with High Intensity Daily Personal Activities [36, 38, 39].

Support Item/Line Number	Time	Visits	Rate (s)	TOTAL (\$)
Assessment Weekly Daytime – RN 01_606_0114_1_1	1 Hour	4	107.25	429.00
Weekday Daytime – SW 01_300_0104_1_1	30 minutes	502	27.73	13,922.97
Saturday – SW 01_302_0104_1_1	30 minutes	104	38.90	4,046.12

Support Item/Line Number	Time	Visits	Rate (s)	TOTAL (\$)
Sunday – SW 01_303_0104_1_1	30 minutes	104	50.08	5,208.32
Public Holiday – SW 01_304_0104_1_1	30 minutes	20	61.25	1,225.10
Travel - Rate1 - Weekday – RN 01_606_0114_1_1	15 minutes	4	26.81	107.24
Travel - Rate1 - Metro Weekday Daytime – SW 01_300_0104_1_1	15 minutes	502	13.86	6,960.23
Travel - Rate1 - Metro Saturday Daytime – SW 01_302_0104_1_1	15 minutes	104	19.45	2,022.80
Travel - Rate1 - Metro Sunday Daytime – SW 01_303_0104_1_1	15 minutes	104	25.04	2,604.16
Travel - Rate1 - Metro Public Holiday – SW 01_304_0104_1_1	15 minutes	20	30.63	612.50
Consumables (NDSS or PBS funded)	N/A	N/A	N/A	N/A
TOTAL				37,201.44

16 Cost savings between the use of Insulin Pumps and Nursing Supports

In considering the cost savings between insulin pump usage and the provision of nursing supports to a participant, the following comparisons will be used and calculations worked out over a one year and four year period.

- A four year comparison period has been selected as warranties for all TGA approved pump devices referenced in this document is four years. Whether or not NDIS may replace a device after the warranty period is yet to be determined. Note that repair costs are provided under the warranty
- Nursing costs are calculated according to the current NDIS price guide (as per the tables above), so it should be considered that these cost may rise over the next four years.
- Nursing costs are calculated according to the example participant given above, who requires two visits per day by an EN including travel, and four assessments per year by an RN including travel.

- The potential cost of training a support worker for the appropriate competency has not been included in the calculations
- The device cost is based on the [Medtronic 770G](#) [5] which is a relatively new device which features continuous glucose monitoring as well as automatic insulin delivery, at a cost of \$8574.00. (This was sourced from a quote submitted for NDIS funding dated 22/12/20 which was referenced in a recent TAPS advice provided to the TAB research team)
- Consumables are not included in the calculations as these are funded by the NDSS or PBS

Period	Insulin Pump Device costs (\$)	Nursing costs (Enrolled Nurse) (\$)	Nursing costs (Support Worker – Level 1) (\$)
1 Year	8574.00	56,277.86 A cost saving of \$47,703.86 (65%)	37,201.44 A cost saving of \$28,627.44 (43%)
4 Years	8574.00	225,111.44 A cost saving of \$216.537.44	148,805.76 A cost saving of \$140.283.60

17 Other cost considerations

- **Internet access** cost for participant to upload device data to be reviewed by health professionals.
- **Computer/laptop** cost in order for the participant to access the internet to upload data.
- Where the type of device gives the user mobile phone monitoring (e.g. glucose levels) or notifications (e.g. if levels are reaching high/low), the participant would require a **mobile phone with an internet data plan**. The [Medtronic 770G](#) [5] device referred to in the costings above has these features.
- Items regarded as **accessories** to the devices may bring ease of use to the participant such as bra and waste pouches to house the device, and waist bands. These have varying costs [17]
- Users would require an intensive training session when first being introduced to an insulin pump.

18 Conclusion

Insulin pumps are more cost effective than providing nursing supports. However, the participant's functional capacity to use an insulin pump would need to be assessed.

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Research – Out of warranty AT replacement

Brief	Is there a need to replace out of warranty assistive technology which is currently well functioning to reduce the risk of catastrophic failure and potential harm to participants and responsibility risk to the agency?
Date	May 17, 2021
Requester(s)	s47F - personal privacy - Senior Technical Advisor (TAB)
Researcher	s47F - personal privacy - Tactical Research Advisor (TAB/AAT)
Cleared	s47F - personal privacy - Research Team Leader (TAB) – Cleared 18/05/21

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters.

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2 Related TAB Research

NED21/73162 RES AT Lifespan of Communication Devices (Augmentative and Alternative Communication) 2021/0157

3 Introduction

The research brief for this paper originated from a TAB advice request (NED21/147873) surrounding a microprocessor-controlled prosthetic knee, which instigated discussion amongst the TAB Technical Practice and Resolution Team, where it became evident that the question exists across a range of assistive technology (AT).

For the purpose of exploring overarching themes for this research, components of the TAB Advice Request will be used as a case study throughout this paper.

The Case

The TAB advice involved a request for a replacement Ottobock Genium knee:

- The agency denied funding for replacement noting that “the Genium knee unit is not recommended to be serviced or replaced at this time.” The advice was later adjusted to “the Genium knee unit is not recommended to be serviced or replaced at this time **unless the provider can submit evidence that catastrophic failure of the knee unit is likely to occur and poses injury risk for the participant by using a fully functioning unit that is out of warranty.**” [TAB Advice 16/03/21, NED21/147873].
- The agency indicated the preferred course of action is for the participant to continue wearing a Genium knee unit that has reached the end of its serviceable life and is outside of the 6 year warranty period [Letter from Supplier 25/03/21].
- The supplier suggested that the agency's position directly contradicted a statement made by the manufacturer (Ottobock) within its “Genium/X3 72 Month Service” documentation, which states that Ottobock recommends replacing these components once the warranty

period has expired to ensure maximum safety and convenience for both prosthetic service provider and end user [Letter from Supplier 25/03/21].

- The supplier further states [Letter from Supplier 25/03/21]:
 - For a Genium under warranty, a service is scheduled every 24 months and is required in order to keep the warranty valid.
 - Once a device is out of warranty, the device is scheduled for maintenance at the same time interval but is not considered mandatory only because there is no longer a warranty to maintain.
 - Ottobock says that all scheduled services are advised to ensure the prosthesis performs in a safe and predictable manner. If the knee unit is not serviced, Ottobock strongly recommends that the Genium unit should be replaced.
- The Supplier stated that “When making this decision we must consider the risks associated with failure of the unit and the consequences of that failure. We also must accept that the question is not if the unit will fail but when.” Depriving the knee unit of a 72-month service means that it will no longer be well-maintained, and the possibility of catastrophic failure becomes greater and greater as the device is continued to be used. In our experience non-serviced knee units are highly unpredictable, and the potential consequences of failure are possibly extreme for this participant. The unpredictability of the knee not only relates to how the knee may fail, but also where and when it may fail.” [Letter from Supplier 25/03/21].
- The Supplier reiterated they “made the recommendation for the replacement of [the participants] microprocessor knee unit that is out of warranty, which is endorsed by the manufacturer and is an accepted industry practice. By denying this recommendation the NDIS, and its clinical advisors, are taking responsibility for the client’s safety until this issue is resolved.” [Letter from Supplier 25/03/21]

Dissecting the Case

The research requester posed additional questions to be considered in this paper which are related to the specific advice (NED21/147873):

- What are the relevant Therapeutic Goods Administration (TGA) requirements in this scenario?
- Who do the TGA deem is responsible if the participant’s AT were to experience catastrophic failure once out of warranty and the provider has recommended replacement, NDIS say no but provider continues to enable use and attaches new parts to the part requiring replacement? That is, does enabling continued use assume the provider indicates it is safe to do so?
- What does the supplier Ottobock (and others across relevant AT) see as the risk associated with use beyond their warranty period? Can they clarify why they use warranty period and

serviceable life terminology interchangeably? Do they consider them as the same thing?

- Are warranty period and serviceable life different concepts? Are there definitions around these terms and catastrophic failure we should be using in TAB when considering whether replacement of an item is R&N at a certain time?
- Is the provider right that a microprocessor knee has increased risk of use past warranty periods as compared to other prosthetic componentry because the provider themselves are not in a position to service the component as required? Is there different decision making to occur depending on the type of AT, the parts included, the risk to the participant if the AT is out of action, the ability for the provider to conduct maintenance and repairs themselves vs the supplier?
- How do these concepts apply across AT, not only to prosthetics?

4 Terminology

Terminology surrounding this subject can be confusing as some terms are used interchangeably by various organisations. Terms such as Life Cycle, Life Span, Effective Life, Physical Life, Useful Life, Serviceable Life, and Catastrophic Failure, are not easy to define as they can be used within different contexts.

Some of the more common interpretations of these terms are provided below. Additional terms referenced throughout this paper are defined and summarised in [Appendix 1](#).

4.1 What is Serviceable Life?

A definition of "serviceable life" could not confidently be sourced. There are many definitions derived from the term "service life" mainly referring to the time a product may be in use (of service) to its owner in terms of an asset i.e. how long it will be useful [1-3].

There are interpretations, which cannot be quantified such as, "service life represents a commitment made by the item's manufacturer and is usually specified as a median. It is the time that any manufactured item can be expected to be "serviceable" or supported by its manufacturer" [4].

Given that the correspondence from the supplier to the Agency (dated 25/03/21), was written in the context of the manufacturer, it may be reasonable to suggest that this is related to the terms of the warranty: "*Genium knee unit that has reached the end of its serviceable life and is outside of the 6 year warranty period*".

There may be justification to define "serviceable life" as the length of time that the manufacturer considers the item to be serviceable as reflected in their warranty.

4.2 What is Catastrophic Failure?

Definitions for Catastrophic Failure can vary in terms of its reference to systems, equipment, events, or products. It can be broadly defined as "**Changes in capability resulting in total loss of useful performance. Operating characteristics of a material, product, or system undergo sudden and drastic change** [5]." Other legal oriented uses of the term can be found at the [Law Insider](#) [6].

4.3 What is Life cycle?

Life cycle is a broad term which can be used in many contexts such as, "a series of stages through which something (such as an individual, culture, or manufactured product) passes during its lifetime [7]." The Law Insider suggests a general legal definition, "all stages which are consecutive or interlinked, including research and development to be carried out, production, trading and its conditions, transport, use and maintenance, throughout the existence of the product or the works or the provision of the service, from raw material acquisition or generation of resources to disposal, clearance and end of service or utilisation [8]."

The above definitions appear to be in keeping with the way the TGA interprets the term for products (devices) undergoing the regulatory approval process, as well as post market monitoring and performance. It appears that the TGA use this term in the context of assessing and monitoring of a device while under their jurisdiction, however, no specific definition by the TGA could be located [9, 10].

4.4 What is Life span?

Life span of a device cannot be quantified. Various organisations use methods to apply a time value on devices and other medical equipment when assessing life span in terms of an asset [11-13].

4.5 What are Warranties?

A warranty is a voluntary promise offered by the person or business who sold the product or service to the consumer. Once the consumer purchases the product or service, the promise becomes a right that can be enforced under the Australian Consumer Law (ACL) [14].

Warranties are separate from automatic consumer guarantees. The consumer guarantees which apply regardless of any warranties suppliers sell or give to the consumer, apply for a reasonable time depending on the nature of the goods or services. This means consumer guarantees may continue to apply after the time period for the warranty has expired [14].

With consumer guarantees, businesses must guarantee products and services they sell, hire or lease for under \$40,000 and over \$40,000 that are normally purchased for personal or household use [15].

Products must be of acceptable quality, that is [15]:

- Safe, lasting, with no faults

- Look acceptable
- Do all the things someone would normally expect them to do.

Services must [15]:

- Be provided with acceptable care and skill or technical knowledge and taking all necessary steps to avoid loss and damage.
- Be fit for purpose or give the results that you and the business had agreed to.
- Be delivered within a reasonable time when there is no agreed end date.

Consumer Guarantees are a provision under ACL, which is regulated by the Australian Competition and Consumer Commission (ACCC) [16].

5 Therapeutic Goods Administration Requirements

5.1 Overview

- The TGA's regulatory requirements for medical devices is about manufacturing standards, and the manufacturer's obligation to apply corrective action in relation to design or production of a device.
- It appears that the TGA does not have specific regulations with regard to obligations of warranty by the manufacturer, and that the TGA's responsibilities finish with the monitoring of the ongoing obligations of the manufacturer.
- The TGA has no jurisdiction in matters where a participant's device were to experience catastrophic failure.
- The Therapeutic Goods (Medical Devices) Regulations 2002 states that if applicable the manufacturer must provide with the device, a time period in which the device can be safely used, and that the device must be designed and produced in a way where it can be regularly maintained according to their instructions.
- **NOTE:** The TGA are currently in the process of reviewing and updating the Australian Regulatory Guidelines for Medical Devices (ARGMD) [17].

5.2 Pre-Market Responsibilities

To maintain public confidence in the safety, performance, benefits and risks associated with the use of medical devices on the Australian market, the TGA may conduct assessments [18]:

- Before a device is able to be supplied to the market in Australia, and
- While a medical device is available on the market.

Before a new medical device can be supplied to the market in Australia, the TGA needs to be involved. The TGA's regulatory requirements vary, depending on what the device is and how it is to be used. The TGA is involved in most of the stages in the life cycle of a medical device [18].

The risks associated with using medical devices can range from little or low potential risk to patients and users to significant potential risks. The level of assessment performed by the TGA before the device is able to be supplied in Australia directly relates to the level of potential risk as per the Risk vs Regulatory Requirements (Figure 1) [17].

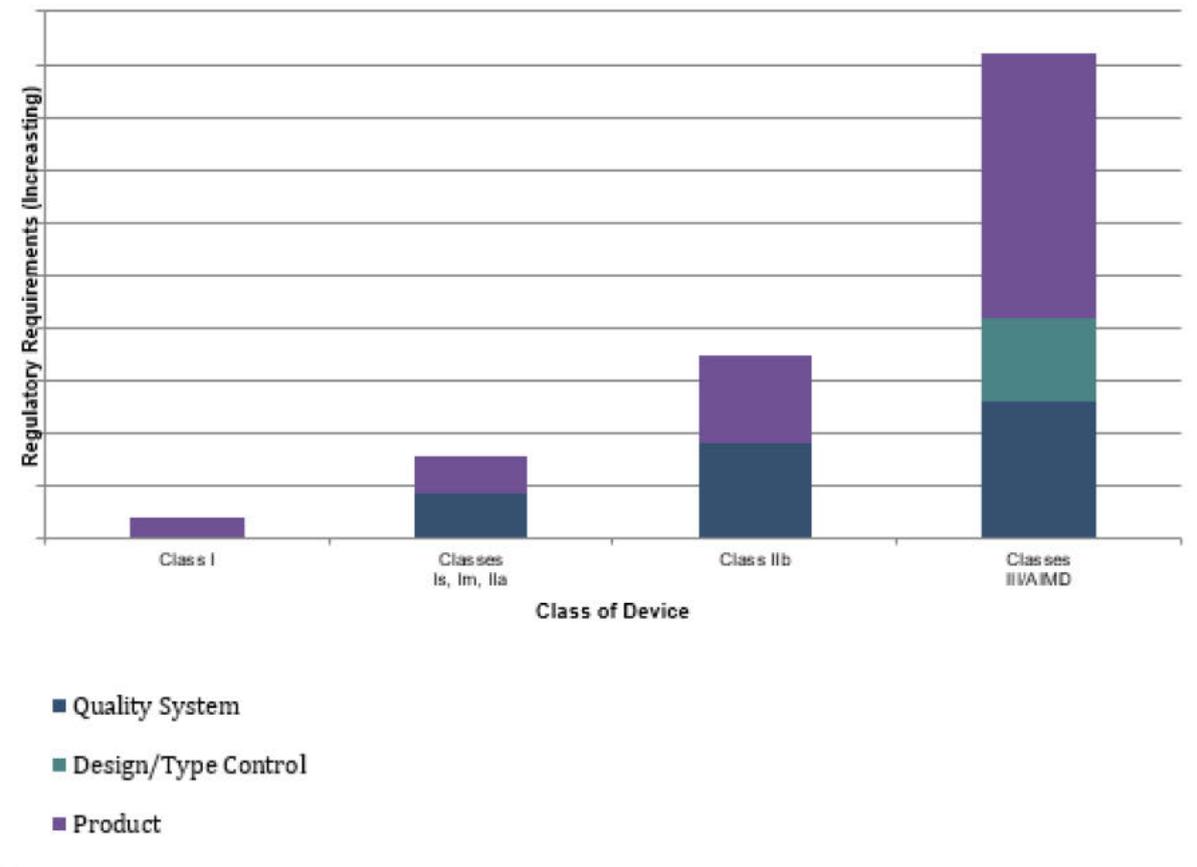


Figure 1: Level of regulatory assessment performed by the TGA based on class of device.

The TGA have a risk-based approach to regulation. It would be inefficient to regulate a tongue depressor with the same rigour as a pacemaker. The extent of regulation therefore depends on [19]:

- The intended purpose of the device.
- The degree of risk the device poses to the patient.
- The degree of risk the device poses to the user and those in the vicinity.
- Whether the device is used internally or externally to the patient.
- The duration of use.

The level of scrutiny by the TGA of a device before it is placed on the Australian Register of Therapeutic Goods (ARTG) and supplied in Australia depends on the risk posed by the device. The TGA has adopted a classification system for devices, based on the level of risk [19].

Using the TGA's classification tool (Figure 2) [20], the Genium knee would be classified as Class 1s/1m with a low potential of harm.

Important considerations

Medical devices are classified according to the level of harm they may pose to users or patients. The following tool will assist in determining the classification of a medical device that is not an In Vitro Diagnostic device. There are separate classification rules for IVD devices.

Medical Device Classification	Level of Potential Harm
Class I	Lowest
Class Is, Class Im	Low
Class IIa	Low to Moderate
Class IIb	Moderate to High
Class III, AIMD	High

Figure 2. TGA classifications.

5.3 On-Market Responsibilities

The TGA does not have specific regulations with regard to obligations of warranty by the manufacturer, and the TGA's responsibilities finish with the monitoring of the ongoing obligations of the manufacturer.

Manufacturers have ongoing legal obligations for medical devices that they manufacture. One is that [17]:

- They implement appropriate means to apply any necessary corrective action in relation to the design or production of a device as soon as practicable after becoming aware of information relating to:
 - Any malfunction or deterioration in the characteristics or performance of the device.
 - Any inadequacy in the design, production, labelling or instructions for use of the device.
 - Any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device that might lead, or might have led, to the death of a patient or a user of the device in Australia, or to a serious deterioration or serious injury to his or her state of health.

5.4 Catastrophic Failure

Current information suggests that the TGA has no jurisdiction in matters where a participant's device were to experience catastrophic failure.

5.5 Manufacturer's Responsibilities within the Therapeutic Goods Administration Regulations

5.5.1 *The Therapeutic Goods (Medical Devices) Regulations*

The Therapeutic Goods (Medical Devices) Regulations 2002 ("the regulations") clearly states that manufacturers are required to indicate a time period in which a device can safely be used, and that the device must be designed and produced in a way where it can be regularly maintained according to their instructions. [21].

5.5.1.1 *Time period in which the device can safely be used*

The regulations state that if applicable the manufacturer must provide with the device, a time period in which the device can be safely used, and if the information with the device does not include such, a statement of the date of manufacture of the device (Schedule 1, Part 1, 13.3, Items 12 & 13) [17, 21].

5.5.1.2 *Long Term Safety and Maintenance*

Schedule 1, Part 1, 4 of the regulations state that [17, 21]:

A medical device must be designed and produced in a way that ensures that if:

- a. the device is used within the period, indicated by the manufacturer, in which the device can be safely used; and
- b. the device is not subjected to stresses that are outside the stresses that can occur during normal conditions of use; and
- c. The device is regularly maintained and calibrated in accordance with the manufacturer's instructions; the characteristics and performances mentioned in clauses 1, 2 and 3 are not adversely affected.

5.5.2 *Information provided by the manufacturer*

In the case of Otto Bock's Genium X3 device, the warranty [22], instructions for use [23], and general information [24] documents were sourced from the internet.

No specific time period were given for which it might be safe to use the device in any of the documents. However, this information may have been provided in other documentation to the participant. The instructions for use document clearly indicates that:

- "Regular service inspections are recommended in the interest of the patient's safety and in order to maintain operating reliability and protect the warranty." (This was also mentioned in the warranty).
- "The duration of use can be individually extended depending on the intensity of use by performing regular service inspections."

Although clearly stating that service inspections are required to maintain the warranty, it appears that Otto Bock are also stating that the duration of use of the device can go beyond the warranty period, as long as service inspections are maintained, which would potentially identify defects.

Interpreting the TGA regulations and the Otto Bock instructions for use of the Genium X3, it would appear that the device is safe to use after expiry of the warranty, providing that it is serviced regularly as recommended by the manufacturer. Where as a result of the service, the manufacturer recommends replacement of certain components or indeed of the device itself, it could be deemed that following through with the recommendations of the manufacturer, or the manufacturer's agent, is doing so based on expert advice.

6 Considering ways of determining life span of a device

6.1 Overview

Many organisations refer to the "life span" of a device or product. The lifespan of AT cannot be precisely determined. No research could be sourced which might indicate precise lifespan, other than general articles indicating that lifespan may be longer or shorter depending on a number of factors. In a recent TAB research paper looking at the lifespan of AT communication device, three manufacturers were contacted asking for the lifespan of their devices, all three indicated that they could not determine lifespan as it depends on a number of factors.

In Australia, the Biomedical Engineering Advisory Group (BEAG) is an industry advisory group where its members provide a link to their broad network and advises on ways to strengthen teaching and research activities through industry engagement [25]. A BEAG guidance paper on the lifespan of biomedical devices suggested that in some cases the life of a biomedical device may be longer or shorter depending on a number of factors [11]. They also reiterate that lifespan estimates provided in their guidance are a guide only and do not always indicate an age after which biomedical devices should not be used. Factors include:

- Frequency of use.
- Nature of use.
- Environment of use.
- Experience and knowledge of the user.
- Care and attention paid to use and operator maintenance.
- Existence, capability and cost of maintenance support.
- Stage in product life cycle.
- Management of scheduled and unscheduled maintenance.
- Availability and cost of consumables and spare parts.
- Availability and cost of replacement devices.
- Relative efficacy and effectiveness of the alternative methods and devices.
- Business and safety risks associated with continued or discontinued use.
- Strategic and political risks associated with continued or discontinued use.
- Compliance with current codes and standards.
- Technological or clinical redundancy.
- Funding availability.

The BEAG recommends that a risk management approach is taken when developing a replacement program for biomedical devices and that risk factors, including those above, are considered together with the age/lifespan ratio [11].

6.2 Life span in terms of risk management in public health service medical equipment

The Medical Equipment Asset Management Framework (MEAMF) has been developed to improve medical equipment asset management in Victoria and, in particular, to help individual health services meet their risk responsibilities [26]. Other states such as Queensland have similar frameworks [12]. The MEAMF involves a broad range of stakeholders across health services and industry groups [26].

A major component of applying the framework is to define what effective life is, and how to estimate the effective life of medical equipment. Knowing the effective life of equipment shows the health service when the equipment may need to be replaced [13].

The framework defines 'effective life' in relation to other terms such as physical life and useful life [13]:

Effective life - the period over which an item of medical equipment can provide the required clinical function or service for a health service. The Department of Health expects that an asset will complete its effective life before being considered for replacement.

Physical life – the total expected number of productive years for an item of medical equipment. The physical life of an item of medical equipment has ended once it has physically deteriorated to an extent that it is no longer capable of being repaired or used for its intended purpose.

Useful life – the period over which an item of medical equipment may be available for productive use by the health service or the number of units of use (for example, hours, procedures, exposures) expected to be achieved by the item of medical equipment by the health service.

Common criteria for determining effective life are [13]:

- technological obsolescence
- an item's fitness for purpose
- maintenance
- support and parts availability
- legislation
- frequency of maintenance
- Use and cost.

Factors that affect the effective life of an individual asset include [13]:

- The frequency, environment and nature of use.
- The care and attention paid to use and operator maintenance.
- The existence, capability and cost of maintenance support.
- The availability of consumables and spare parts.
- The availability of upgrades and renewals.
- Changes in legislative and regulatory requirements.
- Changes in industry or professional standards.

- Variation between manufacturers.
- Poor manufacturing quality.
- Technological or clinical redundancies.

Determining Effective Life

The framework's preferred method for determining the effective life of an item of medical equipment is the MEAMF baseline. The baseline tabulates the effective life for each common GMDN category of medical equipment, using an average value for all makes and models of that category [13].

The Global Medical Device Nomenclature (GMDN) is a comprehensive system of internationally agreed coded descriptors used to identify medical device products. The GMDN enables the standardised naming and categorisation of medical devices, accessories and systems, as well as other healthcare-related products (including technical aids, hospital and home care products). The GMDN specifically includes the original coding given to the Emergency Care Research Institute's Universal Medical Device Nomenclature System (UMDNS) terms. This enables the direct mapping of existing UMDNS-coded medical devices to GMDN coding where the UMDNS descriptor has been adopted unchanged in the GMDN [13].

The Therapeutic Goods Administration (TGA) in Australia is one of more than 20 regulatory bodies worldwide that have adopted GMDN. Others include the Food and Drug Administration (United States) and the Medicines and Healthcare products Regulation Agency (United Kingdom). TGA requires that the GMDN code be included as part of the registration of medical devices on the Australian Register of Therapeutic Goods (ARTG) [13, 18, 27].

The GMDN Device Categories are [28] :

- 01 Active implantable devices
- 02 Anaesthetic and respiratory devices
- 03 Dental devices
- 04 Electro mechanical medical devices
- 05 Hospital hardware
- 06 In vitro diagnostic devices
- 07 Non-active implantable devices
- 08 Ophthalmic and optical devices
- 09 Reusable devices
- 10 Single use devices
- 11 Assistive products for persons with disability
- 12 Diagnostic and therapeutic radiation devices
- 13 Complementary therapy devices
- 14 Biological-derived devices
- 15 Healthcare facility products and adaptations 16 Laboratory equipment

6.3 Life Span examples using the Global Medical Device Nomenclature

The BEAG guidance paper on the life span of biomedical devices gives an extensive list of expected life spans using the GMDN device category codes together with the UMDNS device groups and descriptions. Several examples of the extensive list is below (Table 1) [11]. (NOTE: The document was last updated in 2004. A more recent update to the document could not be sourced).

GMDN Device Category Code	UMDNS Device Group	UMDNS Description	Life Expectancy (years)
4	17159	INFUSION PUMPS, AMBULATORY, INSULIN	10
10	13168	PROSTHESES, JOINT, WRIST	7
2	15613	VENTILATORS	7
4	16214	WHEELCHAIRS, POWERED	5
4	10385	EXERCISERS, BICYCLE	10
4	17187	COMMUNICATION AIDS, VOICE SYNTHESISER	10
13	50038	TELEPHONES, CELLULAR	5

7 Australian Government Safety Reforms for Medical Devices

Regulation reforms are being called for in Australia after the catastrophic failure of various medical devices such as breast implants, surgical mesh, hip implants, and heart valves [29, 30]. The TGA has delayed the commencement of regulatory changes until late 2021 for the following [31]:

- **25 November 2021 for reclassification of certain devices, including**
 - spinal implantable medical devices
 - active implantable medical devices
 - medical devices that administer medicines or biologicals by inhalation
 - medical devices that are substances (or combinations of substances) for introduction into the body
 - active medical devices for therapy that include a diagnostic function to significantly determine patient management, and
 - medical devices that are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system
- **25 February 2021 for medical device software**
- **25 February 2021 for personalised medical devices (including 3D printed devices) and**
- **25 November 2021 for systems or procedure packs.**

The Health Issues Centre (HIC) is an Australian peak consumer health advocacy working with consumers to identify poor practice, policy, and regulation within the health sector [32]. The HIC claim that since recent device failures have been brought to light, they have been alerted to other device malfunction including [32]:

- Hernia and bowel mesh
- Cochlear implants
- Metal hip replacements
- Total knee replacements
- Inter uterine devices
- Insulin pumps
- Pain pumps
- Resuscitation devices
- Ventilators
- The “green whistle” used by paramedics for pain
- Breast implants – not just PIP and cereform
- Shoulder replacements
- Obesity surgery devices
- Stents
- Intraocular lenses

8 Evidence that catastrophic failure of a prosthetic knee is likely to occur

Given that there are regulations in place by the TGA to ensure that safety within the manufacturing of the device, and the monitoring of the safety of the device while it’s in use, the consumer can only trust that these measures are reliable. Catastrophic failures are usually interpreted as “unexpected”, in that there was no intention for the failure or event to occur. If the TGA regulations safeguard the consumer in the safety of devices, then it would be expected that the consumer would trust those regulations. Given the unexpected nature of a catastrophic failure, it’s difficult to obtain evidence which might indicate that a catastrophic failure is likely to occur.

9 Conclusions

- It may not be necessary to replace out of warranty AT which is currently well functioning in an attempt to reduce the risk of catastrophic failure and potential harm to participants, and risk to the agency.
- Certain operations of manufacturers are regulated by the TGA. It appears that the manufacturer Otto Bock, has adhered to relevant TGA regulations. In interpreting the TGA regulations and the Otto Bock instructions for use of the Genium X3, it would appear that the device is safe to use after expiry of the warranty, providing that it is serviced regularly as recommended by the manufacturer. Where as a result of the service, the manufacturer recommends replacement of certain components or indeed of the device itself, it could be

deemed that following through with the recommendations of the manufacturer, or the manufacturer's agent, is doing so based on expert advice.

- It appears the TGA does not have capacity to deem responsibility to a party where a participant's AT were to experience catastrophic failure. The TGA's role is to assess devices for safety prior to reaching the market, and to monitor the manufacturer's responsibility in applying any necessary corrective action in relation to the design or production while the device is on the market. The TGA has no other jurisdiction in matters where the manufacturer's role within a warranty is concerned.
- The TGA regulations exist to safeguard the consumer in the safety of devices. It would be expected that the consumer would place trust in those regulations. Given the unexpected nature of a catastrophic failure, it's difficult to obtain evidence which might indicate that failure is likely to occur.
- In the case presented in this paper, if the manufacturer is recommending that a component be replaced, and the supplier continues to attach new parts to the part recommended for replacement, then it could be determined that the supplier is at risk by not following the advice of the manufacturer, who is giving that advice based on their regulatory requirements.
- Warranty periods and serviceable life are not necessarily different concepts, they are directly related in that the serviceable life is the length of time that the manufacturer considers the item to be serviceable as reflected in their warranty period. Serviceable life can extend beyond the warranty period as per that advised by the manufacturer under regulations of the TGA. For example, provided that the device is serviced at time periods indicated by the manufacturer, which may potentially identify defects.
- In the case presented in this paper, it appears that where the TAB is considering whether replacement of an item is R&N, that time would be when the manufacturer deems the device should be replaced. For example, if the device is out of warranty and is still receiving servicing at intervals recommended by the manufacturer, including the replacement of certain components, where the manufacturer identifies that the device can no longer support the replacement of components and requires complete replacement.
- In the case presented in this paper, the provider is correct when they suggest that there is an increased risk when the microprocessor knee is used past the warranty period (as compared to other prosthetic componentry) because they are not in a position to service the component as required. The reason there is increased risk is because the device is not undergoing the service recommended by the manufacturer which is supported by TGA regulation. The manufacturer is advising regularity of maintenance at certain intervals after the warranty expiry - *"If the knee unit is not serviced, Ottobock strongly recommends that the Genium unit should be replaced"* (Letter from Supplier 25/03/21). If the provider is not in a position to service the device, that raises the question of who can? This has not been investigated.
-

- Life span of a medical device is determined using various methods across different organisations, and are mainly in relation to asset management. What they determine as life span is the time period they continue to use the device before it's replaced. The methods applied to determine this include maintenance frequency and type of use.
- If the TAB were to introduce a term to support discussion surrounding the subject of device warranty and life span - that could be 'effective life'. Where the manufacturer has responsibility to adhere to TGA regulations, it could be considered that they are recommending the "effective life", which can extend beyond a warranty period, as based on their determination of the time period the device can safely be used, and taking into account the frequency of maintenance.
- The supplier Otto Bock or other suppliers have not been approached with regard to their opinion of risk associated with the use of a device beyond their warranty period.
- Currently in Australia, there is controversy surrounding catastrophic failures in medical devices where reform to regulation of devices is being called for, and where the TGA will commence regulatory changes in late 2021. It is recommended that the TAB monitor and keep abreast of these changes.

10 Appendix 1 - Definitions

Definitions referenced throughout this paper.

Term	Definition	Reference(s)
Warranty	A voluntary promise offered by the person or business who sold the product or service to the consumer. Once the consumer purchases the product or service, the promise becomes a right that can be enforced under the Australian Consumer Law.	ACCC [14]
Consumer Guarantee	A law provisioned by Australian Consumer Law, which is regulated by the Australian Competition and Consumer Commission (ACCC), where businesses must guarantee products and services they sell, hire or lease for under \$40,000 and over \$40,000 that are normally bought for personal or household use, apply regardless of any warranties suppliers sell or give to the consumer, and apply for a reasonable time depending on the nature of the goods or services.	ACCC [15] Consumer Law [16]
Serviceable life	The length of time that the manufacturer considers the item to be serviceable as reflected in their warranty	Various [1-4]
Catastrophic Failure	Changes in capability resulting in total loss of useful performance. Operating characteristics of a material, product, or system undergo Sudden and drastic change.	The Law Dictionary [5]

Term	Definition	Reference(s)
Life cycle	All stages which are consecutive or interlinked, including research and development to be carried out, production, trading and its conditions, transport, use and maintenance, throughout the existence of the product or the works or the provision of the service, from raw material acquisition or generation of resources to disposal, clearance and end of service or utilisation.	Law Insider [8]
Life span	Life span of a device cannot be quantified. Various organisations use methods to apply a time value on devices and other medical equipment when assessing life span in terms of an asset.	The Biomedical Engineering Advisory Group (BEAG) [11] State of Victoria [13] Queensland Health [12]
Effective life (Medical Equipment)	The period over which an item of medical equipment can provide the required clinical function or service for a health service.	State of Victoria (Department of Health). Medical equipment asset management framework - Part C 2012 [13]
Physical life (Medical Equipment)	The total expected number of productive years for an item of medical equipment. The physical life of an item of medical equipment has ended once it has physically deteriorated to an extent that it is no longer capable of being repaired or used for its intended purpose.	State of Victoria (Department of Health). Medical equipment asset management framework - Part C 2012 [13]
Useful life (Medical Equipment)	The period over which an item of medical equipment may be available for productive use by the health service or the number of units of use (for example, hours, procedures, exposures) expected to be achieved by the item of medical equipment by the health service.	State of Victoria (Department of Health). Medical equipment asset management framework - Part C 2012 [13]

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Research – Recreational Supports: Off Road Cycles

Brief	Statistics and research to support the development of an NDIS funding position or at least an advice position on Recreational Supports.	
	TAB Advisors are seeking evidence base around Recreational Supports to understand how to apply the legislation consistently for our participants.	
	Off Road Cycles and independence at an entry level to the activity:	
	<ul style="list-style-type: none"> • Entry level of off road cycles focusing on different levels and features. • The technical reasons why participants would require a certain level of equipment. 	
Date	26 November 2020	
Requester(s)	Tiffany ^{s47F - perso} (Senior Technical Advisor – TAB)	
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Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters.

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2 Related TAB Research

RES COPA Recreational Supports - Barriers to Participation (people with a disability vs people without a disability) 2020/0133. Location: NED20/415843

3 Summary

- Mountain Bike (MTB) appears to be the preferred term for bicycles made for off-road use
- Entry level to the recreation of MTB can be determined by the MTB User Type and the Trail Difficulty Rating.
- Entry level equipment for participation by people with a disability depends on a number of considerations based on the User Type, Trail Difficulty Rating and the Disability Type, where the assessment for participant funding needs to be undertaken on a case by case basis.

- The **Australian Adaptive Mountain Biking Guidelines** are the only guidelines of its type which could be sourced. The intention of the guidelines is to provide entry level requirements for inclusive and effective adaptive MTB programs, events, races, equipment, support and riding.

4 Definition of Off Road Cycles

4.1 Mountain Biking

"Mountain bike" (MTB) appears to be the preferred term for bicycles made for off-road use.

Mountain biking is a diverse activity that can be performed almost anywhere from a backyard to a gravel road, but is essentially about riding specialised bikes on off-road trails. Most riders prefer and seek 'single track' trails, which are only wide enough to accommodate a single rider or groups in single file. Single track trails offer riders more intimate experiences of their environment, with the narrow nature of the trails providing a closer connection between the rider and the environment. [1]

Mountain Biking is an activity with increasing participation rates worldwide. It encompasses a broad spectrum of activities ranging from Olympic and Commonwealth Games level cross-country racing, competition downhill and extreme events, to school sport programs and recreational trail riding at levels from novice to experienced. [1]

4.2 Adaptive Mountain Biking (aMTB)

aMTB, sometimes referred to as "off-road para-cycling", encompasses a broad range of riders who typically cannot ride a standard mountain bike and require adapted equipment and trails to suit their physical, intellectual, neurological and sensory abilities. [2]

5 People with a Disability & Off Road Cycling

The ongoing development of cycle technology has now been incorporated into aMTB specifically designed for off-road cycling, including:

- **Handcycling** (for lower body impaired)
- **Legcycling** (for upper body/balance impaired)
- **Tandem** (for vision/auditory impaired)
- **Modified bikes** (for intellectually/other impairments)

This enables people with disabilities to experience the range of mountain bike trails, with aMTB riders seeking the same mountain bike experiences as those without a disability. [1]

6 The Target Market: User Types and Trail Requirements

Mountain biking is a diverse activity. Mountain bikers have been divided into five user types, as detailed in the table below, which are defined by their differing trail requirements and expectations. There is often a significant amount of cross-over between types. The largest market is “Leisure”. [1]

Type	Description	Trail Classification	Market
Leisure	Includes general cyclists of all ages and abilities and is potentially the largest market. Typically they ride infrequently, often have limited skills and require very accessible trails. They are not members of clubs and they are more likely to use highly accessible routes close to home, or make the journey to trail facilities with amenities and services such as bike hire, cafes and toilets.	This group will generally seek easiest classification trails. As they progress, will start to ride moderate classification trails.	Large
Enthusiast	Enthusiasts are purely recreational mountain bikers with moderate skills and variable fitness, and ride weekly. They are typically aged 29-49 and form the existing market majority. [1] They typically don't compete in events and they possess limited outdoors experience. They prefer trails with good trail signs and seek technical but not too challenging trails. Enthusiast Mountain Bikers are the most likely to take short breaks to different areas.	Mostly easy and moderate classification trails. As they progress will start to ride difficult classification trails and have the potential to move into another user type (sport and/or gravity).	Moderate
Sport	Competitive mountain bikers, who ride regular routes multiple times a week and are members of mountain bike clubs, they are a small but influential market. They are willing to seek less accessible trails, have a high fitness level and are technically proficient but may have limited outdoor skills. They ride a very wide variety of trails.	Extreme	Small but influential
Independent	Skilled outdoor enthusiasts who ride once a week and are technically proficient with good level of fitness. Generally they are a small market. Often involved in other outdoor activities, they are capable of planning their own rides and ride a wide variety of trail classifications. The adventurous aspect is more important than the technical challenge and they seek more remote trails.	Easiest to extreme	Small

Type	Description	Trail Classification	Market
Gravity	Highly skilled technical riders who seek very challenging trails, typically ride at least once a week and are often members of clubs. They represent a small market that requires purpose built trails often with an uplift facility, which are repeatedly used in a concentrated manner. Gravity riders seek specific trails with the highest classifications.	Moderate to extreme	Small

Table based on: Davis, D. (2012) Trail Development Protocol and Sustainability Framework for Western Australia (unpublished) [1]

7 Trail Difficulty Ratings

The Trail difficulty Rating system, sourced from the International Mountain Bicycling Association: Australia, can assist trail users to make informed decisions about their MTB involvement with regard to riding ability and style of riding. [3]

	Very Easy  White Circle	Easy  Green Circle	Intermediate  Blue Square	Difficult  Single Black Diamond	Extreme  Double Black Diamond
Description	Likely to be a fire road or wide single track with a gentle gradient, smooth surface and free of Obstacles. Frequent encounters are likely with other cyclists, walkers, runners and horse riders.	Likely to be a combination of fire road or wide single track with a gentle gradient and smooth surface, and relatively free of unavoidable obstacles. Short sections may exceed these criteria. Frequent encounters are likely with walkers, runners, horse riders and other Cyclists.	Likely to be a single trail with moderate gradients, variable surfaces and obstacles.	Likely to be a challenging single trail with steep gradients, variable surfaces and many obstacles.	Will incorporate very steep gradients, highly variable surfaces and unavoidable severe obstacles.
Suitable for:	Beginner/novice	Beginner/novice mountain bikers.	Skilled mountain	Experienced mountain	Highly experienced

	Very Easy  White Circle	Easy  Green Circle	Intermediate  Blue Square	Difficult  Single Black Diamond	Extreme  Double Black Diamond
	cyclists. Basic bike skills required. Suitable for most bikes.	Basic mountain bike skills required. Suitable for off road bikes	bikers. Suitable for mountain bikes.	bikers with good skills. Suitable for better quality mountain bikes.	mountain bikers with excellent skills. Suitable for quality mountain bikes.
Fitness Level	Most people in good health.	Most people in good health	A good standard of fitness.	A high level of fitness.	A high level of fitness.
Trail Width	Two riders can ride side by side.	Shoulder width or greater.	Handlebar width or greater.	Can be less than handlebar width.	Can be less than handlebar width.
Trail surface and obstacles	Hardened with no challenging features on the trail.	Mostly firm and stable. Trail may have obstacles such as logs, roots	Possible sections of rocky or loose tread. Trail will have obstacles such as logs, roots and rocks.	Variable and challenging. Unavoidable obstacles such as logs, roots, rocks, drop-offs or constructed obstacles.	Widely variable and unpredictable. Expect large and unavoidable obstacles.
Trail gradient	Ascents and descents are mostly shallow.	Ascents and descents are mostly shallow but trail may include some moderately steep sections.	Mostly moderate gradients but may include steep sections.	Contains steeper descents or ascents.	Expect prolonged steep, loose and rocky descents or ascents.

8 Defining Entry Level Off-Road Cycling

8.1 People without a disability

When attempting to define entry level activity the user types outlined above might indicate that those who fall in the first two types (leisure and enthusiast) could be regarded as entry level riders.

These two rider types are typically general leisure riders with limited skills who require limited trails. They don't necessarily belong to clubs, and are the more enthusiastic riders who typically don't compete in events, and don't seek highly challenging trails.

The remaining three user types typically opt for competition and adventure. They are technically proficient, seek remote challenging trails and are leaning towards competition sport.

As well, the first three descriptions in the Trail Difficulty Rating outlined above (Very Easy, Easy, and Intermediate) are also suggestive of entry level activity, where the remaining ratings lean towards competition sport.

8.2 People with a disability (PWD)

Entry level riding would be no different for people with a disability as it would be for those without a disability. A person's impairment doesn't necessarily dictate the equipment used since they may be able to ride a range of adaptive equipment. [4] The **Australian Adaptive Mountain Biking Guidelines** [5] suggest that the following should be considered with regard to participating in aMTB:

- What is the rider's ability?
- What is the rider's riding style?
- What is the rider's preferred MTB discipline?
- Does the rider have any medical and health conditions, and do they impact the function of cycling?

8.3 NDIS Operational Guidelines for Recreation Supports

There is no hard evidence which determines precisely what entry level equipment is relevant to a participant. Assessments for participant funding needs to be undertaken on a case by case basis.

To assist in determining entry level funding for MTB equipment the following questions could be asked:

User Type

What type of riding does the participant want to do? This could be determined by the Trail Classification and Trail Difficulty Rating

MTB Type

What type of MTB can the participant use? This will be determined by the type of disability of the participant. The type of MTB will reflect the participant's level of riding ability. The riding ability will be reflected in the Trail Difficulty Rating.

MTB Modifications

Does the participant require modifications to the identified MTB including Electric Assist Technology? This will be dependent on the disability type, and the ability of the modified equipment to adapt to the identified MTB.

NOTE: All MTB Equipment detailed in Australian Adaptive Mountain Biking Guidelines [5] are regarded as entry level equipment.

9 Categories of Entry Level Adaptive Mountain Bikes for people with a Disability

9.1 Overview

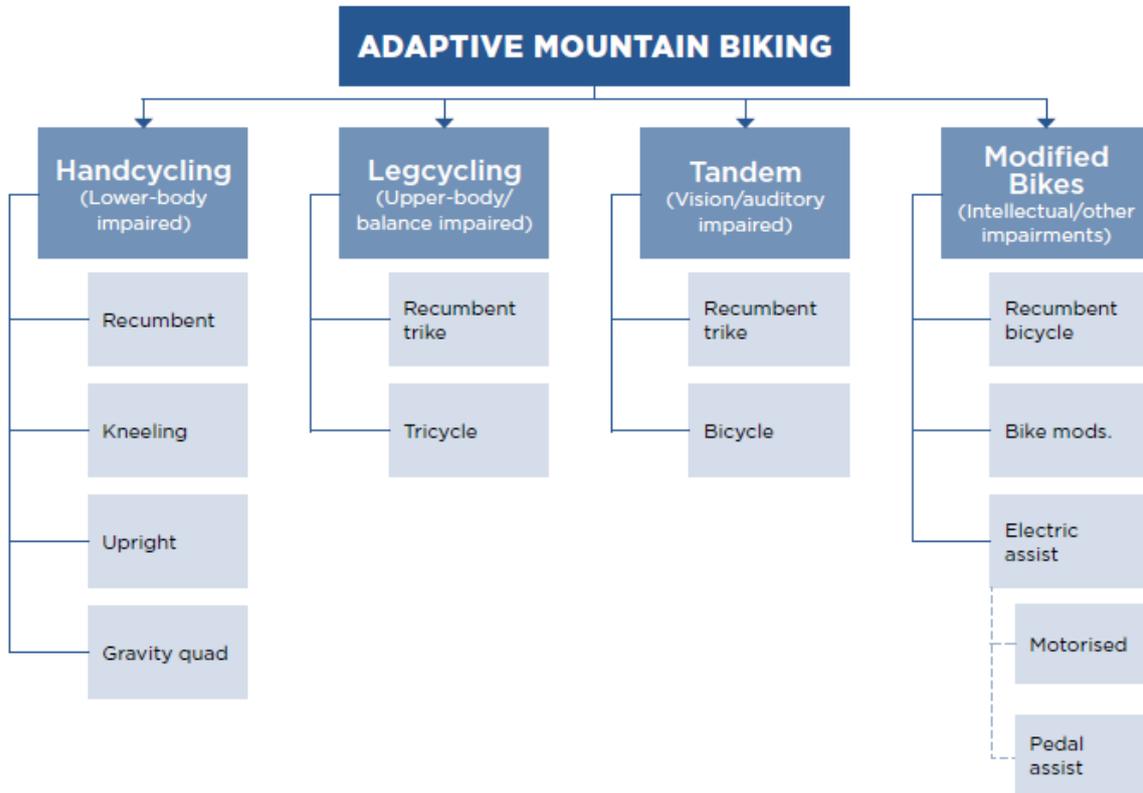
There are varying adaptive mountain bikes available around the world, each designed to meet a rider's specific need. Readily established adaptive equipment includes: handcycles, recumbent leg-cycles, and tandem bikes. [2]

Adaptive MTB can be broken down into categories based on the type of equipment used, since the type of equipment generally reflects the level of someone's ability.

This is a unique way of categorizing aMTB groups, opposed to categorising based on disabilities, which have a vast range and complexity. By choosing to categorise by equipment, it also reduces "unfair" categorization of people with disabilities that cover multiple spectrums and or have disabilities that do not side with classic disability definitions. [5]

The **Australian Adaptive Mountain Biking Guidelines** [5] provide entry level requirements for inclusive and effective aMTB equipment, and by catering for entry level adaptive cycles, the widest possible range of cycles are catered for under the minimum trail standards.

The figure below illustrates the main categories that encompass aMTB. This is followed by summaries of the cycle types which have been sourced from the guidelines.



9.2 HANDCYCLING

Four main types of handcycles are produced around the world, with many more variations being manufactured by independent handcycle enthusiasts.

9.2.1 *Recumbent*

Type	Handcycle - Recumbent
Summary	The most commonly seen and used handcycles
Functionality	<p>Allows the rider to be seated in a "leaning back" position with the legs held forward and typically strapped into supported leg brackets</p> <p>Weight is mostly distributed centre to the frame, which is balanced by two rear wheels. The single front wheel pivots between and with the legs and acts as a primary steering wheel and drivetrain.</p> <p>A backrest typically provides the rider with a stable balancing foundation and the ability to strap themselves with belts for additional stability and comfort.</p> <p>The backrest enables the rider to propel the handcycle by pushing two parallel hand cranks in a circular and forward motion. Hand cranks are typically positioned around chest and head height.</p>

Type	Handcycle - Recumbent
Variation(s)	Rigid frame (no suspension) Full suspension (front and back or rear-only)
Image(s)	<div data-bbox="453 405 1362 1021" data-label="Image">  </div> <p data-bbox="443 1032 580 1061"><i>Rigid Frame</i></p> <div data-bbox="453 1111 1362 1727" data-label="Image">  </div> <p data-bbox="443 1742 753 1771"><i>Full suspension and e-assist</i></p>

9.2.2 Kneeling

Type	Handcycle - Kneeling
<p>Summary</p>	<p>A relatively newer type of handcycle, arranged in a "tadpole" configuration with one wheel at the rear and two at the front.</p>
<p>Functionality</p>	<p>Rider positioned on knees and sitting on a bucket seat, they have less options for strapping their torso and are therefore more suited, although not limited, to people with a higher function and stability.</p> <p>Opposite to the recumbent handcycle, the kneeling handcycle has the drive wheel and train at the back, while two front wheels provide steering and balance.</p> <p>A handlebar group-set (bar, headset, stem, riser etc.) used on most bikes is also used to steer the handcycle, while accommodating for a range of standard bike additions (brakes, gear shifts, hand grips, etc.)</p>
<p>Variation(s)</p>	<p>Full suspension (front wishbone and rear swing arm) Rear only suspension (rear wing arm)</p>
<p>Image(s)</p>	 <p><i>Kneeling Handcycle: Rear only suspension</i></p>

9.2.3 Upright

Type	Handcycle - Upright
<p>Summary</p>	<p>Upright handcycles have a frame and wheel configuration similar to that of kneeling off road handcycles. It can be thought of as a rotation of the seat and leg positions, while raising the hand cranks and drive train via a vertical shaft.</p>

Type	Handcycle - Upright
<p>Functionality</p>	<p>Suitable for riders with enough strength to stay upright is one without a backrest. This allows the rider to "lean into" the hand cranks and exert additional force.</p> <p>Other upright cycles include hybrid wheelchairs. Hybrid cycles are achievable by adding removable front end attachments to wheelchairs. These have the added advantage of keeping riders comfortable and minimise the need for transferring but are limited by the durability of the wheelchair.</p>
<p>Variation(s)</p>	<p>Hybrid attachments can be equipped with standard bike parts, including front disc brakes and gear shifters.</p>
<p>Image(s)</p>	<div data-bbox="539 696 1310 1240" data-label="Image">  <p><i>Upright handcycle: rear suspension</i></p> </div> <div data-bbox="483 1350 1286 1865" data-label="Image">  <p><i>Wheelchair attachments</i></p> </div>

9.2.4 Gravity Quad

Type	Handcycle – Gravity Quad
Summary	<p>Although not technically an off-road ‘handcycle’ due to the absence of a chain drive and thus pedalling, a gravity quad bike is a common form of adaptive MTB amongst downhill riding.</p> <p>The configuration is very similar to that of a go-kart, with four wheels (two steering wheels at the front and two non-steering wheels at the back). Similar to the kneeling handcycle, there is a handlebar group-set which steers the front wheels.</p>
Functionality	<p>A reinforced bucket seat usually with twin suspension) provides the rider with more stability and allows the knees to be tucked close to the body.</p>
Variation(s)	<p>-</p>
Image(s)	 <p><i>Handcycle: Gravity Quad Bike</i></p>

9.3 ADAPTIVE LEG-CYCLING

This group of cycles encompasses non-standard bikes, which are stabilised by a third wheel.

9.3.1 Tricycle

Type	Adaptive Leg-Cycling: Tricycle
Summary	<p>Tricycles are standard bikes, which are stabilised by two same-sized (or similar) rear wheels in place of the standard single rear wheel.</p>

Type Adaptive Leg-Cycling: Tricycle	
Functionality	Trikes are leg-powered and typically used by people who have poor balance due to a neurological or physical impairment in one or both sides of their body.
Variation(s)	<p>Tricycles can be manufactured or adapted with conversion kits that replace the standard rear wheel.</p> <p>Small modifications can be made to the road components to make the tricycle more suitable for off-road use.</p>
Image(s)	<p><i>Off Road Tricycle</i></p>

9.3.2 Recumbent Trike

Type Adaptive Leg-Cycling: Recumbent Trike	
Summary	Typical styles come with the recumbent seating position of a recumbent handcycle in combination with a similar frame configuration as the kneeling-down handcycles.
Functionality	Steering is achieved via the side handlebars on either side of the rider, which directly manoeuvre the steering crossbar. Leg pedalling is done on a fixed axis (i.e. the legs don't move side to side or pivot, they only crank).
Variation(s)	-

Type	Adaptive Leg-Cycling: Recumbent Trike
Image(s)	 <p data-bbox="389 869 572 898"><i>Upright leg trike</i></p>

9.4 TANDEM

'Tandem' refers to the position of more than one person behind the other. On a tandem cycle the front rider (captain) steers, pedals, shifts gears and brakes, while the person at the back (stoker) pedals only.

9.4.1 *Recumbent Trike and Bicycle*

Type	Tandem - Recumbent Trike and Bicycle
Summary	<p>Common cycles are for two riders; however, less common configurations can be set up for more riders.</p> <p>Configurations for tandem bikes include:</p> <ul style="list-style-type: none"> » Two-wheels upright (most common). » Two-wheels recumbent. » Two-wheels upright and recumbent. » Three-wheels recumbent.
Functionality	<p>For riders with vision impairment, the captain provides verbal queues as to the upcoming obstacles, terrain, direction and level of stoker input required to Negotiate trail features.</p>

Type	Tandem - Recumbent Trike and Bicycle
Variation(s)	Various levels of modification. Can be sourced from different countries. Vary in price range.
Image(s)	 <p data-bbox="430 1075 766 1108"><i>Recumbent tandem bicycle 7"</i></p>  <p data-bbox="430 1568 718 1601"><i>Recumbent Tandem Trike</i></p>

Type	Tandem - Recumbent Trike and Bicycle
	 <p data-bbox="432 795 869 828"><i>Hybrid semi-recumbent tandem Bicycle</i></p>

9.5 MODIFIED MOUNTAIN BIKE

9.5.1 *Recumbent Bicycle*

Type	Modified Mountain Bike – Recumbent Bicycle
<p>Summary</p>	<p>Standard up-right bikes can be arranged so that the seating is recumbent with the legs at a horizontal orientation to the ground.</p>
<p>Functionality</p>	<p>These can be suitable for people with lower back, core muscle and leg problems that impair them from balancing or being postured in a standard upright bike.</p>
<p>Variation(s)</p>	<p>Steering arrangements can be in front or by the side of the rider, with varying degrees of seat tilt.</p>

Type	Modified Mountain Bike – Recumbent Bicycle
Image(s)	 <p data-bbox="424 869 687 898"><i>Semi recumbent Bicycle</i></p>  <p data-bbox="424 1514 836 1543"><i>Recumbent bicycle with side steering</i></p>

9.5.2 Bike Modification

Type	Modified Mountain Bike – Bike modifications
Summary	<p data-bbox="416 1877 1302 1939">Specific and minor modifications can be made to bikes to allow someone with an impairment to cycle. Such modifications include:</p> <ul style="list-style-type: none"> <li data-bbox="416 1973 879 2002">» Handlebar arrangements and adaptations.

Type	Modified Mountain Bike – Bike modifications
	<ul style="list-style-type: none"> » Foot crank arrangements and adaptations. » Non-standard seat modifications. » Frame customisation and additions.
Functionality	Foot and leg supports for riders with limited limb mobility, dexterity or strength Quad-grip for handcycles
Variation(s)	-
Image(s)	<div style="text-align: center;">  <p><i>Foot and leg supports for riders with limited limb mobility, dexterity or strength</i></p> </div> <div style="text-align: center; margin-top: 20px;">  <p><i>Quad-grip for handcycles</i></p> </div>

Type	Modified Mountain Bike – Bike modifications
	 <p data-bbox="416 909 802 936"><i>Custom e-bike with bucket seating</i></p>

9.5.3 Electric Assist Technology

The expanding market of electric assist technology in MTB provides greater access to equipment for a wider range of people with disabilities.

Assisting technology can be found as **pre-designed units** that make up the structure of a cycle or they can be **after-market units later applied**.

Type	Electric Assist Technology
Summary	<p>Components of a typical system include the power source (battery), input module or controller and drive motor.</p> <p>There are two main forms of electric- assist technology:</p> <ul style="list-style-type: none"> » Power-assistance (auxiliary), and » Full throttle-assist (motorised).
Functionality	<p><u>Power-assistance (auxiliary)</u> This type of assistance provides a percentage or set level of power output based on the power exerted by the rider's pedalling. The rider must pedal the drivetrain to activate the power-assist and will not operate otherwise.</p> <p><u>Full throttle-assist (motorised cycle)</u></p>

Type	Electric Assist Technology
	This type of electric assistance allows the rider to control the acceleration and power input by way of a trigger or throttle-style control, without having to pedal. This is more common amongst users who have minimal or no strength to pedal but is still capable of operating the remaining features of the cycle (e.g. brakes, gears, steering).
Variation(s)	-
Image(s)	 <p data-bbox="440 1133 810 1167"><i>Typical power-assist components</i></p>

9.5.3.1 Standards and Regulations

Different states and territories in Australia may mandate different regulations on power capacities, durations, speeds and other registration. Reference is made to different standards including:

- [EN 15194:2009 or EN 15194:2009 + A1:2011 Cycles - Electrically power assisted cycles - EPAC Bicycles](#) [6]
- [AS/NZS 1927:2010 Pedal Bicycles and Product Safety Australia – Bicycles](#) [7]

Power output can vastly change between manufacturers and models and needs to be checked before installing or importing into the country and used in different states to meet national and state regulations.

10 References

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7. Standards Australia. Pedal bicycles - Safety requirements 2010 [Available from: <https://www.standards.org.au/standards-catalogue/sa-snz/consumer/cs-110/as-slash-nzs--1927-colon-2010>].



Research Request – Suction machines types and cleaning

Brief	What are the different types of suction machines? What is the best practice cleaning associated with portable suction machine use?
Date	12/09/19
Requester	Kate <small>S47F - perso</small>
Researcher	Aanika

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Key sections of this previous research have been included and additional information re: suction machine types and cleaning have been included.

Tracheostomy

When a participant requires the use of a ventilator, it is common to also require a portable suction machine, air humidifier and for some participants, also a cough assist machine.

Typical equipment and associated consumables required for Tracheostomy

People with tracheostomies may require several pieces of equipment and associated consumables which are explained in the table below.

Machine / equipment	R & N consumables per annum
Ventilator	<p>This mechanical home ventilation guidelines website has a lot of information about the consumables associated with ventilators.¹</p> <p>The equipment required for invasive Tracheostomy ventilation will include at a minimum</p> <ol style="list-style-type: none"> 1. Tracheostomy tube and replacements, including inner cannulas 2. Dressings for Tracheostomy site 3. Volume-cycled ventilator with appropriate alarms and humidifier 4. Backup ventilator for primary ventilator failure 5. Handheld resuscitation bag with Tracheostomy adapter 6. Suction device with catheters for secretion removal 7. Backup power supply for ventilator (battery or generator)² <p>The equipment required for Non- Invasive ventilation at a minimum includes the following:</p> <ol style="list-style-type: none"> 1. Pressure- or volume-type ventilator 2. Appropriate interface mask or mouthpiece 3. Secretion management program or device 4. Backup power supply for ventilator (battery or generator)

Suction Machine

Endotracheal suctioning (ETS) is one of the most common procedures performed in patients with artificial airways. It is a component of bronchial hygiene therapy and mechanical ventilation that involves the mechanical aspiration of pulmonary secretions from a patient's artificial airway to prevent its obstruction. The procedure includes patient preparation, the suctioning event, and follow-up care.

There are two (2) methods of endotracheal suctioning based on the selection of catheter: open and closed. The open suctioning technique requires disconnecting the patient from the ventilator, while the closed suctioning technique involves attachment of a sterile, closed, in-line suction catheter to

¹ <https://intensivecareathome.com/mechanical-home-ventilation-guidelines/>

² <https://intensivecareathome.com/mechanical-home-ventilation-guidelines/>

the ventilator circuit, which allows passage of a suction catheter through the artificial airway without disconnecting the patient from the ventilator.

There are also two (2) methods of suctioning based on the catheter suction depth selected during the procedure: deep and shallow. Deep suctioning is defined as the insertion of a suction catheter until resistance is met, followed by withdrawal of the catheter by 1 cm before application of negative pressure, and shallow suctioning as the insertion of a suction catheter to a predetermined depth, usually the length of the artificial airway plus the adapter³.

Typical equipment and consumables required for suctioning

The tracheostomy table above says that 'section device with catheters for secretion removal' and a secretion management program' are required.

The journal article '**AARC Clinical Practice Guidelines: Endotracheal Suctioning of Mechanically Ventilated Patients with Artificial Airways 2010**' also states that the following necessary and optional equipment is required:

12.1 Necessary Equipment

12.1.1 Vacuum source

12.1.2 Calibrated, adjustable regulator

12.1.3 Collection bottle and connecting tubing

12.1.4 Disposable gloves

12.1.4.1 Sterile (open suction)

12.1.4.2 Clean (closed suction)

12.1.5 Sterile suction catheter

12.1.5.1 For selective main-bronchus suctioning, a curved-tip catheter may be helpful. The information related to the effectiveness of head turning for selective suctioning is inconclusive.

12.1.6 Sterile water and cup (open suction)

12.1.7 Goggles, mask, and other appropriate equipment for standard precautions

12.1.8 Oxygen source with a calibrated metering device

12.1.9 Pulse oximeter

12.1.10 Manual resuscitation bag equipped with an oxygen-enrichment device for emergency backup use

12.1.11 Stethoscope

12.2 Optional Equipment

12.2.1 Electrocardiograph

³ <https://www.aarc.org/wp-content/uploads/2014/08/06.10.0758.pdf> Page 758

12.2.2 Sterile sputum trap for culture specimen

12.3 Personnel. Licensed or credentialed respiratory therapists or individuals with similar credentials (eg, MD, RN) who have the necessary training and demonstrated skills to correctly assess need for suctioning, perform the procedure, and adequately evaluate the patient after the procedure.⁴

This journal article makes no reference to ‘liners’ as requested by providers. Liners are single use Suction receptacle liners for suction canister in a medical suction unit⁵.

Clinical guidelines for indication and use

A journal article from 2010 by the American Association for Respiratory Care ‘**AARC Clinical Practice Guidelines: Endotracheal Suctioning of Mechanically Ventilated Patients with Artificial Airways 2010**’, examining endotracheal suctioning of mechanically ventilated patients with artificial airways concludes that:

- (1) It is recommended that endotracheal suctioning should be performed only when secretions are present, and not routinely;
- (2) It is suggested that pre-oxygenation be considered if the patient has a clinically important reduction in oxygen saturation with suctioning;
- (3) Performing suctioning without disconnecting the patient from the ventilator is suggested;
- (4) Use of shallow suction is suggested instead of deep suction, based on evidence from infant and pediatric studies;
- (5) It is suggested that routine use of normal saline instillation prior to endotracheal suction should not be performed;
- (6) The use of closed suction is suggested for adults with high FIO₂, or PEEP, or at risk for lung derecruitment, and for neonates;
- (7) Endotracheal suctioning without disconnection (closed system) is suggested in neonates;
- (8) Avoidance of disconnection and use of lung recruitment maneuvers are suggested if suctioning-induced lung derecruitment occurs in patients with acute lung injury;
- (9) It is suggested that a suction catheter is used that occludes less than 50% the lumen of the endotracheal tube in children and adults, and less than 70% in infants;
- (10) It is suggested that the duration of the suctioning event be limited to less than 15 seconds⁶.

A clinical guideline has been developed by [Intensive Care NSW](#), to provide clinicians with recommendations to guide the development of local policy/procedures in related to suction through an artificial airway in critically ill adult patients in NSW acute care facilities.⁷

⁴ <https://www.aarc.org/wp-content/uploads/2014/08/06.10.0758.pdf> 760-761

⁵ <https://www.megamedical.com.au/suction-receptal-liner-1500ml>

⁶ Page 758 <https://www.aarc.org/wp-content/uploads/2014/08/06.10.0758.pdf>

⁷ <https://www.aci.health.nsw.gov.au/networks/icnsw/intensive-care-manual/statewide-guidelines/suctioning-an-adult-icu-patient>

This NSW Intensive care NSW document also makes no reference to ‘liners’.

Liners

One portable suction machine provider lists liners in the associated consumables though⁸. It may be that some suction machines require or recommend the liners, while others do not.

For example, this portable suction machine has a built in bottle cavity that can be cleaned⁹. The product information sheet says: NOTE: The canister and lid supplied with the unit are not autoclavable. They must be washed in sterilisation solution.

Medshop Australia lists pumps that have both reusable (washable) canisters and disposable canisters¹⁰.

It appears that the liners are for the canisters that are cleanable and using the liners is about efficiency rather than necessity.

Cleaning of portable suction machines

The following information has been found on cleaning of suction machines and infection control matters.

In terms of the procedure for actually cleaning the canister and tubing, this is entirely dependent of the machine and is apparently stipulated in the machine models guidance material.

The Australian Guidelines for the Prevention and Control of Infection in Health Care and the NSW Infection Control Policy state that:

All procedures that generate or have the potential to generate secretions or excretions require that either a face shield or a mask worn with protective goggles be worn.

Therefore, the use of PPE to prevent mucosal or conjunctival splash injury is mandatory while suctioning the patient (both open and closed suction). This must include mask and goggles or face shield; gloves and gown/apron.

Suctioning of the artificial airway is to be completed using a clean technique for closed system suction and aseptic non-touch technique for (1) for open suction to minimise the potential for introduction of exogenous organisms into the respiratory tract of the critically ill patient¹¹.

An American manufacturer of medical devices states the following:

There are many portable suction units to choose from these days, and each model has its own specific guidelines for maintenance, which can be found in their user’s manual or online. But there are some general procedures that should be followed, no matter the model. So let’s take a look at some of the routine maintenance you should be performing on your suction equipment.

Preventive Care

⁸ <https://www.laerdal.com/au/doc/135/Laerdal-Suction-Unit-LSU#/Webshop/CONSUMABLES>

⁹ <https://dearjane.com.au/wp-content/uploads/7E-A-PORTABLE-SUCTION-PUMP.pdf>

¹⁰ <https://www.medshop.com.au/diagnostic-equipment/suction-units/>

¹¹ <https://www.aci.health.nsw.gov.au/networks/icnsw/intensive-care-manual/statewide-guidelines/suctioning-an-adult-icu-patient/infection-prevention>

- As a healthcare professional, you know the importance of preventive care. The same holds for true for EMS equipment, so to keep your portable suction unit running smoothly, here are a few important reminders:
- Always ensure your batteries are charged – a dead suction unit will be useless to you AND your patient.
- Test your unit at regular intervals – this should be part of your morning/evening checkout.
- Make sure your unit is always clean – for the sake of your patient’s as well as your own safety against pathogens.
- Insure any fluids are contained within the canister and have not worked their way up into the vacuum line – if so, disinfect the unit!

Sanitizing Your Suction Unit

Contaminated equipment has no place in EMS and suction units, by their very nature, can serve as prime reservoirs for biohazardous materials. Blood, saliva, mucous, and tissue are likely sources of infectious pathogens, so sanitizing your unit is just as important as keeping it running. Here are a few guidelines:

- Sanitize after each use – don’t put it off until the end of the shift!
- Discard ALL disposable parts – this includes the canister, patient tubing, and catheters.
- Follow appropriate guidelines for disposal of biohazardous materials.
- Clean your suction unit using a mild detergent and if necessary, use a mixture of bleach and water (1 part bleach/10 parts water). Be sure to rinse thoroughly!
- Follow the instruction manual when it comes to disinfecting the mechanics of the unit.
- NEVER reuse any disposable parts – they are disposable for a reason!
- Do not submerge your suction unit.

Disinfecting Your Suction Unit

Here are a few reminders for disinfecting your portable suction unit:

- Always wear personal protective equipment when handling contaminated equipment:
- Gloves
- Face and Eye Protection
- Protective Clothing
- Disconnect the unit from any power source prior to cleaning.
- Disconnect the battery from the PC Board when cleaning the interior chassis.
- Remember to use disinfectant wipes to clean all outer surfaces of the unit, such as control nobs, screens and handles¹².

Keep It Clean

Portable suction units are inherently at risk for transmitting dangerous pathogens. It is your job to ensure your unit is **kept free of harmful contagions**. Here are a few reminders:

- Sanitize the unit after each use
- Never reuse disposable parts, including the canister, patient tubing, and **catheters**.
- Always dispose of biohazardous materials properly
- Use a mild detergent to clean the unit, preferably a mixture of bleach and water (1 part bleach/10 parts water)
- To disinfect the mechanics of the unit, refer to manufacturer guidelines
- Never submerge your suction unit – it will damage the electronics¹³

¹² <https://blog.sscor.com/the-routine-maintenance-you-should-be-performing-on-your-suction-equipment>

¹³ <https://blog.sscor.com/three-best-practices-for-portable-suction-machine-maintenance>

The Benefits of Power Wheelchair Tilt, Recline and Leg Rests, Power Wheelchair Standing Systems, and Standing Frames for Power Wheelchair Users

The content of this document is OFFICIAL.

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If

Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters

Research question:

What are the benefits for wheelchair users of a wheelchair with powered recline, elevating leg rests, seat elevate and power standing compared to use of:

- i. 'standard'* wheelchair alone
 - ii. 'standard' wheelchair and standing frame
 - iii. wheelchair with powered recline, elevating leg rests, seat elevate and power standing
- *for the purposes of this research, 'standard' means 'without powered recline, elevating leg rests, seat elevate and power standing'

Date: 15/12/2021

Requestor: Brigid s47F - personal privacy

Endorsed by (EL1 or above): Sandi s47F - personal privacy

Cleared by: Megan s47F - personal privacy

1. Contents

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2. Summary

This literature review compares the benefits of standard power wheelchairs to power wheelchairs with recline, tilt and elevating leg rests, power wheelchair standing systems, and standing frames for power wheelchair users. Power wheelchair tilt, recline and elevating leg rest systems offer benefits such as improved posture management, reduced risk of pressure ulcers, and increased independence with activities of daily living. Standing systems and standing frames can support power wheelchair users to stand independently, which offers benefits such as improved independence and community engagement, reduced pressure off the buttocks and back, and improved bowel and bladder function. Which support is reasonable and necessary for a participant will depend on a number of factors including their disability type, their ability to stand or change positions independently, and their level of informal and community supports.

3. Power Wheelchairs

Power wheelchairs can include tilt systems, recline systems, and elevating leg rests [1].

- **Tilt systems** adjust the seat angle in relation to the ground while maintaining the seat backrest and leg rest angles.
- **Recline systems** change the angle of the seat backrest
- **Elevating leg rests** allow the user to adjust the angle of the leg rest and/or foot rest. Some are articulating, enabling the user to extend the knee.

Some power wheelchairs also include a standing system, enabling the user to reach a standing position without transferring out of their wheelchair [2]. Some wheelchair users may use a standing frame in order to stand rather than a power wheelchair standing system if they are able to transfer from their wheelchair.

3.1 Tilt, Recline and Elevating Leg Rests

Tilt, recline and elevating leg rests may be prescribed to address issues related to postural alignment, function, pressure management, spasticity, oedema, and biomechanical issues [1]. Power wheelchair users with a tilt/recline system frequently use the tilt/recline feature, with one study finding that users spent 64% of their time each day in a tilted position, and used the tilt function on average 19 times per day and backrest recline 12 times a day [3].

Wheelchair tilt and recline mechanisms relieve pressure on the buttocks, redistributing body weight to other surfaces such as the back or feet [4,5]. Redistributing body weight is particularly important for people with Spinal Cord Injuries (SCI), who are at high risk of pressure ulcers due to limited mobility and sensation [6]. Redistribution of body weight away from the buttocks may reduce the risk of power wheelchair users with SCI developing pressure ulcers [4,5]. This is further supported by evidence that tilt and recline can improve muscle and skin perfusion around the ischial tuberosities (part of the lower pelvis) in people with SCI, and therefore possibly reduce the risk of pressure ulcers [7,8]. Feet elevation using elevating leg rests when used with back rest recline can also reduce pressure on the buttocks [9]. Although there is experimental evidence that wheelchair tilt and recline systems can reduce pressure on the buttocks and improve muscle and skin perfusion around the ischial tuberosities, there is a lack of longitudinal studies comparing pressure ulcer risk in power wheelchair users with and without tilt/recline function. Pressure on the buttocks can also be managed using wheelchair cushions for people with SCI [10,11]. Studies in elderly wheelchair users indicate that wheelchair seat cushions reduce the incidence rate of pressure ulcers [12,13], however this has not been investigated in people with SCI or other disabilities.

Tilt and recline systems are also used to manage pain [1]. Many power wheelchair users experience pain due to long-term sitting [1], with one study finding that the majority of power wheelchair users reporting that their power wheelchair impacts their pain levels [14]. A survey of power wheelchair users with wheelchairs that had tilt/recline functions revealed that at least 70% used the tilt/recline function to reduce pain [15]. These results have been supported by a

further survey of power wheelchair users and prescribers which found that one of the primary reasons people used their wheelchair tilt/recline mechanisms was to manage pain and discomfort [16]. Furthermore, in a survey of power wheelchair users with Multiple Sclerosis (MS), those who had a wheelchair with a tilt/recline function were more likely to report that their wheelchairs are comfortable than power wheelchair users without tilt/recline functions [17], and people who use power seat functions more frequently experience less wheelchair discomfort [18].

Tilt functions can also increase the wheelchair user's functional capacity. One study found anterior tilt can significantly increase a person's reach, which power wheelchair users noted was meaningful for them to be able to perform some daily activities independently [19]. This study also found that anterior tilt increased safety and reduced the need for assistance during meal preparation.

Some power wheelchair users experience fatigue due to their disability. Tilt/recline systems can enable power wheelchair users who experience frequent fatigue to use their wheelchair to rest comfortably without having to be transferred to a chair or bed [17]. Some standard power wheelchair users who experience fatigue reported that they spent prolonged periods in bed or in chair rather than using their wheelchair, reducing their mobility [17].

3.2 Standing Systems

Standing offers many benefits for wheelchair users such as reducing pressure off the back and buttocks [4], improving independence and social participation [20-23], and possibly improving bowel and bladder function [24,25]. Power wheelchair standing systems can enable power wheelchair users who are unable to transfer to a standing frame to obtain a standing position [2]. Power wheelchair standing systems also enable the user to mobilise while in a standing position [2].

For adolescents with Duchenne Muscular Dystrophy (DMD), power wheelchair standing devices are important for participating in school activities such as sport, social and leisure activities, and for activities of daily living such as toileting independently [20,23]. There is evidence that power wheelchair standing devices can improve the mental health of adolescents with DMD, likely due to the standing system giving increased independence and ability to be more involved in school [21]. Clinicians internationally agree that power wheelchair standing devices are a mobility option which offers independence to children with DMD, and should be ideally trialled when the child is predicted to lose the ability to walk in the next one to two years [26]. For adolescents at the later stages of the progression of DMD, pain can be a barrier for using their wheelchair to stand, with some adolescents ceasing use of the standing system as their DMD progresses to the late stages [20].

Increased independence has also been found in a study exploring the use of power wheelchair standing devices in children with other disabilities including cerebral palsy, spinal muscular atrophy, spina bifida and SCI [22]. Children who use power wheelchair standing devices, their parents, and treating health care professionals frequently mentioned when interviewed that the

standing system enabled the child to stand when they needed to independently, increasing independence with tasks such as hand washing and reaching for objects [22]. This study also noted the mental health benefits of power wheelchair standing systems, with many parents reporting that their child had increased confidence and self-esteem after being prescribed with a power wheelchair standing device.

Power wheelchair standing systems can also be beneficial for people with SCI. People with SCI self-report that prolonged standing results in improvements to respiration, circulation, bowel and bladder function, sleep, and reduces pain and fatigue [27,28]. However, this has not been investigated experimentally. There is also limited evidence that standing for prolonged periods may also prevent loss of bone density and osteoporosis, which are common complications in people with SCI [29]. Wheelchair standing systems can also relieve pressure on the buttocks and back for people with SCI by transferring weight to the feet, possibly reducing the risk of pressure ulcers [4]. Standing provides a more functional position than tilt/recline for the relief of pressure ulcers, enabling power wheelchair users to continue daily activities whilst relieving pressure off the buttocks and back [4]. Although there are many benefits to standing for people with SCI, the cost of equipment and assistance to enable standing is a common barrier to standing more often [27].

3.3 Standing Frames

Standing frames are an assistive technology which support a person to stand. Standing frames may be used by wheelchair users to provide an alternative position to sitting, which has benefits such as reduced pressure off the buttocks and back, improved independence and social participation, and improved bowel and bladder function [2].

For children with Cerebral Palsy (CP), standing frames provide an opportunity to change position, and improve the child's participation in school and social activities [25]. When clinicians who prescribe standing frames for children with CP and parents who have children with CP who have used standing frames were surveyed, they also reported improvements in bladder and bowel function. However, the only study specifically investigating the effect of standing frames on bowel function in children with CP was a case study of a single child [24], which did find that the standing frame improved bowel function. Although clinicians and parents viewed standing frames as having a positive impact overall on the independence and participation of children with CP [25], when young people with CP were interviewed some mentioned that the standing frame reduced their independence and social participation [30]. This was because the standing frame was static, whereas being seated in their wheelchair offers mobility. Additionally, for some young people standing using a frame requires significant concentration and effort, making engaging and participating in activities while using their standing frame challenging. For a standing frame to be beneficial in an educational setting, a multidisciplinary approach is required between health and educational professionals [31, 32]. There is also evidence that daily standing using standing frames in young children with CP

have improved hip joint alignment compared to children with CP who did not regularly stand, possibly reducing risk of hip problems later in life [33].

For people with SCI, standing frames can relieve pressure off the buttocks and improve circulation, bowel and bladder function, and reduce pain [27]. Some individuals with SCI will be able to transfer to a standing frame independently, whereas some will require assistance to transfer. Standing frames have also been shown to be beneficial for people with progressive Multiple Sclerosis (MS), with regular use of standing frames improving motor function, continence, spasms and quality of life [34, 35].

4. Reasonable and Necessary

Power wheelchairs, power wheelchair tilt/recline systems, power wheelchair standing systems and power wheelchairs used with standing frames all offer increased mobility and independence for people with a range of different disabilities. Generally, which support(s) from these are reasonable and necessary for a participant depends on a number of factors including their disability type, their ability to stand independently, and level of informal and community supports.

In this section we discuss further considerations which should be made when determining which support(s) meet reasonable and necessary criteria for the disability types more commonly investigated in the scientific literature.

4.1 Spinal Cord Injury

For people with SCI, each individual's personal circumstances and function must be taken into account when making a reasonable and necessary decision. Standing is important for people with SCI as it reduces the risk of pressure ulcers [4,5], and may improve circulation, bladder function, and help to maintain bone density [27, 29]. Some individuals will be able to independently transfer from their wheelchair to a standing frame, whereas others will require assistance. If a person requires assistance to transfer from their wheelchair to a standing frame this may limit their independence, particularly if they have limited informal supports. For these people, a power wheelchair with a standing system may be more suitable. For individuals with SCI who cannot stand for prolonged periods due to their need for respiratory assistance [27], a power wheelchair with a tilt/recline function may be most suitable to relieve pressure off the buttocks and prevent pressure ulcers [5]. Additionally, many people with SCI experience orthostatic hypotension when standing, with 25% of people with SCI saying that they avoid standing devices such as standing frames and standing wheelchairs due to orthostatic hypotension [36]. For these people, a wheelchair with a tilt/recline function may be more suitable to relieve pressure of the buttocks to prevent pressure sores, rather than a standing device. It is also important to note that wheelchair seat cushions which are a lower cost support can also reduce pressure on the buttocks for people with SCI [10], and has been shown to reduce the incidence of pressure ulcers in elderly patients without SCI [12,13]. However, wheelchair seat cushions do not offer other benefits such as better bladder function,

improved pain management, and increased independence which wheelchair tilt/recline, standing systems and standing frames offer [2].

Due to the clear benefits of tilt/recline systems, standing frames or standing systems in preventing pressure ulcers, and the increased risk of pressure ulcers for people with SCI [6], we suggest that 'standard' power wheelchairs alone may not meet section 34(d) of the NDIS Act 2013 unless the person is able to stand and change positions.

When considering whether a tilt/recline system, standing frame, or power wheelchair standing system meets reasonable and necessary support for a person with SCI, advisors should consider:

- the cost of each support
- whether the participant can independently transfer from their wheelchair to a standing frame. If not, what informal or community supports do they need to assist them to transfer to a standing frame? If the participant has no informal or community supports to assist with transfers, what is the cost of supports to transfer between the wheelchair and standing frame?
- whether the participant requires respiratory assistance which limits their ability to stand
- if the participant currently uses a standard power wheelchair, whether they experience symptoms such as pain, fatigue and poor bladder control which limits their community and economic participation
- whether the participant frequently experience orthostatic hypotension. If so, whether this prevents them from using a standing frame or standing system due to a fear of symptoms such as fainting or nausea.

4.2 Duchenne Muscular Dystrophy

For young people with DMD, power wheelchair standing systems provide increased independence and improved community involvement [20, 21, 23]. Power wheelchair standing systems provide greater independence than standing frames for young people with DMD, allowing them to participate in a greater range of school activities and enabling them to stand when they wish without the need of assistance to transfer to a standing frame [23]. We could not find research on the benefits of standing frames for people with DMD as there is minimal research on the use of assistive standing devices for people with DMD [37], with the limited research focusing on power wheelchair standing devices.

When considering if a standing system is reasonable and necessary for a participant with DMD, advisors should first consider if standing frames meet reasonable and necessary criteria as they are a lower-cost support. When considering if a standing frame is reasonable and necessary, advisors should consider:

- informal and community supports the participant has to transfer from a wheelchair to standing frame

- whether informal supports will be able to continue to safely transfer the participant between a wheelchair and standing frame as they grow and become heavier
- if it safe for caregivers to transfer the participant from a wheelchair to standing frame in community settings.

When determining if a support is reasonable and necessary for a participant with DMD, the stage in the progression of DMD should also be considered. People with DMD are generally able to ambulate until age 11-12 [38], however clinicians recommend that standing systems should be ideally trialled when the child is predicted to lose the ability to walk in the next one to two years [26].

4.3 Multiple Sclerosis

Fatigue is a common symptom of MS [17], which could limit social and economic participation if the participant is required to frequently transfer to an armchair or bed to rest. Power wheelchair tilt/recline systems can enable a participant with MS to rest comfortably whilst outside of their home.

There is limited evidence that standing using a standing frame can improve strength and spasms for people with severe MS. We could not find any research on the use of power wheelchair standing systems for people with MS. As there is evidence that standing frames (a lower cost standing support) are beneficial for people at the late stages of MS [34, 35], it is unlikely that power wheelchair standing systems would meet section 34(c) of the NDIS Act 2013 unless other benefits are identified.

When considering if a power wheelchair with a tilt/recline system and/or standing frame is reasonable and necessary for a participant with MS, advisors should consider:

- the participant's goals. For example, if the participant has goals related to increased economic or community participation, fatigue may be a barrier. In this case, a power wheelchair with a tilt/recline system may be necessary to manage fatigue outside of the participant's home
- whether it safe to frequently transfer the participant from their wheelchair to an armchair or bed if they experience frequent fatigue
- the stage of progression of MS (severity).

4.4 Cerebral Palsy

The scientific literature focuses on the use of standing frames and power wheelchair standing systems in children with CP rather than adults. Standing frames will not meet reasonable and necessary criteria for all children with CP as there is substantial variation in the level and type of impairments for people with CP [39]. For children with CP who are unable to stand without the assistance of a standing frame, standing frames are likely to meet reasonable and necessary criteria as they enable the child to change position [25], improve hip joint alignment

[33], and improve participation in school and the community [25, 30, 31] compared to using the wheelchair alone. Power wheelchair standing systems are unlikely to meet section 34(c) of the NDIS Act 2013 for children with CP as standing frames are a lower cost standing support, unless it is unsafe to transfer the child to a standing frame or it is extremely challenging for the child to balance using a standing frame.

Although there is a lack of research on the benefits of standing frames for adults with CP, it is likely that adults would experience some similar benefits to children such as increased participation in the community and improvements to bowel function [25]. Similarly to children, factors such as the participant's level of impairment, ability to stand independently, and level of informal supports should be considered when making a reasonable and necessary decision.

5. Literature Review

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
Dicianno, Arva, Lieberman, Schmeler, Souza, Phillips, Lange, Cooper, Davis, Betz. Jun 2009	RESNA position on the application of tilt, recline, and elevating legrests for wheelchairs	Assistive Technology 21(1):13-22.	Describe typical clinical applications and evidence from the literature about the application of tilt, recline and elevating leg rests for wheelchair users.	NIL	RESNA recommends the use of tilt, recline and elevating leg rests when they are needed to address issues related to postural alignment, function, physiology, transfers and biomechanical issues, contractures or orthopaedic deformities, oedema, spasticity, pressure management, comfort, or dynamic movement. However, they are not required for everyone and therefore require clinical judgement for prescription.	MODERATE Literature review methods unclear.
Sprigle, Maurer, Sorenblum. Jun 2009	Load Redistribution in Variable Position Wheelchairs in People With Spinal Cord Injury	The Journal of Spinal Cord Medicine 33(1):58-64.	Investigate the amount of force reduction on the seat at different wheelchair tilt/recline angles.	16 subjects (six able bodied, ten with a spinal cord injury) sat on a powered wheelchair with Teskcan pressure	Load reduction off the buttocks increases as the angle of the tilt/recline increases. Standing and recline	MODERATE. Presence of controls but small sample size.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
				mats. Seat load was measured for five different seating positions. Order of position was randomised for each participant.	<p>reduced load on the seat to 40%. Standing also reduced load on the backrest. Tilt reduced load on the seat to 55%.</p> <p>Standing was the only configuration that decreased loads off the backrest and seat at the same time.</p> <p>Tilt, recline, and standing are all options to shift body weight off the seat surface.</p>	
Frank, De Souza, Frank, Neophytou. 2012	The pain experiences of powered wheelchair users	Disability and Rehabilitation 34(9):770-778	To explore the experience of pain and discomfort in users of powered wheelchairs provided by the UK's National Health Service (NHS).	64 power wheelchair users who received their chair between February and November 2002 participated in a telephone questionnaire (N=64) about their pain and discomfort when using their powered wheelchair.	Most participants (67%) reported experiences of pain while using their powered wheelchair. 59% of participants indicated that their pain was influenced by their powered wheelchair, and 25% thought that the chair eased their pain symptoms.	MODERATE Ample sample size. Qualitative study based on participants self-reporting. Open-ended questions may elicit different responses from different people.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
Ding, Cooper, Cooper, Kelleher. Aug 2007	Monitoring Seat Feature Usage among Wheelchair Users	Proceedings of the 29th Annual International Conference of the IEEE EMBS	To examine how power wheelchair users utilise seat features such as seat tilt, recline and elevation during daily activities.	11 power wheelchair users were fitted with a Seat Feature Data Logger for 10-14 days which measures wheelchair use without interfering with the daily activities of the participants.	Tilt, recline and elevation features were frequently used, and participants spent more time in a tilted than upright position. Participants sometimes used smaller angles of tilt and recline than recommended by clinicians.	LOW Very small sample size (N=11). Data on wheelchair use was only collected over a short time period (10-14 days). Did not consider participants' disability types.
Chen, Wang, Lung, Yang, Crane, Jan. Dec 2014	Effect of tilt and recline on ischial and coccygeal interface pressures in people with spinal cord injury	American Journal of Physical Medicine and Rehabilitation 93(12): 1019-30	To investigate ischial and coccygeal interface pressures in response to different wheelchair tilt and recline angles in people with Spinal Cord Injuries.	Power wheelchair users (N=13) sat on a power wheelchair with an Interface Pressure Mapping (IPM) mat. An operator adjusted the wheelchair to six combinations of wheelchair tilt and recline.	For the four smallest angle combinations, ischial pressure was redistributed to the coccyx. For the two largest angle combinations, ischial pressure appeared to be redistributed to the back.	LOW Presence of controls but small sample size. IPM mat was only placed on seating component, not backrest. Did not consider participants' disability types.
Wu, Liu, Kelleher, Pearlman, Ding, Cooper. Jan 2017	Power seat function usage and wheelchair discomfort for power wheelchair users	The Journal of Spinal Cord Medicine 40(1):62-69	To investigate the relationship between power seat function usage and wheelchair discomfort.	Power wheelchair users who had recently been approved for a new power wheelchair (N=13) were fitted with a new power wheelchair with power seat functions.	People who used power seat functions more frequently may experience less wheelchair discomfort.	MODERATE Presence of controls but small sample size. Wheelchair use was measured objectively using rotary encoders and seat switch.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
				<p>Each power wheelchair was fitted with rotary encoders to record changes in tilt, recline, leg rests, seat elevation, and driving distance. A seat switch was fitted to measure wheelchair occupancy. Wheelchair discomfort was measured four times throughout the study (once every two weeks) using the tool for assessing wheelchair discomfort (TAWC). The total length of study was 8 weeks.</p>		<p>Correlation study (does not prove causation).</p>
<p>Lacoste, Weiss-Lambrou, Allard, Dansereau. 2003</p>	<p>Powered Tilt/Recline Systems: Why and How are They Used?</p>	<p>Assistive Technology 15(1):58-68</p>	<p>To characterise the use of powered tilt and recline systems, and user satisfaction.</p>	<p>40 adults who had owned a power wheelchair with a powered tilt and/or recline system for at least one year completed a questionnaire asking them to identify frequency of use and the range of tilt and</p>	<p>97.5% of participants used their powered tilt/recline system every day. 99% of users were satisfied with their tilt/recline system. At least 70% of participants reported that they used their</p>	<p>MODERATE Ample sample size. Participants self-reported wheelchair use.</p>



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Literature Review

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Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
				recline. Participants also selected eight most important reasons for using their tilt/recline system, and were invited to comment on how their system could be improved.	system to increase comfort. <30% use to alleviate pressure sores.	
Jan, Crane, Liao, Woods, Ennis. Oct 2013	Comparison of Muscle and Skin Perfusion Over the Ischial Tuberosities in Response to Wheelchair Tilt-in-Space and Recline Angles in People With Spinal Cord Injury	Archives of physical medicine and rehabilitation 94(10):58-68	To investigate the efficacy of power wheelchair tilt and recline on enhancing skin and muscle perfusion over the ischial tuberosities in people with Spinal Cord Injury.	Power wheelchair users (N=20) with Spinal Cord Injury who were at least six months post spinal injury were seated in a power wheelchair. Each participant was seated in six different variations of tilt and recline for five minutes. Near-infrared spectroscopy was used to continuously measure muscle perfusion.	Wheelchair tilt/recline can improve skin and muscle perfusion for people with Spinal Cord Injury. Angles equal to or larger than 25 degree tilt combined with 120 degree recline are required to reduce muscle and skin tissue ischemia.	MODERATE Presence of controls but small sample size.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
Jan, Liao, Jones, Rice, Tisdell. Apr 2013	Effect of durations of wheelchair tilt-in-space and recline on skin perfusion over the ischial tuberosity in people with spinal cord injury	Archives of physical medicine and rehabilitation 94(4):667-72	To compare the efficacy of different durations of wheelchair tilt and recline on improving skin perfusion over the ischial tuberosity in people with Spinal Cord Injury.	Power wheelchair users (N=9) with Spinal Cord Injury who were at least six months post spinal injury were seated in a power wheelchair. The participants were exposed to three different protocols: 1. 15mins sitting at no tilt/recline, then 3mins at 35° tilt and 120° recline, then 15mins sitting at no tilt/recline, then 15mins sitting at no tilt/recline, then 5mins at 35° tilt and 120° recline 2. 15mins sitting at no tilt/recline, then 1min at 35° tilt and 120° recline, then 15mins sitting at no tilt/recline, then 15mins sitting at no tilt/recline, then 5mins at 35° tilt and 120° recline	Average skin perfusion recovery at the three minute duration was significantly higher than at the one minute and zero minute tilt duration.	LOW Very small sample size.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
				<p>3. 15mins sitting at no tilt/recline, then 15mins sitting at no tilt/recline, then 15mins sitting at no tilt/recline, then 5mins at 35° tilt and 120° recline</p> <p>A Laser Doppler Flowmetry and probe were used to measure skin perfusion.</p>		
<p>Ding, Leister, Cooper, Cooper, Kelleher, Fitzgerald. Oct 2008</p>	<p>Usage of tilt-in-space, recline, and elevation seating functions in natural environment of wheelchair users</p>	<p>Journal of Rehabilitation Research & Development 45(7):973-83</p>	<p>To investigate the use of tilt, recline, and seat elevation in power wheelchair users.</p>	<p>Power wheelchair users with seating functions (N=12) had their wheelchairs fitted with seating function data loggers for two weeks.</p>	<p>On average, powered wheelchair users spent 64% of their time each day in tilted seating positions, and used the tilt function on average 19 times a day. Participants used backrest recline slightly less (on average 12 times a day).</p>	<p>LOW Small sample size. Analysis did not consider disability type.</p>

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
Titus, Polgar. 2018	Reasons for using power tilt: perspectives from clients and therapists	Disability and Rehabilitation: Assistive Technology 13(2):132-9	To investigate why power wheelchair tilt functions are used from the perspective of power wheelchair users and prescribers.	Five people who use powered wheelchair tilt functions and six therapists who prescribe powered wheelchairs were interviewed about the reasons for power tilt use, the reasons for prescribing, and the associated amplitudes of tilt.	Power wheelchair users use powered tilt for a number of reasons which are interlinked. This includes to manage pain, fatigue, physiological needs (breathing, hypotension), and pressure management.	LOW Very small sample size. Qualitative study based on interview.
Rice, Yarnot, Mills, Sonsoff. 2021	A pilot investigation of anterior tilt use among power wheelchair users.	Disability and Rehabilitation: Assistive Technology 16(2):152-9	To examine the effect of use of anterior power tilt on the physical health, function, and user satisfaction of power wheelchair users.	Ten powered wheelchair users completed a baseline assessment of their wheelchair use, functional mobility, shoulder pain, fatigue, spinal cord injury secondary conditions, modified functional reach, performance of self-care, and physical well-being. Participants were then provided with a power wheelchair with anterior tilt function. After two weeks, the participants repeated	Anterior tilt significantly increased participant's reach, which participants noted was meaningful for them to be able to perform some daily activities independently. Anterior tilt also significantly increased safety during meal preparation and reduced the need for assistance during meal preparation.	MODERATE Small sample size but presence of controls.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
				the tests described above.		
Dewey, Rice-Oxley, Dean. 2004	A qualitative study comparing the experiences of tilt-in-space wheelchair use and conventional wheelchair use by clients severely disabled with multiple sclerosis	British Journal of Occupational Therapy 67(2):65-74	To compare the experiences of people with Multiple Sclerosis (MS) who use wheelchairs with and without tilt function.	Wheelchair users with MS who used wheelchairs with tilt function (N=7) and wheelchairs without tilt function (N=16) were interviewed about how they use their wheelchair, pain levels, spasms and pressure sores.	The majority (6/7) of wheelchair users with tilt function reported that their chairs were comfortable, whereas only half of participants without tilt function reported that their chairs were comfortable. 5/7 with tilt function said that they could rest comfortably in their chair when experiencing fatigue, but some standard wheelchair users reported that they transfer to an armchair to rest.	LOW Very small sample size.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
Vorster, Evans, Murphy, Kava, Cairns, Clarke, Ryan, Siafarikas, Rowe, Parkinson, Gaynor. Mar 2019	Powered standing wheelchairs promote independence, health and community involvement in adolescents with Duchenne muscular dystrophy.	Neuromuscular Disorders 29(3):221-30	To investigate how adolescents with Duchenne muscular dystrophy (DMD) use a powered wheelchair and standing device in their day-to-day lives.	Adolescents with DMD (N=12) who used a powered wheelchair standing device, their mothers (N=11) and teachers (N=10) were interviewed about their powered wheelchair standing device.	Participants noted that the powered wheelchair standing device had increased their independence at home and school, and their community involvement. Powered wheelchair standing device can give greater autonomy than standing frames for adolescents with DMD.	LOW Small sample size. Qualitative study with benefits self-reported rather than objectively measured. Study participants had only used standing device for an average of eight months.
Arva, Paleg, Lange, Lieberman, Schmeler, Dicianno, Babinec, Rosen Sep 2009	RESNA position on the application of wheelchair standing devices	Assistive Technology 21(3):161-8	To explain typical clinical use of wheelchair standing devices.	N/A	RESNA's position is that wheelchair standing devices are medically necessary to some individuals as they: <ul style="list-style-type: none"> • Improve functional reach to enable participation in activities of daily living • Enhance independence and productivity • Maintain vital organ capacity 	MODERATE Literature review, however search method not clear.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
					<ul style="list-style-type: none"> • Reduce the occurrence of urinary tract infections • Maintain bone mineral density • Improve circulation • Improve passive range of motion • Reduce abnormal muscle tone and spasticity • Reduce the occurrence of pressure sores • Reduce the occurrence of skeletal deformities • Enhance psychological well-being 	
Stinson, Porter-Armstrong, Eakin. Mar 2003	Seat-interface pressure: A pilot study of the relationship to gender, body mass index, and seating position	Archives of physical medicine and rehabilitation 84(3):405-9	To investigate the relationship between seat interface pressure and BMI, gender, and seating positions.	Able bodied people (N=63) were seated in an armchair and the back/ footrest recline was adjusted to three different angles and the pressure was recorded using a pressure mat.	Average interface pressure decreased when the seat was reclined to 30°C and the subject's feet were elevated.	MODERATE Sufficient sample size and controls. Study undertaken on young, able-bodied participants.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
Bayley, Parkinson, Jacoby, Cross, Morris, Vorster, Schofield, Kava, Siafarikas, Evans, Gaynor. Sep 2020	Benefits of powered standing wheelchair devices for adolescents with Duchenne muscular dystrophy in the first year of use	Journal of Paediatrics and Child Health 56(9):1419-25	To assess the impacts of a powered wheelchair standing device (PWSD) on mental health, muscle and joint pain, and joint angles in adolescents with Duchenne muscular dystrophy.	Adolescents with Duchenne muscular dystrophy (N=14) were provided a PWSD Adolescents and their primary carer were interviewed about the intensity of their muscle and joint pain, and their psychological and social functioning fortnightly over 20 weeks. Baseline data was collected before the participant received their PWSD. Participants were also filmed transitioning from sitting to standing position as soon as they received the PWSD and again after approximately 6 months.	PWSD was not associated with any change in muscle and joint pain. PWSD was associated with better mental health scores.	LOW Very small sample size. Time between interviews varied slightly between participants potentially impacting results.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
Young, Bray, McKinnon, Burns, Bundy. Jul 2021	Everyday Life Participation Using Powered Wheelchair Standing Devices by Boys With DMD	OTJR: Occupation, Participation and Health 41(3):175-84	To investigate factors impacting use of supported standing for participation in boys with Duchenne muscular dystrophy (DMD).	Adolescent boys with DMD (N=9) who had used a PWSD for 24 months were surveyed about activities they used supported standing for, initiation of standing, reasons for using standing, physical and social environments they used standing, and reports of pain.	Participants used supported standing for independent toileting, for school activities such as sports, social and leisure activities, and to stretch. Some participants refused to stand due to pain or fatigue.	LOW Very small sample size. Convenience sampling, so study only considered boys with DMD in Sydney, Australia.
Schofield, Evans, Young, Paguinto, Carroll, Townsend, Kiefer, McGuire, Sodhi, Bray, Bayley.	The development of a consensus statement for the prescription of powered wheelchair standing devices in Duchenne muscular dystrophy	Disability and Rehabilitation	To develop a consensus statement for the prescription of powered wheelchair standing devices for children with Duchenne muscular dystrophy.	A literature review was undertaken and an international multidisciplinary panel was consulted, consisting of clinicians, users of powered wheelchair standing devices with DMD, and the parents of users of powered wheelchair standing devices. A consensus statement was formed using the Delphi method.	Powered standing wheelchair devices are a mobility option which increases choice, control and independence for people with DMD. Standing should occur at least 4-5 times per week for 60 minutes. There are cognitive, behavioural, personal and environmental factors which determine if a powered wheelchair standing device is	HIGH Literature review with international expert opinion to fill in gaps in the literature.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
					suitable for a person with DMD.	
Kenyon, Harrison, Huettner, Johnson, Miller. Feb 2021	Stakeholder perspectives of pediatric powered wheelchair standing devices: a qualitative study.	Developmental Medicine & Child Neurology 63(8): 969-75.	To explore the perspectives of children who use powered wheelchair standing devices (PWSD), their parents, health professionals working with children who use PWSD, and staff at companies manufacturing PWSD.	Children who use PWSD (N=8), their parents (N=12), health professionals working with children who use PWSD (N=12), and staff at companies manufacturing PWSD (N=3) were interviewed about use of PWSD.	Three main themes emerged from the interview data: 'Stand-on-demand' Children with PWSD were able to stand when they wanted, increasing independence in tasks such as washing hands, reaching for objects. 'It's more than weight-bearing' PWSD has psychological benefits and increases confidence and self-esteem.	LOW Small sample size. Interview methods not clear. Interviewer had previously worked with some of the study participants.



Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
					<p>'Ecosystems influencing PWSD acquisition and use' Challenging to get insurance to cover the cost of PWSD. Standard PWSD too large for younger children and therefore children of smaller stature required expensive, custom built chairs.</p>	
<p>Eng, Levins, Townson, Mah-Jones, Bremner, Huston. Aug 2001</p>	<p>Use of prolonged standing for individuals with spinal cord injuries</p>	<p>Physical therapy 81(8):1392-9</p>	<p>To investigate the use of prolonged standing and perceived benefits in people with SCI.</p>	<p>Adults with SCI (N=152) were mailed a survey questionnaire asking about their use of prolonged standing and their perceived benefits of standing.</p>	<p>Participants stood on average 40 minutes at a time, 3-4 times per week. Perceived benefits included improvements in well-being, circulation, bowel and bladder function, and reduced pain and fatigue. Cost of equipment was the most common barrier to not standing more often.</p>	<p>LOW Survey was mailed to >400 people with SCI but only 152 responded within four weeks. May have been a biased sample of people who have the functional capacity and/or support to complete and mail a written survey.</p>

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
Chelvarajah Jan 2009	Orthostatic hypotension following spinal cord injury: impact on the use of standing apparatus	NeuroRehabilitation 24(3):237-42	To understand the proportion of people with SCI who are restricted from using standing apparatus due to orthostatic hypotension or the fear of symptoms.	A survey was published online and publicised to the UK SCI community. The survey had a total of 293 responses from people with SCI.	Orthostatic hypotension restricts the use of standing devices such as standing frames and standing wheelchairs in 25% of people with SCI.	MODERATE Large sample size. Questionnaire validated for reliability and accuracy.
Dunn, Walter, Lucero, Weaver, Langbein, Fehr, Johnson, Riedy Dec 1998	Follow-up assessment of standing mobility device users	Assistive Technology 10(2):84-93	To investigate the use of standing devices in people with SCI.	People with SCI (N=99) who had purchased standing devices were surveyed about how their standing device has impacted them.	Frequency of use of standing frame and time spent standing correlated with more regular bowel movements, decreased spasticity	MODERATE Large sample size. Only 32% of people who were sent the survey responded. This may represent a bias sample of people with SCI who have the support/functional capacity to complete the survey.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
Goodwin, Colver, Basu, Crombie, Howel, Parr, McColl, Kolehmainen, Roberts, Lecouturier, Smith Mar 2018	Understanding frames: A UK survey of parents and professionals regarding the use of standing frames for children with cerebral palsy	Child: Care, Health and Development 44(2):195-202	To investigate the use of standing frames in children with cerebral palsy (CP) and understand the views of parents and professionals regarding their clinical benefits.	Clinical professionals who prescribe standing frames (N=305), health and educational professionals who work with children with CP (N=155) and the parents of children with CP who have used standing frames (N=91) completed an online questionnaire about the use an prescription of standing frames.	There were a range of clinical benefits described by those surveyed. The most frequently mentioned benefit was opportunity to change position. Respondents also perceived that the standing frame assisted with bladder and bowel function. Respondents noted that standing frames assisted with the child's enjoyment, participation, and communication.	MODERATE Large sample size. Potentially bias sample of people who were able to access the online survey.
Rivi, Filippi, Fornasari, Mascia, Ferrari, Costi Sep 2014	Effectiveness of standing frame on constipation in children with cerebral palsy: A single-subject study	Occupational therapy international 21(3):115-23	To investigate the effect of standing frame use on bowel function in children with CP.	One chronically constipated child with CP and quadriplegia was prescribed a standing frame. A baseline measure was taken prior to starting to use the standing frame, where the child's parents and teaching assistant filled out a diary noting frequency of	The standing frame did not impact the frequency of defecation or stool characteristics. The standing frame reduced pain the number of inductions of evacuation.	VERY LOW Conclusions cannot be applied to all children with CP as the study only had a single participant.

Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
				defecation and stool characteristics. Parents also completed a questionnaire on the 'burden of care'. These were repeated after the child was provided with a standing frame.		
Goodwin, Lecouturier, Crombie, Smith, Basu, Colver, Kolehmainen, Parr, Howel, McColl, Roberts. Mar 2018	Understanding frames: A qualitative study of young people's experiences of using standing frames as part of postural management for cerebral palsy	Child: care, health and development 44(2):203-11	To explore the opinion of standing frames in young people with CP.	Young people with CP (N=12) were interviewed using a semi structured interview format. The interview data was analysed using a thematic analysis.	Young people reported benefits to their independence. For some young people standing helped with their pain, but some found standing painful and reduced participation and independence.	LOW Small sample size. Convenience sample of young people with CP in the UK who had the capacity to answer interview questions.
Goodwin, Lecouturier, Smith, Crombie, Basu, Parr, Howel, McColl, Roberts, Miller, Cadwgan. May 2019	Understanding frames: A qualitative exploration of standing frame use for young people with cerebral palsy in educational settings	Child: care, health and development 45(3):433-9	To understand the views of parents of young people with CP, educational professionals, and clinicians on the use of standing frames in young people with CP in educational settings.	Five focus groups consisting of eight to nine participants (parents of young people with CP, educational professionals, and clinicians) were conducted in various locations in the UK, facilitated by a researcher. The	If a standing frame is used in an educational setting, there must be a multidisciplinary approach between education and health professionals.	MODERATE Clear, semi-structured interview methods. Comprehensive qualitative analysis.



Literature Review

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Author / Date	Title	Source	Aim / Objective	Methods	Results	Quality of Research
				facilitator followed a topic guide covering the perceived benefits of standing frames, challenges associated with standing frames, and support needs to use standing frames in schools. Focus groups were audio recorded and transcribed.		

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7. Version control

Version	Amended by	Brief Description of Change	Status	Date
1.0	MBK223	Research paper comparing features of standard and above standard wheelchairs.	Approved	13/01/2022