# Research Request – Early intervention for agoraphobia, anxiety or schizoaffective disorder

Brief	Check to see if there is any research about "early intervention" for adults with diagnosis of agoraphobia, generalized anxiety or schizoaffective disorder.
Date	07/08/2020
Requester	s47F - personal privacy (Senior Technical Advisor)
Researcher	s47F - personal privacy (Research Team Leader)

## Contents

1.	Summary	2
2.	What is early intervention?	2
3.	Generalised Anxiety Disorder	2
4.	Schizoaffective Disorder	3
5.	Agoraphobia	4
6.	Reference List	5

#### 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

## 1. Summary

- Early intervention should be delivered to individuals at risk of developing a disorder or showing early or mild signs of the problem
- Various interventions have been explored for anxiety and schizophrenia, however, there is little on agoraphobia
- Papers rarely provided an sort of timeline for when these intervention should be delivered, other than to say it should be 'early' or when symptoms were mild to moderate
  - One paper on schizophrenia noted it should occur within 3 years of psychotic illness

## 2. What is early intervention?

Early intervention is the process of providing specialist intervention and support to a person who is experiencing or demonstrating any of the early symptoms of mental illness.

Intervention is not only critical for preventing or reducing the progress of a mental illness, but for improving a person's mental and physical health, community participation and socioeconomic outcomes far into the future.

## 3. Generalised Anxiety Disorder

1. In relation to anxiety, early intervention programs are distinguished from prevention programs, as early intervention programs target individuals at risk of developing a disorder or showing early or mild signs of the problem. On the other hand, prevention programs in the true sense do not require that an individual is either at risk or showing any signs of a disorder [1].

Aims of early intervention for anxiety [1]:

- 1. Increase resilience
- 2. Social confidence
- 3. Regulation of emotion
- 4. Ability to anticipate and solve problems

No mention of precise time frame for when delivery of early intervention should occur (e.g. within a year of symptoms developing) [1].

 The Beyond Blue Foundation [2] performed an evidence review of prevention and early intervention strategies for depression and anxiety. This included adults with <u>mild to moderate disease.</u> As symptoms can emerge across the lifespan, it is suggested that opportunities to prevent and manage occur early on in the diagnosis.

# What early intervention and prevention policies, programs, or services are effective at managing anxiety in adults?

- It is highly recommended that internet- and mobile app-delivered interventions be implemented for people experiencing mild–moderate anxiety [2].
- There is some evidence that unguided interventions are effective for anxiety, but more research needs to explore the role of therapist support in this context [2].
- As with depression, it is recommended that these interventions be implemented among non-treatment-seeking populations, or those who are otherwise unable to engage with usual, high-quality care in order to maximise the impact of these interventions on anxiety symptoms [2].
- Exercise-based interventions are also recommended for young people wanting to reduce worry [2].

## 4. Schizoaffective Disorder

A Cochrane Review has evaluated the effects of early intervention strategies for schizophrenia [3].

In broad terms, early intervention has two objectives: the first is to prevent the onset of schizophrenia in people with <u>prodromal symptoms (mood changes such as anxiety</u>, depression, mood swings, sleep disturbances, irritability, anger, and suicidal ideas); the second is to provide effective treatment to people in the <u>early stages of schizophrenia</u> (including first episode of psychosis), with the goal of reducing the ultimate severity of the illness [3].

The 18 included studies produced emerging, but inconclusive evidence that people in the prodromal phase of psychosis can be helped by some interventions. There is some support for specialised early intervention services, but further trials would be desirable, and there is a question of whether gains are maintained. There is some support for phase-specific treatment focused on employment and family therapy, but again, this needs replicating with larger and longer trials [3].

Older literature has suggested that early intervention and early diagnosis teams are expected to meet needs of people for the first time during the **first 3 years of psychotic illness** (usually within the ages of 14-35 years) [4].

## 5. Agoraphobia

Unable to find any early intervention strategies which focus solely on agoraphobia.

One study looked at panic disorder with secondary symptoms of agoraphobia [5]. The early intervention course developed specifically for adults and was based on cognitivebehavioural principles and makes use of interventions that have appeared effective in the treatment of the full-blown panic disorder.

Participants labelled as 'early' were those presenting with subthreshold or mild panic disorder, defined as having symptoms of PD falling below the cut-off of 13 on the Panic Disorder Severity Scale-Self Report (PDSS-SR). <u>No mention of time since diagnosis/symptom onset [5].</u>

## 6. Reference List

- Dadds M, Seinen A, Roth J, Harnett P. Early Intervention for Anxiety Disorders in Children and Adolescents. Clinical Approaches to Early Intervention in Child and Adolescent Mental Health, Volume 2. Australian Early Intervention Network for Mental Health in Young People, c/o CAMHS Southern, Flinders Medical Center, Bedford Park, South Australia 5042. For full text: http://auseinet. flinders. edu. au.; 2000.
- Kay-Lambkin F, Gilbert J, Pedemont L, Sunderland M, Dalton H et al. Prevention and early intervention for people aged 18 and over with, or at risk of, mild to moderate depression and anxiety: An Evidence Check rapid review brokered by the Sax Institute (www.saxinstitute.org.au) for Beyond Blue, 2018. Retrieved from <u>https://www.beyondblue.org.au/docs/default-source/policy-submissions/mildmoderate-depression-and-anxiety-in-adults\_final-2.pdf?sfvrsn=d182bcea\_6</u>
- 3. Marshall M, Rathbone J. Early intervention for psychosis. Cochrane Database of Systematic Reviews. 2011(6).
- 4. Birchwood M, Todd P, Jackson C. Early intervention in psychosis: the critical period hypothesis. The British journal of psychiatry. 1998 Jun;172(S33):53-9.
- Meulenbeek P, Willemse G, Smit F, van Balkom A, Spinhoven P, Cuijpers P. Early intervention in panic: randomized controlled trial and cost-effectiveness analysis. Trials. 2008 Dec 1;9(1):67.



## **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	- Tactical Research Advisor (TAB/AAT)
Cleared	- 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.

### 1 Contents

2	Related TAB Research2			
3	Intro	oduction	2	
4	Terr	ninology	4	
	4.1	What is Serviceable Life?	4	
	4.2	What is Catastrophic Failure?	5	
	4.3	What is Lifecycle?	5	
	4.4	What is Lifespan?	5	
	4.5	What are Warranties?	5	
5	TGA	Requirements	6	
	5.1	Overview	6	
	5.2	TGA's Pre-Market Responsibilities	6	
	5.3	TGA's On-Market Responsibilities	8	
	5.4	TGA and Catastrophic Failure	8	
	5.5	Manufacturer's Responsibilities within the TGA Regulations	9	
	5.5.	1 The Therapeutic Goods (Medical Devices) Regulations	9	

#### FOI 24/25-0151



	5.5	5.2 Information provided by the manufacturer	9
6	Cor	nsidering ways of determining Life Span of a device	10
(	6.1	Overview	10
(	6.2	Lifespan in terms of risk management in public health service medical equipment	11
(	6.3	Life Span examples using the GMDN	12
7	Aus	stralian Government Safety Reforms for Medical Devices	13
8	Evi	dence that catastrophic failure of a prosthetic knee is likely to occur	14
9	Cor	nclusions	14
10	A	Appendix - Definitions	16
11	F	References	17

### 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 <u>Appendix 1.</u>

#### 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 <u>quantified</u> 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 <u>What is Catastrophic Failure?</u>

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 <u>What is Life cycle?</u>

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 <u>What are Warranties?</u>

A warranty is a <u>voluntary</u> 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 <u>consumer guarantees</u>. 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 <u>Overview</u>

- 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 <u>Pre-Market Responsibilities</u>

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 <u>most of the stages in the life cycle</u> 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]<u>, the Genium knee would be classified as Class</u> <u>1s/1m with a low potential of harm.</u>



### 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:
  - $\circ$   $\;$  Any malfunction or deterioration in the characteristics or performance of the device.
  - $\circ$   $\;$  Any inadequacy in the design, production, labelling or instructions for use of the device.
  - Any use in accordance with, or contrary to, <u>the use intended by the manufacturer of the kind of device that might lead</u>, or might have led, to the death of a patient or a user of <u>the device in Australia</u>, or to a serious deterioration or serious injury to his or her state <u>of health</u>.

#### 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 <u>Manufacturer's Responsibilities within the Therapeutic Goods Administration</u> <u>Regulations</u>

#### 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, Part1, 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. <u>The device is regularly maintained and calibrated in accordance with the manufacturer's</u> <u>instructions</u>; 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 <u>the device is safe to use after expiry of the warranty</u>, <u>providing that it is serviced</u> <u>regularly as recommended by the manufacturer</u>. 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 <u>Overview</u>

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 <u>do not always indicate an age after which biomedical devices should not be used</u>. 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 <u>effective life</u> 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. <u>The Department of Health expects that an asset will</u> <u>complete its effective life before being considered for replacement</u>.

*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

#### FOI 24/25-0151



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).

Table 1. Examples of GMDM device category codes and UMDNS devices groups				
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
  - o spinal implantable medical devices
  - o active implantable medical devices
  - o 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 participants 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.

#### FOI 24/25-0151



- 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]

### FOI 24/25-0151



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]

#### 11 References

1. Blanchard S. The Major Difference Between the Service Life of an Asset and Its Physical Life. Chron. not date.

2. Organisation for Economic Co-operation and Development. Service Life (of an asset) 2003 [Available from: <u>https://stats.oecd.org/glossary/detail.asp?ID=2430</u>.

3. T. Cooper. Beyond Recycling: the longer life option London: New Economics Foundation; 1994 [Available from:

https://www.academia.edu/31425579/Cooper T 1994 Beyond Recycling the longer life option London New Economics Foundation?auto=download.

4. Wikipedia. Service Life 2021 [Available from: <a href="https://en.wikipedia.org/wiki/Service\_life">https://en.wikipedia.org/wiki/Service\_life</a>.

5. The Law Dictionary. What is catastrophic failure? no date [Available from:

https://thelawdictionary.org/catastrophic-

failure/#:~:text=Changes%20in%20capability%20resulting%20in,undergo%20Sudden%20and%20dra stic%20change.

6. Law Insider. Catastrophic Failure definition no date [Available from:

https://www.lawinsider.com/dictionary/catastrophic-failure.



7. Merriam-Webster. Life cycle no date. [Available from: <u>https://www.merriam-webster.com/dictionary/life%20cycle</u>.

8. Law Insider. Life cycle definition no date. [Available from:

https://www.lawinsider.com/dictionary/life-cycle.

9. Australian Government - Department of Heath - Therapeutic Goods Administration (TGA). Safety first! How a risk based, life-cycle approach to medical device design improves patient safety 2019 [Available from: <u>https://www.tga.gov.au/sites/default/files/tga-presentation-termis-apabmc7-2019-congress-14-17-october-2019.pdf</u>.

10. Australian Government - Department of Heath - Therapeutic Goods Administration (TGA). Researcher considerations 2020 [Available from: <u>https://www.tga.gov.au/researcher-considerations</u>.

11. Biomedical Engineering Advisory Group (BEAG). Life span of Biomedical Devices 2004 [Available from: <u>http://cedglobal.org/download/Life%20Span%20of%20Biomedical%20Devices%20-%20Guidance%20Paper%20Final.pdf</u>.

12. Queensland Health. Medical equipment asset class - Categories and useful life guidelines 2020 [Available from: <u>https://www.health.qld.gov.au/ data/assets/pdf file/0008/1022201/qh-gdl-483.pdf</u>.

13. State of Victoria (Department of Health). Medical equipment asset management framework - Part C 2012 [Available from: <u>https://crm.hfma.org.au/sites/default/files/uploaded-</u> <u>content/website-content/medical equipment asset.pdf</u>.

14. Australian Competition & Consumer Commission (ACCC). Warranties 2021 [Available from: <u>https://www.accc.gov.au/consumers/consumer-rights-guarantees/warranties#warranty-against-defects</u>.

15. Australian Competition & Consumer Commission (ACCC). Consumer guarantees 2021 [Available from: <u>https://www.accc.gov.au/consumers/consumer-rights-guarantees/consumer-guarantees</u>.

16. Consumer Law. Consumer guarantees 2006 [Available from:

https://consumerlaw.gov.au/sites/consumer/files/2016/05/0553FT ACLguides Guarantees web.pdf.

17. Australian Government - Department of Heath - Therapeutic Goods Administration (TGA). Australian regulatory guidelines for medical devices (ARGMD) 2020 [Available from:

https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd.

18. Australian Government - Department of Heath - Therapeutic Goods Administration (TGA). Australian regulatory guidelines for medical devices (ARGMD) 2011 [Available from:

https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd. 19. Australian Government - Department of Heath - Therapeutic Goods Administration (TGA). The regulation of medical devices 2011 [Available from: <u>https://www.tga.gov.au/behind-news/regulation-medical-devices</u>.

20. Australian Government - Department of Heath - Therapeutic Goods Administration (TGA). What classification is my medical device? 2021 [Available from: <u>https://www.tga.gov.au/sme-assist/what-classification-my-medical-device#107</u>.

21. Australian Government. Therapeutic Goods (Medical Devices) Regulations 2002 2002 [Available from: https://www.legislation.gov.au/Details/F2020C00822.

22. Ottobock. Genium X3 Service pass no date [Available from:

https://shop.ottobock.us/store/medias/46D875-EN-05-

<u>1810.pdf?context=bWFzdGVyfHJvb3R8MTkzNDczfGFwcGxpY2F0aW9uL3BkZnxoZTgvaGFiLzg4OTI2M</u> zQyMzQ5MTAucGRmfDMyNTk2OWY5MzBhYWFmOGI2ZjdmYjYwODM2ZTBiN2QyNTdiZDFiZDgxOW M0ODk4NmVjNjlkNmUzYzgwNzEwOTE&attachment=true#:~:text=Ottobock%20offers%20two%20w arranty%20packages,and%20a%20six%2Dyear%20warranty.&text=This%20service%20pass%20gives %20you,it%20is%20due%20for%20servicing.

23. Ottobock. Genium X3 3B5-2/3B5-2=ST - Instructions for Use no date [Available from: https://shop.ottobock.us/media/pdf/647G1149-INT-05-1703w en 2018.pdf.



24. Ottobock. Genium Reclaim your strength no date [Available from:

https://professionals.ottobock.com.au/document?mediaPK=8923931836446&attachment=true.

25. University of Melbourne (Faculty of Engineering and Information Technology). Industry Advisory Groups no date [Available from: <u>https://eng.unimelb.edu.au/about/advisory-groups</u>.

26. State of Victoria (Department of Health). Medical equipment asset management framework - Part A & B 2012 [Available from:

https://www2.health.vic.gov.au/about/publications/policiesandguidelines/medical-equipmentasset-management-framework-part-a-b.

27. Department of Health (TGA). Global Medical Device Nomenclature - GMDN. 2013.

28. World Health Organisation (WH). GMDN User Guide: A comprehensive guide to the Global Medical Device Nomenclature (Version 2010) 2008 [Available from:

https://www.who.int/medical\_devices/innovation/GMDN\_Agency\_User\_Guide\_v120810.pdf.

29. ABC News. Rules designed to protect patients from faulty medical devices delayed until next year 2020 [Available from: <u>https://www.abc.net.au/news/2020-06-21/tga-rules-to-provide-more-oversight-medical-devices-delayed/12373290</u>.

30. ABC News. Warnings of more "catastrophic failures" of medical devices without serious reform 2018 [Available from: <u>https://www.abc.net.au/radio/programs/am/warnings-catastrophic-failures-medical-devices-without-reform/10146304</u>.

31. Australian Government - Department of Heath - Therapeutic Goods Administration (TGA). Delays to the commencement of certain medical device regulatory changes 2020 [Available from: <a href="https://www.tga.gov.au/delays-commencement-certain-medical-device-regulatory-changes">https://www.tga.gov.au/delays-commencement-certain-medical-device-regulatory-changes</a>.

32. Health Issues Centre. Medical Device and Implant Failure 2020 [Available from: <u>https://hic.org.au/medical-device-and-implant-failure/</u>.



FOI 24/25-0151

[Research Paper]

**OFFICIAL** 

For Internal Use Only

## **Accreditation of Assistance Animals**

### 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 questions:**

What does the Agency consider to be an 'accredited assistance animal provider?

What are the relevant state-based legislation/accreditation requirements for each state? How do they determine suitability of a provider in each state?

What are the implications if NDIS funding was provided under the Commonwealth DDA but not the law of the state or territory in which the participant resides? Are there legal implications for public access and what are these?

What are the best practice approaches to Assistance Animal training/certification?

Date: 5/5/2022 Requestor: Endorsed by (EL1 or above): Researcher: s47F - personal privacy Cleared by: s47F - personal privacy

#### 1. Contents

Accred	itation of Assistance Animals	1
1.	Contents	1
2.	Summary	2
3.	Definition of Assistance Animal	3
4.	State and Territory Legislative Requirements	5
V1.0 27	7-04-2022	Page 1 of 17



## [Researeta-Paper]

## OFFICIAL For Internal Use Only

4.1	New South Wales	5
4.2	Victoria	6
4.3	Queensland	7
4.4	South Australia	9
4.5	Western Australia	9
4.6	Tasmania	.10
4.7	Australian Capital Territory	.10
4.8	Northern Territory	.11
5.	Regulations and Accreditation of Assistance Animals	.11
6.	NDIA funding for Assistance Animals	.12
7.	Organisations that train assistance animals	.13
8.	References	.15
9.	Version control	.17

## 2. Summary

The *Disability Discrimination Act 1992* (Commonwealth) states an animal can meet the criteria of being an assistance animal (AA) in three ways:

- 1. State accreditation
- 2. Territory accreditation or;
- 3. Trained through an accredited training organisation or trained independently to meet the needs of a person with a disability.

All users of AA have public access rights under the *Disability Discrimination Act 1992* (Cth) regardless of whether the handler has a Public Access Test card, ID card or if the AA is wearing a special harness (City Services, n.d.).

Under the *Disability Discrimination Act 1992* (Cth) it is not considered discrimination to ask a person for proof an animal is a legitimate AA. If proof cannot be provided it is also not considered discrimination to refuse entry or ask the person to leave the premises. Therefore, the introduction of accreditation for AA and public access tests by Queensland, South Australia, Western Australia, and the Australian Capital Territory enable a person to gain formal recognition for their AA and receive an accreditation card that can be produced on demand.

The <u>NDIS Guidelines</u> have clear parameters for funding Assistance Animals. An AA must be trained by an **accredited organisation**, perform <u>3 tasks or behaviours</u> to support the



## [Researer Paper]

## OFFICIAL

### For Internal Use Only

individual with a disability and pass a **public access test**. The NDIS Guidelines has additional criteria defining AAs compared to the legal definition in the *Disability Discrimination Act (Cth)*. The benefit of encouraging a participant to use an accredited AA training organisation for their AA is that upon successful completion they receive a handler's card. Producing this card on request may reduce the number of negative social events experienced by a participant when in public if they are asked for proof that their dog is a legitimate assistance dog. <u>RES 239 Animal Assisted Therapy and Assistance Animals</u> provides additional information regarding the evidence of stigma and discrimination experienced by users of assistance animals.

## 3. Definition of Assistance Animal

The legal definition of an Assistance Animal, set out by section 9 (2) of the *Disability Discrimination Act 1992* (Commonwealth), is a dog or animal that:

a) is accredited under a law of a State or Territory that provides for the accreditation of animals trained to assist a person with a disability to alleviate the effect of the disability; or

b) is accredited by an animal training organisation prescribed in the regulations; or

c) is trained:

i. to assist a person with a disability to alleviate the effect of the disability; and

ii. to meet standards of hygiene and behaviour that are appropriate for an animal in a public place.

Under the *Act*, an individual is free to choose how their assistance dog is trained. There is no one prescribed way for an animal to meet the definition of an AA. As long as the individual using the AA has the means to prove the animal is a genuine AA it does not matter under this Act how the animal is trained. However, a person using an AA must be able to prove that the animal is a genuine AA, and business owners or carer takers of public spaces and public transport have the right to refuse entry if evidence is not provided (Human Rights Commission, 2016). Methods of proof can be a letter from a medical specialist confirming the disability and AA, it could be an identification card obtained after being trained by an accredited training organisation, or it could be by providing a valid state Public Access Test card.

The National Disability Insurance Scheme differs in the definition of what is an AA. As described in NDIS Guidelines (NDIS, 2021):

"An assistance animal is an animal specially trained by an accredited assistance animal provider to help you do things you can't do because of your disability....The La Trobe University report defines assistance animal as "an animal that is trained to perform at least 3 tasks or behaviours which mitigate the effects of a person's disability". This means an assistance animal that has been trained to do at least 3 specific thing that you need, but can't do because of your disability."

V1.0 27-04-2022





### OFFICIAL

#### For Internal Use Only

The NDIS has taken on a definition recommended by the authors of a 2019 NDIS commissioned report "La Trobe University Report – Key terms for animals in disability assistance roles". In this report, the authors say:

"Assistance animal is defined, building on the definition in the Australian Commonwealth Disability Discrimination Act, as an animal that is trained to perform at least three tasks or behaviours which mitigate the effects of a person's disability....They must also be trained to a high level of obedience. This enables them to access public spaces that are typically off-limits to animals..." (Howell et al, 2019, p. 7).

In this report, Howell et al (2019, p. 12) says:

"There are no official regulatory bodies or training standards supported by the Disability Discrimination Act. There are, however, numerous organisations in Australia dedicated to training assistance animals, and breeding/sourcing of animals, training, and accreditation processes differ between these organisations. Some provider organisations fall under an umbrella such as Assistance Dogs International (ADI) or the International Guide Dog Federation (IDGF)."

Further in this report, Howell et al (2019, p. 20) advises:

the "current legal definition is vague, particularly in Part (C). For this reason, we recommend adopting the standards of umbrella organisations such as ADI or IGDF, when determining whether an animal is sufficiently trained to access public spaces and can perform at least three specific tasks that 'alleviate the effect' of the owner's disability."

Upon communication with Assistance Dogs International (ADI) requesting background information relating to how the organisation developed the definition of AA, I was advised (via email, 27/4/22):

"ADI member organisations determined our definitions in the early 1990's. when ADI was formed. The US American with Disabilities Act (1990) states that a Service Animal must perform at least one task to mitigate a disability. ADI members determined that our standards and definitions should be stronger, so they decided on three tasks to mitigate an individual's disability."

Communication from Howell regarding the definition of AA stated (via email, 28/4/22):

"I do agree with the US law and ADI that it is important that assistance dogs be trained to perform specific tasks that mitigate the impact of the person's disability. Assistance animals need to be differentiated from emotional support animals (ESA), who require no specific training of any kind. Trained tasks are one way to tell them apart from ESAs. That is why we recommended that tasks be part of the definition of an assistance animal."

This communication from Howell appears to overlook the fact that the Disability Discrimination Act 1992 states an AA must be "trained to assist a person with a disability to alleviate the



## [Researer Paper]

## OFFICIAL

### For Internal Use Only

effect of the disability". By recommending an animal perform three tasks, it sets the bar higher for an animal to be considered an AA. This may unintentionally exclude some animals from being considered an AA because they perform only one task or behaviour, no matter how significant, that helps alleviate the effect of a disability. Additionally, emotional support animals and therapy animals have no legislative protection and no public access rights which already differentiates them from AAs.

A comprehensive search of the Administrative Appeals Tribunal (AAT) outcomes did not reveal any decision made with respect to the stricter definition of AA by NDIS requiring that an AA must perform at least three tasks. However, the condition that an AA was "specially trained by an accredited assistance animal provider" has been successfully challenged. The case between Nottle and National Disability Insurance Agency [2021] AATA 1014 (9 April 2021) related to funding for acquisition, training and maintenance of a hearing assistance dog where the participant, an experienced dog trainer, requested funding for a second assistance dog as her current dog was nearing retirement. Part of the response from NDIS was that Nottle was not proposing to have an accredited trainer for the assistance dog but wanted to take the responsibility of training the dog herself. The only accredited trainer in her region would not allow a second dog at home, which would not allow Nottle to also keep her older assistance dog. The Tribunal found Nottle had the capability to acquire and train the dog herself and determined the NDIS decision be set aside.

In another legal case, in the Full Court of the Federal Court between Mulligan V Virgin Australia Airlines Pty Ltd [2015] FCCA 157, Mulligan claimed Virgin Airlines discriminated against him by refusing to allow his assistance dog. The assistance dog had been trained by a dog training school, but not one that was 'accredited'. The Court found that Virgin's conduct amounted to unlawful discrimination under the DDA. Specifically, that "an animal may be an AA under the DDA if it has received relevant training, regardless of who has provided that training" (Human Rights Commission, 2016).

## 4. State and Territory Legislative Requirements

## 4.1 New South Wales

AA in New South Wales are covered by the *Companion Animals Act 1998* (NSW). The definition of AA is aligned with the *Disability Discrimination Act 1992* (Commonwealth). It is noted that currently neither the Commonwealth nor New South Wales laws provide for the accreditation of AA (Office of Local Government, 2022).

The Office of Local Government (2022) highlights that a person with a disability is free to choose how their AA is trained, however the method must allow them to provide proof that the training meets the definition of an AA as per the *Companion Animals Act 1998* (NSW)/ *Disability Discrimination Act 1992* (Commonwealth). Staff in charge of access to public places and public transport are entitled to request reasonable proof the animal is a genuine AA (Office of Local Government, 2022). Staff may be guided by their organisation's policies.

V1.0 27-04-2022

Page 5 of 17



## [Researer Paper]

## OFFICIAL

### For Internal Use Only

Councils can request proof an animal is a legitimate AA, which may include evidence: of a disability, the animal is trained to alleviate the disability, and the animal is trained to meet standards of hygiene and behaviour appropriate for an animal in a public place (Office of Local Government, 2022). An animal does not need to be registered with their local council as an AA under the *Companion Animals Act 1998* to be permitted access to a public place or public transport (Office of Local Government, 2022).

To take an AA on public transport the handler must have an accepted type of accreditation – access can be refused if valid accreditation cannot be produced when asked. Accepted accreditation includes:

- AA Permit issued by Transport for NSW (Transport for NSW, n.d.) to obtain a permit an individual needs a medical certificate confirming the disability within the meaning of the *Disability Discrimination Act 1992* (Commonwealth), a document showing the AA has been registered with the handler's local council (where relevant), a colour photograph of the AA, documentation dated within the last 6 months from either an organisation registered with the Transport for NSW (see below), an organisation not registered with the Transport for NSW or the individual themselves detailing the skills and action the animal has been trained to undertake and how these alleviate the effects of the disability, how they meet the appropriate behaviour and hygiene standards for a public place and how the animal is controlled. Current registered organisations include Assistance Dogs Australia, Centre for Service and Therapy Dogs of Australia Pty Ltd, Hans van Heesbeen t/a Service Dog Training, Integra Service Dogs Australia, K9 Tales Pty Ltd, Miracle Assistance Dogs Inc, Personal Assistance Dog Solutions, Pets Education Training Support, Smart Pups Assistance Dogs for Special Needs Children Inc.
- Accreditation from organisations endorsed by Transport for NSW Australian Lions Hearing Dogs, MindDog Australia, Guide Dogs Australia and Vision Australia Seeing Eye Dogs (Transport for NSW, 2021).
- Interstate accreditation recognised by Transport for NSW Victorian Public Transport AA Pass, WA Department of Local Government Public Access Permit, Queensland Government Handler Identity Card, SA Dog and Cat Management Board Pass, and additional passes accepted in SA (Assistance Dogs Australia Pass, Righteous Pups Australia, Royal Society for the Blind) (Transport for NSW, 2021).

## 4.2 Victoria

The rights of guide dog users is covered by the *Disability Discrimination Act 1992* (Commonwealth) and *Domestic Animals Act 1994* (Vic), both overriding the Health Act that prohibits dogs from entering food premises (Agriculture Victoria, 2022). The *Equal Opportunity* 

## [Research Paper]



### **OFFICIAL**

### For Internal Use Only

*Act 2010* (Vic) protects people with disabilities from discrimination, including if they have an assistance dog.

Under the *Equal Opportunity Act 2010* (Vic), an assistance aid includes an assistance dog that alleviates the effects of a person's disability. It is considered that if a person is accompanied by an assistance aid, the aid is to be taken as a characteristic of that person. Therefore, treating a person differently due to the presence of their assistance aid is considered discrimination (*Equal Opportunity Act 2010* (Vic)).

Assistance dogs are required to be; non-aggressive, obedient to the handler, quiet/ no barking, experience in real life situations, calm in confined and crowded spaces, and calm in noisy and stressful situations (Agriculture Victoria, 2022). Victoria does not have a Public Access Test for AA, however it is strongly recommended trainers use the previous requirements as a guide to minimum standards of behaviour and hygiene.

To use public transport with an AA, an AA Pass is required (note: guide dogs, hearing dogs and guide dogs in training do not require this pass). To apply, an individual needs to provide information regarding the trainer including their qualifications, AA card number if applicable, description of animal, photograph of the animal, health professional declaration from AHPRA registered professional confirming the AA information is accurate (Public Transport Victoria, 2019).

## 4.3 Queensland

The *Guide, Hearing and Assistance Dogs Act 2009* (Qld) aims to assist people with an AA to have independent access to the community and ensure the quality and accountability of guide, hearing and assistance dog training services (Disability Services, 2009). This Act reaffirms an individual's right of access if they are supported by an AA. The *Guide, Hearing and Assistance Dogs Act 2009* (Qld) does not override the rights of the *Disability Discrimination Act 1992*, therefore even if a dog does not display an approved badge they still have access rights and if a person with a disability feels they have been discriminated against they have the right to lodge a complaint under the *Disability Discrimination Act 1992* (Disability Services, 2009).

However Part C of the Public Access Test, obtaining a handler identity card, states:

"It is a requirement under the *Guide, Hearing and Assistance Dogs Act 2009* (Qld) that a person has a Handler Identity Card to identify themselves as a person who is accompanied by a guide, hearing or assistance dog, certified to access public places, places of accommodation and public passenger vehicles."

To clarify the situation, on the 20<sup>th</sup> April 2022 I called the Queensland Guide, Hearing and Assistance Dogs Office and was advised it was mandatory for assistance dogs to be certified otherwise a person could not take them out in public. When I pointed out that people are protected under the DDA she said dogs must be certified to maintain quality and safety of



## [Researer Paper]

### OFFICIAL

### For Internal Use Only

assistance dogs and assistance dog trainers. However, in resources for businesses provided by the same Queensland Government office it clearly states:

"It should be noted that the Commonwealth *Disability Discrimination Act 1992* also provides access rights. People from interstate may not have Queensland identification but, in Australia, all people with a disability who are accompanied by a support animal are provided with the right of public access under the DDA, which makes it unlawful to discriminate against a person on the grounds of that person's disability."

In another resource titled: Legislation and Public Access, it states legislation supporting the rights of people with a disability to have the same access to public places, public passenger vehicles and places of accommodation are the Commonwealth *Disability Discrimination Act 1992* and the *Guide Hearing and Assistance Dogs Act 2009* (Qld).

On 3<sup>rd</sup> May 2022, I received email confirmation from the Guide Hearing and Assistance Dogs Office, Queensland Government, that "certification of a guide, hearing and assistance dog under Queensland's *Guide, Hearing and Assistance Dog Act 2009* (the GHAD Act) is not mandatory however, it is strongly recommended."

Dogs can be certified under the *Guide, Hearing and Assistance Dogs Act 2009* (Qld) if they (Department of Seniors, Disability Services and ATSI Partnerships, 2018):

- Can perform physical tasks and behaviours to assist a person with a disability in a way that reduces that person's need for support
- Can pass a public access test conducted by an approved trainer or institution
- Are not a restricted breed under the Local Government Act 1994
- Are desexed and vaccinated
- Have not been declared a dangerous dog under local law

Dogs must pass a public access test to become certified to ensure they are safe to take in public places or public passenger vehicles. A dog that displays aggressive, uncontrolled or unhygienic behaviour will not pass the test (Disability Services, 2009). If an individual or business exercising control of a public place or public vehicle has doubts of an AA authenticity, it is reasonable to ask to see the person's ID card to ensure the dog is certified under the Act (Disability Services, 2009). There are penalties for people and businesses who do not allow access to certified AA (Department of Seniors, Disability Services and ATSI Partnerships, 2018).

A long list of Australia-wide training services approved under the *Guide, Hearing and Assistance Dogs Act 2009* (Qld) can be found at <u>Approved Trainers and Training Institutions.</u>





OFFICIAL

For Internal Use Only

### 4.4 South Australia

Recognition of assistance dogs in South Australia is under the *Dog and Cat Management Act 1995* (Sth Aust) (Dog and Cat Management Board, n.d.). There is no recognition for companion dogs, therapy dogs or emotional support dogs.

Assistance dogs can only be accredited under the *Dog and Cat Management Act 1995* (Sth Aust) by either the Dog and Cat Management Board or the following prescribed accreditation bodies: Royal Society for the Blind, Guide Dogs Australia, Lions Hearing Australia, Assistance Dogs Australia, Righteous Pups Australia, Vision Australia, Australian Veterinary Behaviour Services and Integra Service Dogs Australia (Dog and Cat Management Board, n.d.).

To apply for accreditation through the Dog and Cat Management Board, the handler needs to demonstrate the need for an AA, such as medical certificate detailing the disability and how the AA alleviates the effects of the disability, and relevant training of the AA indicating how the dog is trained to alleviate the effects of the disability and meets hygiene and behaviour standards, such as a certificate from a veterinarian or training organisation (Dog and Cat Management Board, n.d.).

The Dog and Cat Management Board (n.d.) highlight it is not discrimination to ask a person to leave a public place if they are unable to produce evidence the dog is an AA or if they don't meet appropriate standards of hygiene or behaviour. Dogs that are accredited under the *Dog and Cat Management Act 1995* (Sth Aust) are issued with an identity card that the handler can show when requested.

For dogs being claimed as an AA under the Disability Discrimination Act 1992 (Commonwealth), the handler will need evidence of both the need for an AA, such as a medical certificate stating they have a disability and the animal alleviates the effects of the disability, and evidence of appropriate training from a veterinarian or training organisation.

The Dog and Cat Management Board can only accredit dogs as an AA. The dog can be any breed but must be trained specifically to alleviate the effects of the disability. A veterinarian must declare the dog physically fit and not dangerous, a nuisance or menace. A dog does not need to be wearing a harness or jacket under South Australian or Commonwealth legislation (Dog and Cat Management Board, n.d.).

Dogs accredited interstate are not automatically accredited in South Australia. Individuals need to contact the Dog and Cat Management Board to get information specific to their situation before relocating.

## 4.5 Western Australia

It is not mandatory for an assistance dog to be accredited, however under Commonwealth law the handler of an AA has the onus to prove: they possess a disability, the dog is needed for the disability and the dog is suitably trained to be taken into public areas (Department of Local

V1.0 27-04-2022



## [Researer Paper]

### **OFFICIAL**

### For Internal Use Only

Government, Sport and Cultural Industries (DLGSCI), 2021). For dogs not formally accredited, the handler may have difficulty proving the dog is a genuine AA and might increase the chance that the dog will be refused entry to public areas.

The DLGSCI provides an accreditation system for AA under the *Dog Act 1976* (Western Aust). To be approved, the dog and handler must pass the public access test, which is the minimum standard to be considered safe to access public areas and public transport (DLGSCI, 2021). Independent Public Access Test assessors are approved by the government. Once a dog is approved, the dog has an initial 6 month probationary period and then moves onto a 2 year approval. The handler is issued a card to provide evidence upon request that the dog is a genuine AA (DLGSCI, 2021). The card should always be carried by the handler so it can be produced if requested by an authorised person.

People with AA trained by the following organisations are automatically granted public access rights under the *Dog Act 1976* (Western Aust): Assistance Dogs Australia, Lions Hearing Dogs, Seeing Eye Dogs Australia, VisAbility WA, Royal Guide Dogs Association of Australia and affiliated bodies (DLGSCI, 2021). A dog that is accredited under a law in another state or territory has public access rights in WA under the *Dog Act 1976* (Western Aust).

People can also choose to train their assistance dog privately. Public access rights for privately trained dogs may be granted on application to the department after the applicant has demonstrated a need for the assistance dog and the dog meets the training criteria (DLGSCI, 2021).

## 4.6 Tasmania

The *Guide Dogs and Hearing Dogs Act 1967* (Tas) applies to guide dogs and hearing dogs but not assistance dogs (Department of Premier and Cabinet, n.d.). *The Disability Discrimination Act 1992* (Commonwealth) says a person cannot be discriminated against for having an AA or dog, however a person with an assistance dog can be asked to show proof the dog is an AA and trained to meet the standards of hygiene appropriate for a dog in a public place. No further information found with respect to AA training regulations.

## 4.7 Australian Capital Territory

The ACT has a legislative framework within Part 5 of the *Domestic Animals Act 2000* (ACT) that allows for AA to be accredited as meeting the ACT's public access standards. The accreditation is voluntary but clarifies the rights of access for people with a disability who use AA (City Services, n.d.). Once accredited, the Registrar of Domestic Animals may register the AA and issue the handler with an ID card for up to 2 years.



## [Researer Paper]

### OFFICIAL

### For Internal Use Only

The voluntary public access test involves providing evidence of a disability from a medical practitioner, veterinarian declaration that the animal meets health requirements, and a 2-3 hour test conducted by an ACT registered trainer and assessor (City Services, n.d.).

Approved trainers are (City Services, n.d.):

- Isabela Lisiecka, Wooft Dog Training <u>https://www.wooft.net/</u>
- Jessica McNamara, ABCDOG Training <u>https://www.abcdog.biz/</u>
- Dee-Anne Gunter <u>dalo7@ymail.com</u>
- Tessa Stow, K9 Support <u>http://www.k9support.com.au/</u>
- o Jessica Torrance, Assistance K9 https://www.facebook.com/assistancek9
- Emelia Wilmot, Paws for Assistance Dog Training <u>https://pawsforassistance.com.au/</u>

A person with accreditation under a recognised organisation or other jurisdiction can apply to have their AA registered by providing evidence of the accreditation without undertaking the public access test (City Services, n.d.).

AA accredited by organisations that meet the ACT standards of behaviour and hygiene include (City Services, n.d): Assistance dogs Australia, Australian support dogs, Guide Dogs Australia and their affiliated bodies (NSW/QLD/SA/NT/TAS/VIC/WA), Integra Service dogs Australia, mindDog Australia, Seeing Eye Dogs Australia – Vision Australia, any AA organisation, Australian or International, that is formally recognised by Assistance Dogs International and the International Guide Dog Federation.

## 4.8 Northern Territory

At the time of this research, minimal information regarding AA was found in relation to Northern Territory regulations. The *Disability Services Act 1993* (NT) does not reference AAs. Limited council information was located that highlighted assistance dogs are excluded from by-laws relating to registration and restricted areas (Wagait Shire Council, 2019).

## 5. Regulations and Accreditation of Assistance Animals

Currently in Australia the specific training of AAs is not regulated by Federal, State or Territory law. As per the *Disability Discrimination Act 1992* (Commonwealth), there are three pathways that an animal can qualify as an AA.

There are a number of training organisations, as mentioned in the State and Territory information and in Section 7, that have automatic approval for their trained assistance dogs. These organisations have a proven track record of training assistance dogs for people with a





### **OFFICIAL**

### For Internal Use Only

disability and the dogs meet standards of hygiene and behaviour as outlined in the Disability Discrimination Act 1992.

Assistance Dogs International, as described in the report by Howell et al (2019), is an organisation committed to providing minimum standards of training, including public behaviour, and ethical treatment for assistance dogs. ADI members in Australia include: Assistance Dogs Australia, Australian Lions Hearing Dogs, Australian Support Dogs, Guide Dogs NSW/ACT, Guide Dogs Queensland, Guide Dogs SA/NT, Righteous Pups Australia, Royal Society for the Blind, Guide and Assistance Dog Service and Vision Australia Seeing Eye Dogs.

For States and Territories that offer an accreditation or certification pathway, including the Victorian Public Transport Pass, assistance dog trainers need to apply to the regulating authority detailing their experience in selecting and training AAs for people with a disability to be a recognised AA trainer. However there does not appear to be a defined 'standard' that trainers need to meet in order to achieve this recognition. Evidence that needs to be provided to state and territory bodies includes relevant qualifications, knowledge or experience in dog obedience training and what training methods will be used.

## 6. NDIA funding for Assistance Animals

A search of the *National Disability Insurance Scheme Act 2013* (Cth), *National Disability Insurance Scheme (Supports for Participants) Rules 2013* and NDIS Quality and Safeguards Commission does not provide information regarding what is required for an animal to be considered an AA with regards to NDIS funding.

Funding criteria for an AA is described in NDIS Our Guidelines (NDIS, 2021):

- The AA must be trained to do at least 3 specific tasks or behaviours that a participant needs but can't do because of their disability
- The AA must meet Reasonable and Necessary support
- The AA must meet the NDIS Rules for funding a support
- The provider needs to be an accredited AA provider; the provider may be registered with the NDIS Quality and Safeguards Commission or with the relevant state or territory authority for AAs
- The AA must pass a public access test so it can become qualified, which should be arranged by the training provider
- The AA must meet Commonwealth, state and territory laws

As detailed in Section 3, the criterion that an AA must be trained by an accredited organisation has been successfully challenged at the Administrative Appeals Tribunal by a participant with dog training experience and also through a legal case against Virgin Australia Airlines.



## [Researer Paper]

### OFFICIAL

### For Internal Use Only

Therefore, while there are clear benefits of using an accredited assistance dog trainer it also provides a risk to the Agency if a suitable alternative is proposed and not funded.

The *Disability Discrimination Act 1992* (Commonwealth) states there are three pathways for an animal to be recognised as an AA. The State and Territory accreditation pathways are one approach to having a recognised and certified AA. However, as stated clearly by Western Australian and South Australian authorities, having state or territory accreditation does not provide additional protection for people with a disability and not having this accreditation does not remove public access rights for people with an AA. The benefit of having an AA either trained by a recognised training organisation or with state or territory accreditation is that it provides the AA user with a way to easily prove their AA is genuine when they are accessing public spaces.

Although not presented as an option in NDIS Our Guidelines, if a participant wanted to take the third pathway of AA recognition as per the *Disability Discrimination Act 1992* (Commonwealth) – training the animal themselves to meet their disability needs – they inadvertently increase their burden of proof that the AA is legitimate. As mentioned earlier in this report, it is not discrimination to request proof an AA is genuine and it is not discrimination to prevent an animal from accessing public spaces or public transport if proof cannot be provided.

For individuals who do not have a State or Territory accreditation card, or a training card from a recognised organisation, their proof may involve presenting a medical certificate as well as veterinarian certificate that the AA is genuine. As noted in <u>RES 239 Animal Assisted Therapy</u> and <u>Assistance Animals</u>, people with an AA are vulnerable to discrimination when in the community. Therefore, opting for a dog that can easily achieve State or Territory accreditation or that is trained through a recognised organisation may lessen negative interactions experienced by individuals with an AA while in public.

## 7. Organisations that train assistance animals

The following training organisations are listed on the Federal Government 'Disability Gateway' website as being recognised for their expertise in training assistance animals.

- o Assistance Dogs Australia
- o Aware Dogs Australia
- o Guide Dogs Australia
- o Guide Dogs SA/NT
- o <u>MindDog</u>
- o Royal Society for the Blind Guide and Assistance Dogs
  - \* Guide Dogs



## [Researer-Paper]

OFFICIAL

For Internal Use Only

\* Autism Dogs

\* Operation K9 for Veterans with PTSD

Additional organisations recognised for their expertise in training AAs are listed under each state and territory.





OFFICIAL For Internal Use Only

#### **References** 8.

- Agriculture Victoria. (2022). Guide dogs, seeing eye dogs and assistance dogs. Victorian Government. Accessed from https://agriculture.vic.gov.au/livestock-and-animals/animalwelfare-victoria/dogs/guide-dogs-seeing-eye-dogs-and-assistance-dogs
- Companion Animals Act 1998 (NSW). Accessed from https://legislation.nsw.gov.au/view/whole/html/inforce/current/act-1998-087
- Department of Premier and Cabinet. (n.d.). Dog Control FAQ. Accessed from https://www.dpac.tas.gov.au/divisions/local government/legislation/current legislation/d og control/dog control fags
- Department of Local Government, Sport and Cultural Industries. (2021). Applying for assistance dog approval. Government of Western Australia. Accessed from https://www.dlgsc.wa.gov.au/local-government/community/cats-and-dogs/applying-forassistance-dog-approval
- Department of Seniors, Disability Services and ATSI Partnerships. (n.d.). Frequently asked questions - businesses. Accessed 28/4/22 from https://www.dsdsatsip.qld.gov.au/resources/dsdsatsip/disability/guide-hearingassistance-dogs/facts-fags-business.pdf
- Department of Seniors, Disability Services and ATSI Partnerships. (2018). Guide, hearing and assistance dogs. Queensland Government. Accessed from https://www.gld.gov.au/disability/out-and-about/ghad
- Department of Seniors, Disability Services and ATSI Partnerships. (n.d.). Legislation and public access. Accessed 28/4/22 from https://www.dsdsatsip.qld.gov.au/resources/dsdsatsip/disability/guide-hearingassistance-dogs/facts-legislation-and-access.pdf
- Disability Discrimination Act 1992 (Commonwealth). Accessed from https://www.legislation.gov.au/Details/C2022C00087
- Disability Services. (2009). Guide, hearing and assistance dogs legislation. Information for businesses. Queensland Government. Accessed from https://www.gld.gov.au/ data/assets/pdf file/0030/216687/ghadogs-businessesbooklet.pdf
- Disability Services Act 1993 (NT). Accessed from https://legislation.nt.gov.au/en/Legislation/DISABILITY-SERVICES-ACT-1993
- Dog Act 1976 (Western Australia).
- Domestic Animals Act 2000 (ACT). Accessed from https://www.legislation.act.gov.au/DownloadFile/a/2000-86/current/DOCX/2000-86.DOCX



## [Research Paper]

OFFICIAL FO

For Internal Use Only

- Domestic Animals Act 1994 (Vic). Accessed from http://www5.austlii.edu.au/au/legis/vic/consol\_act/daa1994163/index.html#s7
- *Equal Opportunity Act 2010* (Vic). Accessed from <u>https://content.legislation.vic.gov.au/sites/default/files/2022-03/10-16a025.docx</u>
- Guide Dogs and Hearing Dogs Act 1967 (Tas). Accessed from https://www.legislation.tas.gov.au/view/whole/html/inforce/current/act-1967-042
- Guide, Hearing and Assistance Dogs Act 2009 (Qld). Accessed from https://www.legislation.gld.gov.au/view/pdf/2013-12-06/act-2009-004
- Howell, T., Bennett, P., & Tepper, D. (2019). Key terms for animals in disability assistance roles. Department of Psychology and Counselling, La Trobe University. Access from <u>https://www.ndis.gov.au/media/2542/download</u>
- Human Rights Commission. (2016). *Assistance animals and the Disability Discrimination Act* 1992 (Cth). Accessed from <u>https://humanrights.gov.au/our-work/disability-</u> <u>rights/projects/assistance-animals-and-disability-discrimination-act-1992-</u> <u>cth#:~:text=There%20is%20local%20government%20legislation%20providing%20for%</u> <u>20animals,dog%20meets%20certain%20standards%20of%20behaviour%20in%20publi</u> <u>c.?msclkid=ca60d9c9aafd11ec81bbb5ee89c69229</u>
- National Disability Insurance Scheme. (2021). *Assistance animals including guide dogs*. Accessed from https://ourguidelines.ndis.gov.au/media/1566/download?attachment
- National Disability Insurance Scheme Act 2013 (Commonwealth) accessed from https://www.legislation.gov.au/Details/C2013A00020
- National Disability Insurance Scheme (Supports for Participants) Rules 2013. Accessed from https://www.legislation.gov.au/Details/F2013L01063
- National Disability Insurance Scheme Quality and Safeguards Commission. (n.d.). Accessed from <u>https://www.ndiscommission.gov.au/</u>
- Office of Local Government. (2022). *Assistance Animals*. New South Wales Government. Accessed from <u>https://www.olg.nsw.gov.au/public/dogs-cats/responsible-pet-ownership/assistance-animals/?msclkid=fa3e4b3cb0d511ecac933256283c0d0b</u>
- Public Transport Victoria. (2019). *Assistance Animal Pass*. Victorian Government. Accessed from <u>https://www.ptv.vic.gov.au/assets/default-site/tickets/myki/concessions-and-free-</u> <u>travel/assistance-animal-pass/6c06e5093f/Assistance-Animal-Pass-Accessible-Version-Effective-November-2019.docx</u>
- Transport for NSW. (2021). Assistance animal policy. New South Wales Government. Accessed from

https://transportnsw.info/document/5511/transport for nsw assistance animal policy.p



## [Research Paper]

OFFICIAL

For Internal Use Only

Transport for NSW. (n.d.). *Apply for an assistance animal permit*. New South Wales Government. Accessed from <u>https://transportnsw.info/tickets-opal/ticket-eligibility-</u> <u>concessions/people-with-disabilities/apply-for-assistance-animal</u>

Wagait Shire Council. (2019). *Dog Management by-laws*. Accessed from <u>https://legislation.nt.gov.au/api/sitecore/SubordinateLegislation/Word?id=5372B</u>

## 9. Version control

Version	Amended by	Brief Description of Change	Status	Date
0.5	SJP131	Document created	Draft	28/4/22
0.9	MDN475	Minor Revision	Draft	04/05/22
1.0	SJP131	Final review	Cleared	5/5/22



#### FOI 24/25-0151

Research paper

**OFFICIAL** 

For Internal Use Only

## Ageing and disability

#### 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 advice provision. 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 questions:**

1. Is there an expert consensus on the relationship between disability and ageing? Do people with disabilities generally experience premature or accelerated ageing compared to people without disability?

2. Are there specific conditions or disability populations who are at greater risk of premature or accelerated ageing?

3. What level of functional impairment is typical for people ageing without other disability?

4. What services and supports are available for older people through My Aged Care compared to NDIS? How are these differences presented to the public?

Date: 01/05/2023 Requestor: <sup>\$47F - personal privacy</sup> Endorsed by: <sup>\$47F - personal privacy</sup> Researcher: <sup>\$47F - personal privacy</sup>, <sup>\$47F - personal privacy</sup>, <sup>\$47F - personal privacy</sup> Cleared by: <sup>\$47F - personal privacy</sup>



OFFICIAL

For Internal Use Only

## 1. Contents

Age	eing a	nd disability	1		
1	1. Contents2				
2	. Sum	mary	3		
3	. Agei	ng, accelerated ageing and disability	4		
4	. Agei	ng with specific conditions	6		
	4.1	NDIS participants	6		
	4.2	Schizophrenia	7		
	4.3	Intellectual disability	8		
	4.4	Dementia	9		
	4.5	Acquired Brain Injury	9		
	4.6	Parkinson's disease	10		
	4.7	Multiple Sclerosis	10		
5	. Agin	g into disability	11		
	5.1	Typical patterns of ageing	11		
	5.2	Aging into disability in Australia	13		
6	. My A	\ged Care	16		
	6.1	My Aged Care Support Options	16		
	6.2	NDIS and My Aged Care	17		
	6.3	Challenges affecting NDIS-to-MAC transition	23		
	6.4	Future Directions for Reform to Aged Care Services	24		
7	. Appe	endices	24		
	7.1	Appendix 1 – My Aged CHSP and HCP Funding Structures	24		
	7.2	Appendix 2 – HCP At-Home Subsidies and Supplements	27		
	7.3	Appendix 3 – NDIS Service Categories Grouped by Support Budget	28		
	7.4	Appendix 4 – MAC Aged Care Specialist Officer locations	29		
8	8. References				





OFFICIAL

For Internal Use Only

## 2. Summary

Ageing and disability are complex physical and social phenomena that affect people differently depending on factors which may be physiological, psychological, lifestyle related, economic, social, and environmental factors. The relationship between disability and ageing is challenging to characterise due to individual lived experience of aging and heterogenous characteristics of specific disabilities. Researchers often suggest people with disability are likely to experience premature or accelerated ageing, however there is no consensus defining accelerated ageing or how to identify it in cohorts. TRT also found substantial quality issues in the literature supporting this general claim. This is discussed in section <u>3. Ageing, accelerated ageing and disability</u>.

Strong evidence exists to support the claim that accelerated ageing is a factor in specific conditions. For example, the neurodegenerative processes characteristic of conditions such as Parkinson's disease and multiple sclerosis resemble and exacerbate the physiological processes of ageing. For these populations we can more reliably point to a likelihood that ageing related symptoms or impairments are experienced earlier and with greater severity compared to the general ageing population. Refer to section <u>4. Ageing with specific conditions</u> for more detail on the role of age in selected conditions.

Generalisations are also made problematic by a variety of competing models used to understand ageing, the large variation in functional outcomes and characteristics of older people and by the different cohorts included for analysis. Australian sources generally describe someone over 65 years of age as an 'older person'. International sources describe people over 60 as fitting into this group.

Despite these limitations, evidence demonstrates clear trends. Functional capacity declines with age, though it will happen differently for different people. Older people are more likely to experience disability and health problems and are more likely to require support for daily activities compared with younger adults. Half of older Australians report having a disability. On average, at 65 years of age, Australians can expect to live another 10 years without disability. After 75, Australians can expect to live with some level of disability. After around 80 years of age, Australians can expect to require support than older men, which may be explained by longer life-span and more years living with disability. Section <u>5. Ageing into disability</u> gives an overview of patterns in the functional capacity and health outcomes for older people in general.

In Australia, older people with a disability may be covered by two different support schemes: NDIS or My Aged Care. Section <u>6. My Aged Care</u> compares supports available through these two service systems. Older people with disability can receive NDIS supports if they entered the scheme prior to the age of 65. Older people requiring support can be supported by My Aged Care after they turn 65 or earlier in some cases. There are significant differences between the two support systems. My Aged Care Home Care Packages are typically capped at \$53,268.10 for someone with high care needs, with some additional funding available in some

Ageing and disability

Page 3 of 39





### OFFICIAL

#### For Internal Use Only

circumstances such as for those requiring enteral nutrition or dementia support. NDIS funding is not capped. My Aged Care requires a co-contribution from the client determined through means-testing, whereas NDIS reasonable and necessary supports are fully funded. From the available information, it appears access to information and services may be easier for NDIS participants compared to My Aged Care clients. For example, NDIS appear to have more local staff coverage and more detailed decision-making material available online.

## 3. Ageing, accelerated ageing and disability

There are multiple and complex connections between ageing and disability. Ageing is both a physiological process and a social process. Disability is a general term covering the relationship between impairment and environment. As such, the relationship between ageing and disability is affected by physiological, personal, social, and environmental factors. It can also be affected by *when* an impairment is developed. Researchers draw a distinction between *ageing with* disability and *ageing into* disability. Someone is ageing with disability if they live with disability prior to experiencing the effects of ageing. Someone is ageing into disability if their impairments can be traced back to the typical effects of ageing. These two groups have distinct but overlapping experiences (Chen et al, 2022; Nalder et al, 2020; Molton & Ordway, 2019).

While the relationship between ageing and disability is complex, some generalisations are possible. As in Australia (5.2 Older Australians with disability), life expectancy for people with disability is increasing around the world and the likelihood of having disability or health problems increases with age. Level of functional impairment among older people with disability is affected by social factors such as level of education and economic security (UN, 2023).

It has also been suggested that people with disability are more likely to experience accelerated or premature ageing (Lim, 2022; Putnam et al 2021; Bigby, 2020; Campbell & Putnam, 2017; Goetz et al 2010). It is likely that accelerated ageing is a factor in several diagnosed conditions such as diabetes, Parkinson's disease or younger onset dementia (refer to <u>4. Ageing with specific conditions</u>).

However, it is unclear whether this claim can be generalised for people with disability as a whole. People with disability are a heterogenous group representing all subgroups of society and so generalisations are often difficult. The claim that accelerated ageing is more likely to affect people with disability is more often mentioned than argued for. In the research we gathered, authors will cite the claim without defending it or support the claim with citations that do not actually support the claim. For example, when Campbell & Putnam (2017) note that secondary conditions for people with disability are often linked to premature or accelerated ageing, neither of the two references they cite explicitly defend that claim. Lim (2022) makes the claim explicit, "[p]eople living with long-term disabilities have various problems associated with premature ageing as their biological age is higher than their chronological age" (Lim, 2022, p.61). However, this is supported by a single citation to an article discussing only people with physical disabilities and not people living with long term disabilities in general. The cited article also does not mention differences in chronological and biological age in people with disabilities.

Ageing and disability





### OFFICIAL

#### For Internal Use Only

Other limitations in the literature include a lack of consensus definition about what accelerated ageing is. Many studies fail to define the term at all. Some studies use a broad definition which compares symptoms or impairments common in people with disabilities with symptoms or impairments common in a general ageing phenotype. Symptoms or impairments in people with disabilities are taken as evidence of premature or accelerated ageing if the condition is typical of ageing and experienced earlier than would be typical for the general population.

However, this inference is unwarranted as conditions often associated with ageing can be caused by non-ageing related conditions as well (Hannekam, 2020; Margolit & Ferrucci, 2015). In general, it can be difficult to distinguish ageing related symptoms from disability related symptoms. This may be due the possibility of similar symptoms arising from multiple conditions (for example, bladder dysfunction in spinal cord injury or as a chronic age-related condition) or to the fact that ageing and disability related impairments can exacerbate each other (for example, bone density loss can follow reduced mobility and also increase the risk of falls for people with reduced mobility) (Seeman, 2022; Putnam et al, 2021; Campbell & Putnam, 2017; Field & Jette, 2007).

Researchers respond to this limitation with more restrictive definitions of accelerated ageing. In the context of defining progeroid or premature ageing syndromes, Hannekam (2020) suggests that conditions more closely resembling the general phenotype of ageing are more likely to be a result of premature or accelerated ageing. As above, the author offers a definition based on the general phenotype of ageing, but with an added requirement that a certain number of phenotypical ageing characteristics must be present. The author suggests that 13 out of a list of 31 characteristic features of ageing must be present to classify a disease as progeroid. On this definition, only 17 conditions, mostly rare genetic disorders, meet the criteria.

However, it is not agreed whether progeroid syndromes are a good model for understanding early ageing in general. Margolit & Ferrucci (2015) offer an alternative which goes beyond phenotype to include the underlying mechanism. The inclusion of the underlying mechanism criterion explicitly excludes impairments with different causes or for which the cause is unknown. Furthermore, conditions need to include features of all four groups of ageing related characteristics: body composition, energy balance, homeostatic regulation, and neuronal function. On this definition, Werner syndrome, which is a prototypical progeroid condition on Hannekam's definition, may be a less complete premature ageing disorder than type 2 diabetes, which is not often included among true progeroid conditions.



OFFICIAL

For Internal Use Only

## 4. Ageing with specific conditions

The relationship of ageing to disability is affected by the specific conditions or impairments an individual may experience. In the sections below, we present a snapshot of the research relating to ageing and some specific conditions. The conditions we examined were chosen as they represent some of the most common conditions among over 45 year old NDIS participants (refer to 4.1 NDIS Participants).

## 4.1 NDIS participants

Around half of all NDIS participants are under 18 years old. A quarter of NDIS participants are older than 45 and 4% are over 65 (NDIS Quarterly Report to disability ministers, Dec 2022, p.118).

For participants middle-aged and older (+45 years), the ten most frequent primary disability groups were:

- 1. Psychosocial Disability
- 2. Intellectual Disability (ID)
- 3. Other Neurological
- 4. Other Physical
- 5. Acquired Brain Injury (ABI)
- 6. Multiple Sclerosis (MS)
- 7. Stroke
- 8. Hearing Impairment
- 9. Vision Impairment
- **10.** Other.

When grouped by age group, the five most common disability groups were the same for the 45-54 group and the 55-64 group (although ABI and Other Neurological were in 3rd and 5th position respectively for the 45-54 group). Psychosocial disability and ID were the two most frequent categories for these age groups as well. The biggest difference was in the over 65 group. In this group, ABI was replaced by Stroke in 5th position and Other Neurological went from 3rd position to 1st (NDIA, 2022a).

Several of the most common disability groups for participants over 45 include conditions associated with functional decline over time or conditions that become more common with age (NDIA, 2022b). The category of Psychosocial Disability includes conditions associated with progressive decline in function and potential neurodegeneration such as schizophrenia (Taube et al, 2023; Nguyen et al, 2017). Other Neurological includes progressive and age-related conditions like Parkinson's disease, Alzheimer's disease and unspecified dementia. Other Physical includes rheumatoid arthritis and other arthritis. ABI includes glioblastoma, a type of

Ageing and disability

Page 6 of 39





### OFFICIAL

#### For Internal Use Only

brain cancer with an average age of diagnosis of 64 years (Davis, 2016). MS is a progressive condition. Stroke is more frequent among older people, with 80-95% occurring in people over 50 years old (Smajlović, 2015; ABS, 2022). Sensory sensitivity including hearing and vision tend to decline with age, which may make Hearing and Vision impairments more common. The general category Other includes early onset dementia, rapidly progressing dementia and other medical conditions related to cancer or respiratory problems which are more common with age (ABS, 2022).

Regarding outcomes for NDIS participants, older participants are more likely than younger participants to report poor health outcomes, less likely to be employed, and more likely to express satisfaction with the amount of choice they have compared to younger adult participants. Rates of reported community participation are increasing and are roughly similar for participants regardless of age group, averaging at 42%. The percentage increase is smallest for participants aged over 55 years (NDIA, 2022c).

The average total plan budget increases with age. The average for 45-54 age group is \$88,500 and this increases to \$97,400 for the 55-64 and \$100,500 for over 65s. The average payment size for 45-54 age group is \$63,600, increasing to \$69,400 for 55-64 age and \$73,500 for over 65s. Participant plans are also increasing over time and increasing the longer a participant stays in the scheme. The rate at which plans are increasing is highest for participants over 65 years, at roughly 8% per year (NDIA, 2022c).

## 4.2 Schizophrenia

It is likely that people with schizophrenia experience earlier physical decline and age-associated diseases and are more likely to die earlier than the general population. This may be partly due to personal and social factors including high rates of smoking, sedentary lifestyles and poor access to health services (Taube et al, 2023). There is evidence pointing to accelerated ageing as the underlying mechanism for worsening health with age, although there is still some unclarity due to the design and quality of studies. Similar conclusions are evidenced for major depressive disorder, bipolar disorder and post-traumatic stress disorder.

A systematic review from Nguyen et al (2018) summarises the literature on health-related complications for people with schizophrenia:

It has been known for more than a century that schizophrenia is associated with markedly increased physical comorbidity and mortality. Physiological changes seen throughout the body with normal ageing occur at an earlier age in people with schizophrenia than in healthy comparison subjects. Younger adults with schizophrenia are prone to diseases associated with ageing such as diabetes and cardiovascular disorders. The average life span of a person with schizophrenia is 15–20 years shorter than that of an unaffected person and patients with schizophrenia have 2–12 times higher mortality rate than age-comparable general population (p.398).



### OFFICIAL

#### For Internal Use Only

This is partially supported by a recent large scale New Zealand-based study of almost 170,000 aged care assessments (Taube et al, 2023). The authors found people with schizophrenia over 65 years of age generally required care 5.5 years earlier than the general population and generally required a higher level of care. The rates of diabetes and chronic obstructive pulmonary disease were higher in people with schizophrenia. However, other conditions such as coronary heart disease, congestive heart failure and stroke were less frequent than in the general population.

There is also evidence of early mortality and high rates of comorbid conditions for post-traumatic stress disorder, bipolar and major depressive disorder (Montejo et al, 2022; Han et al, 2018; Lohr et al, 2015).

In a recent narrative review (Seeman, 2022), the author suggests a general consensus that accelerated ageing is characteristic of schizophrenia. While there is evidence to support this, the hypothesis that comorbid conditions and early mortality is caused by accelerated ageing is not proven (Nguyen et al, 2018). Studies using neuroimageing with machine learning have shown subjects with schizophrenia have brain age higher than their chronological age. Constantinides et al (2023) conducted a large brain age study of 5000 subjects which showed participants with schizophrenia have a brain age 3.55 years greater than the control group. This is inline with other studies that found participants with schizophrenia have a brain age 2.6 - 7.8 years greater than the control group (Constantinides et al, 2023; Seeman, 2022; Chen et al, 2022).

However, the clinical or functional importance of this finding is not clear. Constantinides et al did not find a significant correlation between brain age and symptom severity in schizophrenia, though other studies have (Chen et al, 2022). Nor did they control for other factors which could increase brain age such as smoking or body mass index. When examining a wider range of biomarkers for ageing, Nguyen et al (2018) found more equivocal results mainly due to limitations in the design and quality of included studies. Despite this, all studies we've reviewed suggest that evidence is pointing towards validation of the accelerated ageing hypothesis.

The accelerated ageing hypothesis is also supported for other psychiatric conditions. There is evidence of accelerated ageing from brain age scans and other biomarkers in people with major depressive disorder, bipolar disorder and post-traumatic stress disorder (Ballester et al, 2022; Clausen et al, 2022; Bersani et al, 2019; Han et al, 2018; Lohr et al, 2015).

## 4.3 Intellectual disability

The lifespan of people with ID began to grow in the 1970s, possibly due to deinstitutionalisation and other improvements in care and services (Garcia-Dominguez et al, 2020; Tse et al, 2018; NICE, 2018).

Health conditions and impairments typically associated with ageing can occur earlier in people with ID (Garcia-Dominguez et al, 2020; Bigby, 2020; Trollor et al, 2017). A Spanish study of over 1,000 people with ID concluded that people over 44 years of age with ID may experience health

Ageing and disability

Page 8 of 39





### **OFFICIAL**

#### For Internal Use Only

conditions more frequently than older people without disability (Garcia-Dominguez et al, 2020). Another large study showed over 50s with ID had a mean frailty score similar to over 75s in the control group (Scharfour et al, 2022).

Risk factors which can contribute to the presence of ageing related concerns and other health conditions in people with ID include: access to health services, food and accommodation insecurity, sedentary lifestyles, and use of multiple medications (Garcia-Dominguez et al, 2020; NICE, 2018; Trollor et al, 2017).

Evidence suggests premature ageing is a feature of Down Syndrome, a genetic condition causing ID. Up to 80% of people with Down Syndrome may develop dementia by 65 years of age compared to less than 1% for people without disability (NICE; 2018; Tse et al, 2018; Lauterescu et al, 2017).

Bigby (2020) argues that while premature ageing is shown to affect people with Down Syndrome and certain other subgroups of ID, it may not be a major concern for other subgroups. ID is a heterogenous group encompassing many distinct but related conditions and causes and generalisations about the group as a whole may be misleading.

### 4.4 Dementia

Age is the most significant risk factor in developing dementia (ABS 2019b; Grande et al, 2020). In Australia, the risk of developing dementia increases substantially after 75 years of age. Other risk factors include hypertension, obesity, smoking and diabetes (Prince et al, 2016), each of which are common for people with disabilities in Australia (refer to <u>5.2 Older Australians with disability</u>).

Just 0.1% of people under 65 have dementia (ABS 2019b). Younger onset, or early onset, dementia is diagnosed when symptoms occur prior to 65 years of age. Several conditions are identified as potential causes of younger onset dementia including Huntington's disease, Parkinson's disease, traumatic brain injury and Down Syndrome (Vieira et al, 2013; Fann et al, 2018).

Ageing has also been identified as a likely underlying mechanism in the aetiology of dementia. Interventions aimed to slow the rate of brain ageing have been shown to delay the onset of symptoms and slow the progression of symptoms associated with dementia (Liu, 2022; Grande et al, 2020).

## 4.5 Acquired Brain Injury

Traumatic brain injury has been associated with early cognitive decline, including problems with memory and attention and higher risk of dementia (Fann et al, 2018; Wood et al, 2017). People with traumatic brain injury are at increased risk of developing comorbid conditions as they age and risk of sustaining a traumatic brain injury is higher for people with existing conditions (Hanafy et al, 2021).



### OFFICIAL

#### For Internal Use Only

Age is an important risk factor for stroke (Grefkes & Fink, 2020; Cojocaru et al, 2013). However, Hunter and Kelleher (2023) argue that relying too much on age to assess risk of stroke may lead to over-serving of the older population. This is because the importance other risk factors vary by age. For example, body-mass index, cholesterol, blood pressure and smoking are risk factors for stroke, although their predictive power declines with age (Hunter and Kelleher, 2023; Smajlovic, 2015).

Stroke can exacerbate age related functional decline. Both stroke and the typical process of ageing can lead to loss in muscle strength and mobility. When stroke occurs in an older person, muscle atrophy and accumulation of intramuscular fat is accelerated beyond the typical rate of ageing (Sions et al, 2012).

### 4.6 Parkinson's disease

Parkison's disease has been linked to premature ageing, with prevalence and severity increasing with age. Older people with Parkinson's disease experience motor impairment, cognitive impairment and falls earlier than the general ageing population (Tenison & Henderson, 2020). Researchers disagree about how best to characterise the relationship between ageing and the disease, although it is clear ageing is a factor along with other genetic and environmental factors (Tenison & Henderson, 2020; Kilzheimer et al, 2019).

Parkinson's disease is a neurodegenerative disease. Symptoms are often recognised during mid-life with major motor symptoms increasing in severity after 60 years of age (Kilzheimer et al, 2019). Prevalence of Parkinson's disease rises exponentially with age. Processes characteristic of typical ageing are also recognised as features of Parkinson's disease, such as increasing inflammation and weakening immune system, and these processes likely exacerbate the functional decline typical of ageing (Tansey et al, 2022; Tenison & Henderson, 2020; Pang et al, 2019; Collier et al, 2017). Comorbidity and frailty are more frequent in older people with Parkinson's and can exacerbate the progression of the disease (Tenisons & Henderson, 2020). Conditions such as traumatic brain injury, anxiety and depression are also risk factors for developing Parkinsons (Pang et al, 2019).

## 4.7 Multiple Sclerosis

Older age is the strongest predictor of greater levels of disability for people with MS. Compared with younger people with MS, older people are more likely to experience depression, falls, bladder dysfunction, pain associated with muscle spasticity, and are more likely to require assistive with mobility and self-care (Roy et al, 2017; Sanai et al, 2016).

Cognitive impairment is common in people with MS, affecting 40-60% of people and it is more common in older people with MS. However, evidence suggests that the rate of cognitive decline in MS is similar to typical ageing. MS is not thought to exacerbate cognitive decline in the same way that it exacerbates decline in motor skills and mobility (Branco et al, 2019; Roy et al, 2017; Sanai et al, 2016).



### OFFICIAL

#### For Internal Use Only

Similar rates of age-related conditions such as diabetes, hypertension and hyperlipidaemia are found in older people with MS compared with the general ageing population. However, presence of these conditions may exacerbate mobility difficulties and lead to need for earlier mobility support (Sanai et al, 2016).

Processes characteristic of typical ageing such as menopause, decreasing effectiveness of the immune system, increasing inflammation, accumulation of iron and oxidative stress may exacerbate the neurodegenerative process in MS (Zeydan & Kantarci, 2020; Sanai et al, 2016). Disease modifying treatments may also become less effective with age (Zeydan & Kantarci, 2020).

Most cases of MS initially present with a relapsing-remitting phase, in which the person experiences new symptoms or worsening symptoms followed by a period of recovery (MS Australia, n.d). Recovery after a relapse becomes less efficient with age. Transition to the progressive phase of the disease usually begins around the age of 45 when symptoms gradually worsen. Relapses still occur during the progressive phase but become less frequent as neurodegeneration occurs. When a relapse occurs in older people, this can lead to a significant new level of functional challenges due to the slower recovery time and progressive nature of the symptoms (Zeydan & Kantarci, 2020; Sanai et al, 2016; MS Australia, n.d).

While most people with MS go on to experience a progressive phase of the disease, up to a third remain in the relapse-recovery phase despite ageing. There may also be a relationship between age of onset and risk of developing the progressive form of the disease. Onset at 40 years may double the risk of transitioning to the progressive phase compared to onset at 20, while onset at 50 was showed to triple the risk (Sanai et al, 2016).

## 5. Aging into disability

## 5.1 Typical patterns of ageing

Researchers use many different models and theoretical frameworks to understand typical ageing. Forming consensus in this area is an ongoing project for research communities (Abud et al, 2022; WHO, 2020). This lack of consensus can make generalisations difficult. Across models and frameworks, researchers are also finding heterogeneity in the outcomes for ageing people. While some generalities are possible regarding typical patterns of ageing, studies emphasise the wide spread of functional outcomes across this group (WHO, 2020; WHO, 2015).

There is also evidence to suggest increasing heterogeneity of outcomes with age. The World Health Organisation has mapped the care needs for older people in 37 different countries based on three outcomes: ability to get dressed, ability to take medication and ability to manage money. Together these three outcomes are taken as a proxy for care needs in general and provide a basic needs score (0 - 100), with higher score indicating a person's greater ability to meet their own needs). In Figure 1 below, we can see a left-hand clustering of basic needs score about 90 for all countries included in the analysis. This shows at around 60 years of age, most people can



### **OFFICIAL**

### For Internal Use Only

meet most of their basic needs. As age increases, the average trends downwards indicating decreasing capacity. But also, as age increase and especially after 80 years, the scores for each country begin to diverge showing a much greater variety in basic needs (WHO, 2020). Other studies show similar trends using different measure of general functional capacity (Beard et al, 2019; WHO, 2015).

Recent studies have identified general trajectories of progression of functional capacity over time (Moreno-Augusto et al, 2020; WHO, 2020). Moreno-Augusto et al (2020) found evidence of three trajectories over a ten-year period: relatively high functional capacity which is fairly stable over time; relatively low functional capacity which is stable over time; fast decline from high capacity to low capacity. Identifying factors likely to place someone on either of these trajectories could assist in determining which populations are at greater risk of the following the low-stable or rapid-decline trajectory. At this stage, physical activity has been shown to increase the likelihood that someone follows the high stable trajectory.



Figure 1, Basic needs score by age (WHO, 2020).



OFFICIAL

For Internal Use Only

## 5.2 Aging into disability in Australia

Population ageing is a global phenomenon occurring in almost every country in the world. The number of people over 65 is increasing faster than the number of people under 65 (UN, 2023). In an Australian context, this is confirmed by survey data from the Australian Bureau of Statistics' (ABS) Survey of Disability, Ageing and Carers (SDAC) (ABS, 2019a).

Life expectancy for Australians is increasing, including for Australians with disabilities. Disability prevalence increases with age (AIHW, 2017; ABS, 2019a). In the most recent SDAC, half of Australians over 65 years of age identified as having a disability compared to 1 in 9 people 64 years and under.

A report from the Australian Institute of Health and Welfare (AIHW, 2017) suggests that while increasing life-expectancy and increasing disability prevalence with age may result in more people living with disability in old age, it does not result in more years Australians are living with disability due to age (compare Figures 2 and 3 below). The improved longevity of Australians appears to show up in years free of disability. On average, women over 65 years can expect to live another 10 years without disability, and another 12 years with some level of disability. On average, men over 65 years can expect to live another 9 years without disability, and another 10 years with some level of disability. Among older Australians with disability, 35.5% identified profound or severe limitations, 15% identified moderate limitations and 40% identified mild limitations (ABS, 2019a).



Figure 2, Prevalence of disability by age in 2015 and 2018 (AIHW, 2017)



OFFICIAL

### For Internal Use Only

Figure 3, Health life expectancies over time by age, males and females (AIHW, 2017)



The prevalence of physical and sensory or speech disability begins to rise steeply from 34-44 age group. By the age of 65, Australians with disability are around twice as likely to have sensory or speech disability and around three times as likely to have physical disability compared to ID, ABI or psychosocial disability (AIHW, 2022a).

Australians with disability and older Australians are more likely to report their health status as either Fair or Poor (AIHW, 2022a) and this remains true when comparing age groups and disability status. Older Australians with disability are more likely than any other group to report poor health outcomes (refer to <u>Table 1</u>).

Table 1: Percentage of older Australians with disability reporting poor health outcomes with and without disability by age group

Age	With disability	Without disability	Either with or without disability
Under 65	39.3	6.3	12.2
Over 65	44.3	9.9	26.1
Any age	41.2	6.7	14.8

Source: (AIHW, 2022b).

People with disability show higher rates of some health risk factors and behaviours for poorer health outcomes compared to people without disability (AIHW, 2022a). Compared to older people without disability, people with disability are less likely to consume a healthy diet or get adequate exercise and more likely to be overweight or obese, smoke cigarettes and experience problems with blood pressure. Older people with disability are less likely to smoke and drink but are also less active and more likely to have problems with weight and blood pressure compared to younger people with disability (AIHW, 2022c).

Chronic health conditions can be associated with a level of disability, and the prevalence of chronic health conditions increases with age (AIHW, 2022a; ABS, 2022). Most older Australians (86.5%) reported one or more long-term health conditions, increasing to 98% by 85 years.

Ageing and disability



### OFFICIAL

#### For Internal Use Only

Prevalence of dementia jumped to 27.5% by 95 years, compared to 0.1% for people under 64, 0.7% for 65-74 age group, 3.6% for 75-84 age group and 19% for 85-94 age group (ABS, 2019b). The most common health conditions for older Australians are arthritis, hypertension and back problems. The most common health conditions for people with disability are arthritis and back problems (ABS, 2019a; AIHW, 2022a).

AIHW (2022a) note that 30% of Australians with disability have musculoskeletal problems such as arthritis or back problems. SDAC note that as a group Australians with disability are less likely to have arthritis than older people (12.7% compared to 15.6%) but more likely to have back problems (12.6% compared to 8.7%), psychosis and mood disorder (7.5% compared to 4.6%), intellectual and development disorders (6.5% compared to 0.1%) and neurotic, stress related and somatoform disorders (6.1% compared to 2.1%) (ABS, 2019a).

Based on SDAC data, AIHW (2022a) also note that 15% of older people with a disability have a health condition that was caused by ageing. Under 2% of adults 25-64 report a health condition caused by ageing (AIHW, 2022d). However, as the SDAC data is based on self-reported survey responses, this can only be a rough guide to aetiology.

Not all older Australians with disabilities identified a need for assistance. While half of older Australians identified as having a disability, only 53% of that group identified a need for assistance. Older Australians with disabilities were most likely to require assistance with healthcare (84%), mobility (56.6%) and self-care tasks (42%).

Among older Australians regardless of disability status, 38% identified a need for assistance. This group was most likely to require assistance with health care, property maintenance and household chores. Among those who required assistance with specific activities, they were generally more likely to receive assistance from family and friends than governments or private organisations. The exception was healthcare. Most people needing assistance with healthcare (65%) received services from formal supports (ABS, 2019a). Women were more likely to require support across every domain. This may be due to longer average lifespan and more years living with disability (ABS, 2019a; AIHW, 2022e). This gender-based trend is also supported by international sources (UN, 2023; WHO, 2020). Around two-thirds of older Australians with disability receive a government pension, compared to less than half of people without disability (AIHW, 2022a).





OFFICIAL

For Internal Use Only

## 6. My Aged Care

## 6.1 My Aged Care Support Options

There are two My Aged Care support options similar to the NDIS that can be accessed by ageing Australians with a disability to assist with their daily living needs if they are still living at home. These options are Commonwealth Home Support Programmes (CHSPs) and Home Care Packages (HCPs) (Commonwealth Home Support Packages, n.d.; Home Care Packages, n.d.; Commonwealth Home Support Programme: Interaction with Home Care Packages, n.d.). There is some overlap between these two programs as described below (refer to Table 2 and Table 3).

Individuals accessing My Aged Care are referred to as "clients" in the same way that individuals accessing the NDIS are referred to as "participants" (What is the NDIS?, 2022; My Aged Care, 2020). There are different co-contribution rules for individuals who have entered an aged care home (Department of Health and Aged Care, 2023a), however this is outside the scope of this paper as the individual would generally no longer be eligible to be a participant with the NDIS (Leaving the NDIS, 2022). Therefore, all mentions of CHSPs and HCPs in this document will be assumed to be within the context of an at-home basis.

Table 2: Similarities between CHSPs and HCPs

Property	CHSPs and HCPs
Purpose	Both provide funding to ageing Australians to maintain capacity at home
Eligibility Assessment	Both require an aged care assessment for eligibility
Service Compatibility	Clients may be eligible to access both services if assessed as such

Source: (Commonwealth Home Support Packages, n.d.; Home Care Packages, n.d.; Commonwealth Home Support Programme: Interaction with Home Care Packages, n.d.)

Table 3: Differences between CHSPs and HCPs

Property	CHSPs	HCPs
Varying levels of care?	No, fixed subsidies	Yes, categorised based on care level (1-4)
Assessing Team/Service	Regional assessment service	Aged care assessment team/service
Funding Structure	Government grants to providers in exchange for subsidise services	Monthly funding comprised of a government contribution and client co- contribution
Government Contribution	Less	More/potential subsidies and supplements

Ageing and disability



### OFFICIAL For Internal Use Only

Property	CHSPs	HCPs	
Client Co- Contribution	No	Yes, multifactorial co-contribution calculation	
Income tested?	No	Yes	
Ease of approval	Easier to obtain approval	Harder to obtain approval	
Access waiting times	Shorter	Longer, higher level = longer wait (esp. L2-4)	
Level of care	Basic care	Complex care	
Care duration	Occasional or short-term basic care	Ongoing regular or short-term complex care	

Source: (Commonwealth Home Support Packages, n.d.; Home Care Packages, n.d.; Commonwealth Home Support Programme: Interaction with Home Care Packages, n.d.; Leaving the NDIS, 2022; Department of Health and Aged Care, 2023b; Department of Health and Aged Care, 2022a; Department of Health and Aged Care, 2017; Commonwealth Home Support Programme costs, n.d.; Home Care Package costs and fees, n.d.; Department of Health and Aged Care, 2022b; Department of Health and Aged Care, 2022b; Department of Health and Aged Care, 2022c; Department of Health and Aged Care, 2022b; Department of Health and Aged Care, 2022c; Department of Health and Aged Care, 2022c; Department of Health and Aged Care, 2022d)

For further details on funding structures and costs refer to <u>Appendix 1 My Aged Care CHSP and</u> <u>HCP Funding Structures</u>. For further details on subsidies and supplements refer to <u>Appendix 2</u> <u>HCP At-Home Subsidies and Supplements</u>.

## 6.2 NDIS and My Aged Care

### 6.2.1 Comparison of program structures/financial models

The NDIS is not intended specifically to support ageing Australians in the same way that the MAC program is. Instead, individuals who enter the NDIS due to disability prior to the age of 65 may continue to receive disability support and in the process tangentially receive support for their aged care needs (What is the NDIS?, 2022; About us, n.d.).

The structural and financial factors described in <u>Table 4</u> could be a factor in discouraging individuals from making the transition from the NDIS to MAC. Assuming an individual satisfies the entry criteria for both services, the individual may have a significantly faster and smoother onboarding process, access to more funding, and better ongoing support through the NDIS compared to MAC. In particular, as noted in the Royal Commission into Aged care, the wait time for receiving an approved package from MAC can exceed 12 months for some applicants as there is a cap on the number of MAC support packages available. This may lead individuals to favour applying for the NDIS over MAC and to continue utilising the NDIS over the age of 65 instead of transitioning to MAC.



OFFICIAL

### For Internal Use Only

Table 4: Comparison of Structures and Financial Models of the NDIS and MAC Program

Property	NDIS	MAC
Funding model	Insurance model: participant's needs are assessed; funding is allocated according to needs	Welfare model: client is categorised into a CHSP and/or HCP/category program based on needs; funding is provided monthly according to category rather than specific needs
Age limits	Must be under 65 to enter the scheme, participant can remain on the scheme past 65 if they are able to remain at home	Must be over 65 to enter the scheme; except for indigenous Australians, who can enter the scheme at 50
Income testing?	No	Yes
Funding Capped?	No funding caps	Funding caps based on service and HCP category
Co-contributions?	No co-contributions	Co-contributions based on service and category
Funding increments	Funding is upfront in a lump sum for capital supports, delivered quarterly in PACE	CHSP subsidies delivered to providers directly, HCP Funding is delivered in monthly increments
Service/support access timeframe	Participant receives necessary services/supports as soon as possible	Cost of services/supports must be accumulated via monthly payments; client may wait months or years regardless of urgency
Funding transparency	All services/supports have a corresponding support line item listed in plan, easy for participant to understand where funding is allocated	Due to the fixed nature of funding based on category, client does not receive any information regarding which needs/services/support make contribute to their funding amount
Funding flexibility	Flexible funding allocation within support categories	Choice of service provider, but no guaranteed flexibility of funding allocation
Service/support flexibility	Participants are free to choose which services are paid for using funding provided they are within "reasonable and necessary" criteria	No guaranteed flexibility on services/supports offered by provider, minimal communication on why specific services/supports are chosen



OFFICIAL

### For Internal Use Only

Property	NDIS	MAC
Wait times	<ul> <li>SLT has NDIS wait time stats on- band</li> </ul>	2-6 week wait for
	nand	approval/assessment
	<ul> <li>In short, NDIS wait times are</li> </ul>	<ul> <li>Exact wait times not publicly</li> </ul>
	significantly shorter and more	published
	tightly regulated than MAC wait	<ul> <li>Time between assessment</li> </ul>
	times	and offer unclear
		<ul> <li>HCP L1 reported 3-6 month</li> </ul>
		wait, L2-4 may take >12
		months
		2020 Productivity Commission
		Report on Government Service
		Statistics:
		<ul> <li>HCP L1 average 7-month</li> </ul>
		wait
		<ul> <li>HCP L4 average 34-month</li> </ul>
		wait

Source: (Post Polio Victoria, 2021; Am I Eligible?, 2022; What is the wait time for services?, n.d.; Royal Commission, 2021).

### 6.2.2 Comparison of application process accessibility between NDIS and MAC

The application process is the first contact between an individual and a given support service. Accessible review services are essential to support individuals throughout their application, and during their ongoing care under a given support scheme. Individuals may have differing experiences when applying to the NDIS or MAC, as described in <u>Tables 5</u>, <u>6</u>, <u>7</u> and <u>8</u>.

Across all discussed application methods, the NDIS offers more accessible and robust application processes and more extensive support resources to assist with completing an application through any method. Dedicated reviews and resolutions infrastructure ensures that NDIS participants who are unhappy with any aspect of their application and ongoing care have a clear pathway to address these concerns, and that they retain a full account of all review and resolution outcomes in a single, continuous record. In comparison, MAC clients have limited application options, less support throughout the application process and must navigate a complicated series of disconnected complaint channels if they are unhappy with any part of their application or ongoing care. Due to the fragmented nature of these complaint processes, it would be difficult to keep track of a MAC client's complaint outcome history if they had faced significant challenges throughout their application and ongoing care. Furthermore, the reasoning behind decisions such as whether or not to provide both a CHSP and HCP or only one, what level of HCP is offered (if any), and the option to accept a lower-level interim HCP while waiting for a high-level HCP, for example, is not clearly communicated to MAC clients on the MAC website,





#### OFFICIAL

#### For Internal Use Only

potentially making it harder for clients to be informed when requesting a review or making a complaint.

The extensive network of LACs and NDIS offices provides a wide catchment for regional and rural participants wishing to make a face-to-face application. When a face-to-face application is unfeasible or not preferable, the NDIS maximises opportunity for regional and rural participants to apply for the scheme by providing a robust online application service and continuing to operate a verbal application service. In comparison, the limited Aged Care Specialist Officer (ACSO) network might make face-to-face applications for the MAC difficult in states and territories where ACSO coverage is insufficient. Furthermore, a lack of dedicated verbal applications services and online application assistance compromise the accessibility of alternative application methods. Having full translation services capable of assisting with all aspects of an NDIS application significantly increases accessibility for linguistically diverse participants. In comparison, the lack of clearly indicated translation services for the MAC may have the opposite effect.

However, the existence of accessibility services alone does not guarantee a diverse applicant is aware of their existence to seek them out in the first place. Furthermore, barriers to entry may compound for applicants with a multitude of diverse experiences. Therefore, it is important to acknowledge regional and rural indigenous communities whose experiences may intersect all three discussed axes of diversity (Department of Social Services, 2021).

Table 5: Comparison of NDIS and MACS online application methods:

NDIS			MAC	
•	Google searched "How to join NDIS", first result takes applicant directly to NDIS "How to Apply" page "How to Apply" page clearly describes the	•	Google searched "How to join My Aged Care", first result only takes applicant to MAC homepage Application instructions and support	
	application process and support resources on a single page		resources may be hidden behind buttons and modules	
•	Primary application method: Access Request Form	•	Primary application method: "3-step" online application process	
•	Support resources for alternate methods of completing application clearly outlined on first page of request form, application can be fully completed verbally if required	•	<ul> <li>Check for eligibility</li> <li>Submit details</li> <li>Organise assessor</li> <li>Option provided to call a general support</li> </ul>	
•	Translation services clearly indicated		hotline, though whether a full application can be completed over the phone or with verbal assistance is unclear	
		•	No clear instructions to access translation services	

Source: (How to apply, 2023; Access Australian aged care information and services; n.d; Apply for an aged care assessment online, n.d).

Table 6: Comparison of NDIS and MACS phone application methods

Ageing and disability



## OFFICIAL

#### For Internal Use Only

N	DIS	МАС	
•	Able to complete entire application verbally/with phone assistance Option available to request physical copy of application form be mailed out for completion and return via post	<ul> <li>Applicant seems expected to submit the initial application without over-the-phone assistance. If information is correct application will proceed to organising a assessment. Otherwise, an error is flagged and the application is halted until a operator reviews the case and contacts the applicant to resolve the error</li> <li>MAC recommends accessing the Older Persons Advocacy Network for assistance but network is third-party, has limited locations compared to the LAC network.</li> </ul>	

Source: (How to apply, 2023; Access Australian aged care information and services; n.d; Apply for an aged care assessment online, n.d).

Table 7: Comparison of NDIS and MACS face-to-Face application methods:

NDIS	MAC	
<ul> <li>Numerous and widespread LACs and NDIA</li></ul>	<ul> <li>No dedicated shopfronts</li> <li>Instead, Aged Care Specialist Officer</li></ul>	
offices available as shopfronts fo	(ACSO) service implemented via Service	
accessible in-person assistance and	Australia in 2021 <li>Operates out of Services Australia centres</li> <li>Limited locations (refer to <u>Appendix 4</u>)</li> <li>ACSO Services:         <ul> <li>Give in-depth information about the</li></ul></li>	
comprehensive advice on all NDIS services	different types of aged care services <li>Check aged care services eligibility</li> <li>Refer for an MAC assessment</li> <li>Give you financial information about</li>	
if necessary	aged care services <li>Help appoint an MAC representative</li>	

Source: (Offices and contacts in your area, n.d; Aged Care Specialist Officer, 2023)



OFFICIAL

### For Internal Use Only

Table 8: Comparison of NDIS and MACS Review/Complaints Submission Methods:

NDIS			MAC	
•	Dedicated reviews and resolutions team, and publicly available information detailing how a review can by lodged by a participant, their carer, or guardian "Right of review" Clearly defined and tightly regulated response timeframes	•	Complicated complaints/reviews process with different processes depending on the level/nature of complaint Only complaint process handled directly by MAC is for direct issues with MAC application process - No clear timeframes beyond acknowledgement after 10 business days Any issues from assessment onwards are handled through separate parties (refer to <u>Appendix 5</u> ) - No central management/record of complaints - No timeframes provided	

Source: (Request a review of a decision, 2022; Contact Us, n.d.; How to make a complaint, 2020; Making a complaint about aged care services, n.d).

### 6.2.3 Comparison of services provided by the NDIS and MAC

The NDIS and MAC do not offer identical supports and services, although there is significant overlap between the two programs. MAC separates its offered services amongst 4 categories based on the aspect of daily life that the service aims to support, whereas the NDIS separates its offered services amongst 15 categories that are organised under the three different support budgets, which are also based on the aspect of daily life that each budget aims to support (Request a review of a decision, 2022; Contact Us, n.d.; How to make a complaint, 2020; Making a complaint about aged care services, n.d;). Refer to <u>Appendix 3</u> for a list of services covered by each NDIS service category (Supports and services funded by the NDIS, 2021; Support budgets in your plan, 2022; Aged Care Services, n.d.).

There is no exact equivalence between the two schemes' categorisations. Refer to <u>Table 9</u> and <u>Table 10</u> for a description of overlapping services.

Table 9: MAC Service Category: "Services for keeping me well"

MAC Service Offered	Overlapping NDIS Service Categories
Bathing, hygiene, and grooming	1
Help with impairments or continence	1, 3, 5, <mark>6</mark>
Meals and food preparation	1
Nursing"	15
Podiatry, physiotherapy, and other therapies	12