Australian e-Health Research Centre

Australia's National Science Agency

Framework for Artificial Intelligence-enabled Assistive Technology as Supports under the National Disability Insurance Scheme

Final Report

Silvera, D., Packer, K., Higgins, L., Walker, J., Niven, P., Li J., Byrnes, J., Khanna, S., Liu, D., Freyne, J.

EP2022-1642

Prepared for the National Disability Insurance Agency
May 2022

Citation

Silvera, D. et al (2022) Framework for Artificial Intelligence enabled Assistive Technology as Supports under the National Disability Insurance Scheme: Final Report.

Executive Summary

Background

Artificial intelligence (AI) offers enormous opportunities for people with a disability (PWD) and will continue doing so in the coming years. These innovations have the potential to promote better functioning as well as greater independence and dignity. This is particularly evident where AI is embedded with assistive technology (AT).

The National Disability Insurance Scheme (NDIS) is committed to ensuring that participants in the Scheme have access to the most effective supports to achieve their goals. The use of digital tools, services and products that support various aspects of daily life have seen huge sector growth. While many products have applicability for PWD (e.g., domestic robots, digital assistants, autonomous vehicles, etc.) there is a significant shortfall of AI-enabled products and services being developed in Australia specifically for the disability sector. Furthermore, there is little guidance available for users, funders, or creators of AI-enabled AT that support use and innovation in this space.

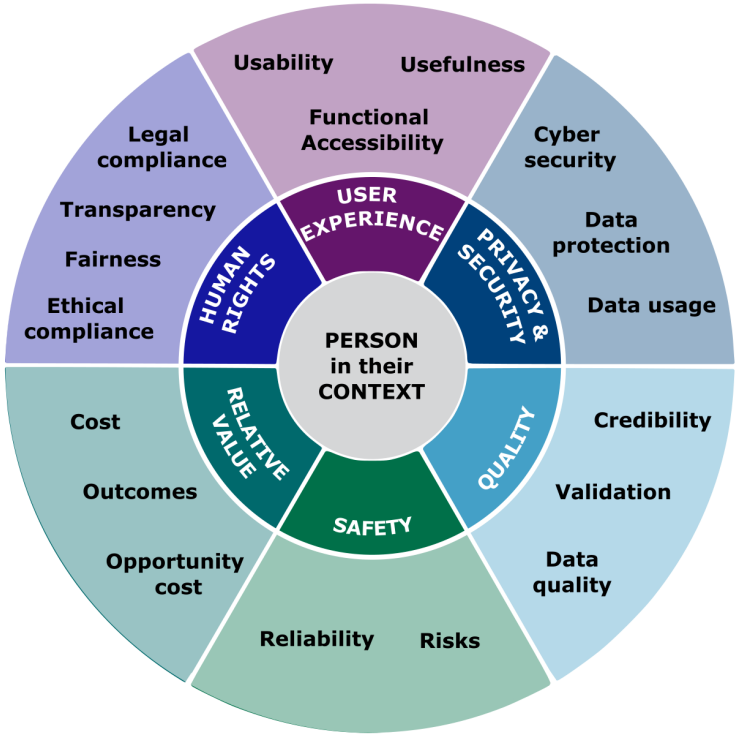
The National Disability Insurance Agency (NDIA) have led the way in developing a framework to promote innovation through the development of safe and effective AI-enabled AT. The aim is to build the NDIA and government's capacity to make decisions about AI-enabled AT, while ensuring public trust and providing PWD with a range of options to choose what works best for them. It is also expected that this framework will provide guidance to industry in ensuring appropriate and considered development of AT.

To commence this process, in April 2021 the NDIA convened a "RoundTable on the role of AI in NDIS funded supports". The purpose of this discussion was to explore the role that AI can play in supporting PWD and issues that need to be addressed to deliver best outcomes for National Disability Insurance Scheme (NDIS) participants. The outcome from the roundtable discussion was a recommendation for the development of a framework and roadmap to guide NDIS stakeholders through the development, testing, and implementation of AI-enabled AT.

Framework for AI-enabled AT

The NDIA commissioned CSIRO's Australian e-Health Research Centre (AEHRC) to design a framework (the Framework) and roadmap (the Roadmap) for AI-enabled AT. This process was undertaken in two main stages: (1) AI and AT frameworks review, (2) consultation with a variety of stakeholders (e.g., PWD, carers, and representatives from industry, peak bodies, and government departments). This process resulted in a new Framework (below) which focuses on six core domains: User Experience, Privacy and Security, Quality, Safety, Relative

Value and Human Rights. This Framework also highlights the importance of a user-centric approach which places the person with a disability and their context (e.g., environment, social and cultural factors, community etc.) at the centre of the Framework.



Framework for AI-enabled AT

Next steps: Implementation Roadmap

To support the implementation of the Framework, we are currently working with NDIA to finalise the Roadmap that will provide a pathway to implementation and adoption of the Framework. The Roadmap will be founded on key considerations identified during the development of the Framework.

Ongoing collaboration with end-users, families, carers, disability workforce, and industry stakeholders will be critical in the development and implementation of the Roadmap, and in the refinement of an equitable and effective Framework that boosts innovation and facilitates access to safe, appropriate, and beneficial AT for all.

Contents

Background 1

Framework for AI-enabled AT 1

Next steps: Implementation Roadmap 2

1 Introduction 6

1.1 Project Overview 7

1.2 AI and Assistive Technology Framework Review 7

1.3 Stakeholder consultations 8

1.4 Framework development 8

2 The Framework 9

2.1 User Experience 10

2.2 Privacy and Security 11

2.3 Quality 12

2.4 Safety 13

2.5 Relative Value 14

2.6 Human Rights 14

3 Next steps: Implementation Roadmap 17

4 Conclusion 18

References 19

Appendix 24

Definitions

Artificial Intelligence: a collection of interrelated technologies used to solve problems autonomously and perform tasks to achieve defined objectives, in some cases without explicit guidance from a human being (Hajkowicz et al., 2019).

Artificial intelligence-enabled assistive technology: a term to denote assistive technology that incorporates artificial intelligence.

Assistive products: Physical or digital device (whether acquired commercially, modified, or customized) whose primary purpose is to maintain or improve functional capabilities and independence of people with a disability, and thereby promote their well-being.

Assistive technology: an umbrella term for the combination of devices and services used by individuals with a disability to perform tasks that might otherwise be difficult or impossible to complete due to their disability.

Many assistive products are purpose-built assistive technology specifically developed to support people with a disability. There is also a range of commonplace products that fall under the umbrella of assistive technology when meeting these disability needs.

Context: the social, physical, cultural, and other factors that define the person's environment such as where a person lives, works, learns, and plays; including reliability of internet and computer access, societal structure and attitudes, cultural considerations, as well as the person's family, carers and other significant people surrounding the person.

Disability: Disability is an evolving concept resulting from individual, attitudinal and environmental barriers that hinder an individual's full and effective participation in society on an equal basis with others (United Nations, 2006).

End-User: The consumer who will ultimately use assistive products or services. In most cases, this would be a person with a disability. In some cases, an end-user may also be a person who supports a person with a disability.

Persons with disability: Individuals who have long term physical, mental, intellectual, or sensory impairments which, in interaction with various barriers, may hinder their full and effective participation in society on an equal basis with others (United Nations, 2006).

Acronyms

ADHA	Australian Digital Health Agency
AEHRC	Australian e-Health Research Centre
AI	Artificial Intelligence
AT	Assistive Technologies
CDR	Consumer Data Right
CRPD	Convention on the Rights of People with Disability
CSIRO	Commonwealth Scientific and Industrial Research Organisation
GDPR	General Data Protection Regulation
HREC	Human Research Ethics Committee
ICF	International Classification of Functioning, Disability and Health
IRG	Independent Reference Group
ISO	International Organisation for Standardization
NDIA	National Disability Insurance Agency
NDIS	National Disability Insurance Scheme
NGO	Non-Government Organisations
PFEI	Participant First Engagement Initiative
PWD	Person/People with a Disability
TAM	Technology Acceptance Model
TGA	Therapeutic Goods Administration
UN	United Nations
WCAG	Web Content Accessibility Guidelines

Acknowledgments

This work was commissioned by the National Disability Insurance Agency (NDIA). This report also acknowledges the contributions of the NDIA Participants First Engagement Initiative, the members of the independent reference groups and all the NDIS participants, industry representatives, and other stakeholders who engaged in the process and provided their valuable insights.

1 Introduction

The National Disability Insurance Scheme (NDIS) has transformed the way people with disability in Australia receive supports to participate socially and economically in their communities. Technology plays an important role in meeting the needs of participants in the NDIS, with over 70% using some form of assistive technology (AT). Working with participants and providers of supports, the National Disability Insurance Agency (NDIA) began planning for best use of current and new artificial intelligence solutions in the NDIS.

Artificial intelligence (AI) and assistive technology (AT) have the capacity to promote better health outcomes, greater independence, and greater participation in social and community roles for people with a disability (PWD). AI enabled AT are successfully being used by some people with a cognitive disability to access on-demand support, which has increased their independence at home, at work and travel. Others who may be losing function as a result of their degenerative disability have been able to use AI enabled AT to record their natural voice, which is then programmed into an AI enabled communication device; to allow them to share what they want to say in their own voice, although a little slower. Some Australian research centres are building tools that will map a person's muscular patterns, and then use artificial intelligence to manage muscle stimulation and external braces to compensate for weakness or control gaps that could lead to falls or other problems.

The development of AI-enabled AT is occurring at a rapid pace, leading to enormous choice and exciting opportunities to enhance the lives and social participation of PWD. Consequently, there is an emerging interest and demand to incorporate AI-enabled assistive products and services into the everyday life of PWD, to enable and support them with activities they would otherwise have difficulty managing or be unable to do without support. Currently, the NDIA does not have a transparent and robust process to objectively evaluate existing and new AI-enabled AT. This limits the NDIA's capability to match assistive products and services to specific functional needs and cohorts, compare AI-enabled AT with one another or to other available supports, set measures of effectiveness, and determine the level of intervention or responsibility in the market that is required to fully realise the benefit of the innovation for participants of the NDIS.

To address this limitation, the Commonwealth Scientific Industrial and Research Organisation's (CSIRO) Australian e-Health Research Centre (AEHRC) was engaged by the NDIA to develop an evaluation framework (the Framework) and roadmap (the Roadmap) to guide NDIS stakeholders through the development, testing and implementation of AI-enabled AT. The aim of this development is to encourage innovation, build consumer confidence, and increase the uptake of AI-enabled AT by PWD.

This work was guided by: the NDIS Act 2013 (National Disability Insurance Scheme, 2013) the NDIS Corporate Plan 2021-2025 (National Disability Insurance Agency, 2021) and the United Nations Convention on Rights of Persons with Disabilities (United Nations, 2006).

A.1 Project Overview

To undertake this work, the CSIRO assembled a multidisciplinary team with a broad range of expertise, including AI, clinical, economics, and evaluation expertise, to develop the Framework and Roadmap for AI-enabled AT. In addition, a steering committee with representatives from CSIRO and the NDIA, and an independent reference group (IRG) were formed to oversee the project. Four people across the steering committee and IRG identify as people with a disability.

This project comprised two main stages:

1. AI Technology Framework review.
2. Stakeholder engagement.

Ethical approval from the CSIRO Human Research Ethics Committee (2021_077_HREC) was obtained for this project.

A.2 AI and Assistive Technology Framework Review

This stage established the foundations of the Framework. Desktop research was completed to review a range of existing and proposed guidelines and assessment frameworks relevant to health (including digital health), disability, and AI domains. The regulatory and economic assessment areas were explored to reflect on key safety, quality, and cost effectiveness considerations.

In addition to expert advice, two approaches were undertaken to source representative frameworks, yielding substantial lists of proposed and implemented frameworks for the areas of health technology, AI, and AT.

1. A review of publicly available frameworks. These sources included grey literature, public websites from national government and agency websites (e.g., Department of Health, Australian Digital Health Agency, National Institute for Health Care Excellence), news articles and company policies.
2. A review of academic databases (e.g., MEDLINE, Scopus), to identify relevant academic publications (e.g., journal articles, conference proceedings, and books). As part of this process, key terms derived from the project definitions were used to guide the search, including evaluation framework, disability, assistive technology, artificial intelligence, digital health, ethics, and human rights.

A summary of the outcomes of this review is available in Appendix A1.

A.3 Stakeholder consultations

This stage explored the current needs, opportunities and potential barriers for the development and implementation of the Framework, to inform the final stages in the development of both the Framework and the Roadmap.

In this stage, focus groups and semi-structured interviews were completed with two key stakeholder groups: (1) PWD and their carers (n = 20), and (2) industry representatives, researchers, service providers, NDIA leaders and representatives from other relevant organisations (n = 18). More information about the procedure, participants, and outcomes of this stage is available in Appendix A2.

A.4 Framework development

The Framework was developed by incorporating both the insights from the desktop research and stakeholder engagement, and by balancing stakeholder priorities and practicalities of implementation. Four workshops were conducted with members from the IRG and the steering committee to refine the preliminary stages of development.

2 The Framework

The Framework was developed based on available literature and consultations with NDIA participants (i.e., PWD and carers), and representatives from industry, peak bodies, and government departments. It supports a person-centric approach for assessing AI-enabled AT, with a consideration of the context in which AI-enabled AT is to be used. It acknowledges the unique capabilities, preferences, and goals of end-users, as well as their environment.

The Framework supports decision making by four user groups:

- ***People with a disability and their community*** will use the Framework when making decisions regarding the suitability of AI-enabled AT products and services to support an identified need.
- ***NDIA/NDIS*** will use the Framework when developing polices and guidelines around AI-enabled AT and assessing support for AI-enabled AT in NDIS plans.
- ***AI-enabled AT developers and researchers*** will use the Framework as a benchmark for quality as they design, develop, and evaluate AI-enabled assistive products and services.
- ***Research and industry funding bodies*** will use the Framework in assessing support for funding applications pertaining to AI-enabled AT research and development.

Other groups, including service and product regulators (such as the NDIS Quality & Safeguards Commission and Therapeutic Goods Administration), are also likely to draw on the Framework for their roles in the provision of AI-enable AT in Australia.

The principles-based Framework is guided by a set of six core domains: User Experience, Privacy and Security, Quality, Safety, Relative Value and Human Rights (Figure 1). Each domain encompasses a principle, and two or more critical measurement areas.

A **successful** implementation of the Framework should:

1. Support decision-making capability for all stakeholders
2. Facilitate choice and control to individuals, families, and carers
3. Improve access to safe, appropriate, and beneficial AI-enabled AT
4. Protect and promote the human rights of end-users.

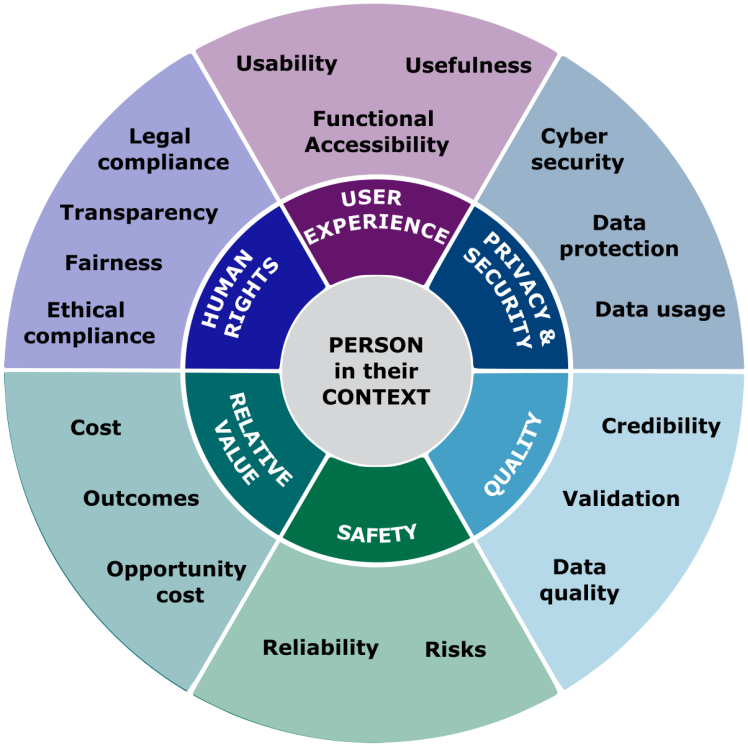


Figure 1. Framework for AI-enabled AT

A.1 User Experience

AI-enabled AT should provide a productive and positive experience to PWD.

User experience encompasses all aspects of interactions between users and a product, including purchase, setup, usage, and maintenance. Including user experience in the Framework will ensure that assistive products align to an individual's needs, abilities and limitations, and provide a positive experience to all users (usability.gov, 2021b). The Framework outlines three fundamental measures of user experience that are required to deliver AI-enabled AT that work effectively and engage users on a longer-term basis.

Measures	Guiding principles
Usability	The AI-enabled AT should promote, enable, or facilitate use, learning, engagement, and control. It should align appropriately to the end-user needs and abilities, and the contexts in which the technology will be used.
Usefulness	The AI-enabled AT should be beneficial and fulfil a need or goal for the end-user. This includes promotion, improvement or maintenance of an ability, role and/or participation within a given context.
Functional accessibility	The AI-enabled AT should be appropriate for the end-user's abilities, preferences, and context of use.

Usability: Achieving high usability rates requires in-depth knowledge of stakeholders and contexts in which the technology will be used (Klaassen et al., 2016). Typically, usability is measured relative to users' performance on a given set of tasks. Key measurements include effectiveness, efficiency, learnability, memorability, and satisfaction (Nielsen, 2012; Sheehan et al., 2012; Zapata et al., 2015). Alternative models propose instruments to assess the usability and acceptability of

technology by considering factors such as: impact, perceived usefulness, perceived ease of use, perceived intention to use, and user control (Schnall et al., 2018; Venkatesh & Davis, 2000).

Usefulness: Determines if the technology fulfills a need or goal for the end-user. The International Classification of Functioning, Disability and Health (ICF) Framework (World Health Organisation, 2002) is an example of a tool that can be used to assess the utility of an assistive product.

Functional accessibility: Accessibility has become part of regulatory and compliance standards (International Organisation for Standards, 2014) for the development of AT such as web content and applications (usability.gov, 2021a). In Australia, for instance, government agencies are required to meet the Web Content Accessibility Guidelines (WCAG) 2.0 Level AA (World Wide Web Consortium, 2008) when developing web interfaces (Digital Transformation Agency, 2021). Products that implement accessibility best practices ensure that PWD can equally access, understand, interact with assistive products and have a positive and productive experience (usability.gov, 2021a).

A.2 Privacy and Security

AI-enabled AT should ensure all people's data is protected.

Privacy and security considerations encompass the collection, storage, transfer, and usage of user data. Establishing and maintaining information security practices is a professional and legal requirement when using digital systems in the delivery of AT. Three measures required to evaluate privacy and security are proposed.

Measures	Guiding principles
Cyber security	AI-enabled AT should be designed and certified to ensure best security practices and relevant cybersecurity guidance have been followed.
Data protection	All data must be protected in transit and in storage to ensure confidentiality and integrity, following relevant data privacy policies and regulations.
Data usage	Data should only be used for purposes consented by users. Personal data must not be kept for longer than it is needed.

Cybersecurity: The connection of technologies to networks or the internet exposes them to increased cyber threats that can potentially lead to increased risk of harm to the user and those living with them. Consequently, current best practice approaches to minimising cyber security risks ensure that both the manufacturer of a technology and the end-user are mindful of the changing risk profile over the total life span of a technology. In this vein, Cyber Security Principles from Australian Signals Directorate (Australian Signals Directorate, 2021) and the Therapeutic Goods Administration (TGA) Cyber security standards for medical devices (Department of Health - TGA, 2019b) should be followed to protect data security.

Data Protection: The key legislation relevant to the protection of personal information are The Privacy Act (Australian Government, 1988) and the Australian Privacy Principles (Office of the Australian Information Commissioner, 2014). Data protection should consider all individuals who

access an assistive product or service, including people with a disability, their carers and family members.

Data usage: The Consumer Data Rights (CDR) stipulates that providers must get explicit consent to use data collected from an individual (Consumer Data Right, 2020). The promotion of openness in the usage of data is also highlighted by the European Union General Data Protection Regulation (European Union, 2016) which states that personal data must be processed lawfully, fairly and in a transparent manner in relation to the data subject. Australian provision of AI-enabled AT should follow similar principles. The collection of data should be adequate, relevant, and limited to what is necessary.

A.3 Quality

AI-enabled AT should reliably produce desired or intended results. Quality should be sustained.

The International Organisation for Standardization (ISO) standards define quality as the degree to which a set of inherent characteristics fulfil the desired set of requirements (International Organisation for Standardization, 2021). Three fundamental measures of quality are proposed.

Measures	Guiding principles
Credibility	The AI-enabled AT should be created or certified by a trustworthy entity.
Validation	The AI-enabled AT, including all models and solutions, must undertake a robust, transparent, explainable, and reproducible validation process that ensures the AT meets and continues to meet its purpose over the life of the product.
Data quality	The data used to develop and improve AI-enabled AT should meet appropriate data quality indicators such as accuracy, relevance, and representativeness.

Credibility: Credibility is judgment based. Researchers analysing the credibility or reputation of an entity have used a variety of measures. To date, however, no standardised, reliable and validated approaches to measure credibility exist (Newell & Goldsmith, 2001). Ideals to consider include reputation, track record, expertise, transparency, trustworthiness, use of quality management systems, ethics policies, full disclosure of developer, authors and affiliations, consideration of motivations and conflicts of interest.

Validation: The efficacy of technology, referred to as the ability of products to produce a desired or intended result, is evaluated in controlled settings using rigorous scientific methodologies. There are guidelines for the evaluation and validation of AI-enabled technology (Mathews et al., 2019; Myllyaho et al., 2021). It is important to ensure appropriate rigor is applied in designing, developing, and validating AT, including appropriate performance metrics. When considering whether an assistive product or service is fit for purpose, product evaluation should be considered in parallel with user experience factors that consider the needs, goals, and environments of the end-user.

Data quality: Vast amounts of good quality data are vital for the development of any AI solution (Digital Curation Centre et al., 2020). Quality indicators such as the appropriateness, trustworthiness, relevance, accuracy, and identification of potential biases are frequently used to assess data quality (Trewin et al., 2019). In designing AI-enabled AT, an additional quality indicator is data representativeness (Digital Curation Centre et al., 2020), particularly important because

disability metrics and experience is often missed in broader datasets. Measuring data quality requires an understanding and interrogation of the data used in model development and implementation.

A.4 Safety

AI-enabled AT should do no harm, minimise negative outcomes and not deceive people.

Assessment of safety should consider the potential risk relative to benefit, and associated mitigation strategies. For all AT that meets the definition of a medical device, safety triggers the need for regulatory approval (Department of Health - TGA, 2019a). However, all assistive products need to meet fundamental safety requirements and standards under Australian Consumer Law (Australian Competition & Consumer Commission, 2018; Australian Government, 2010; Commonwealth of Australia, 2016) even if they do not meet the definition of a medical device. In addition, several standards are currently under development in both the areas of assistive products and AI (ISO/IEC JTC/SC42 -Artifical Intellegence, 2022; ISO/TC173 - Assistive Products, 2022), and it is anticipated that they will become available in the coming years. Two fundamental aspects required to evaluate safety are proposed.

Measures	Guiding principles
Risks	Comprehensive information should be provided about the potential long-term risks relative to benefits to people and their environment when the AI-enabled AT is used.
Reliability	Comprehensive information should be provided about the long-term performance of an AI-enabled AT.

Risk: A range of social and environmental factors can impact the safe use of AT. Considerations range from low-risk assistive products that are simple and used in everyday life, to high-risk products that need professional assistance or training for safe use. Safety considerations include:

- **Stigma:** Self-stigma and stigmatising responses that could impact the mental wellbeing and social interactions of users (Qian et al., 2021).
- **Health and comorbidities*:*** Considerations that may compromise the ability of an end-user to use assistive products as they are intended.
- **Cognitive load:** Devices associated with a large cognitive load may be associated with cognitive fatigue, disengagement, or inappropriate use (How et al., 2013; World Wide Web Consortium, 2021).
- **Psychological:** Considers the possibility of negative user experience that may impact on the wellbeing of the user, including their sense of competency, self-determination, and distress (Chen, 2020; Ienca et al., 2018; Scherer, 2017; Shore et al., 2020).
- **Social:** The potential impact on the user's risk of isolation and the loss of human contact (Chen, 2020; Ienca et al., 2018).

Reliability: In AI, it is key to understand how the performance of AI models (algorithms) change overtime, including the model's ability for continuous learning and generalisation of previously unseen data. AI systems should be monitored periodically to ensure the outcomes of the models continue to meet their intended purpose.

A.5 Relative Value

AI-enabled AT should provide better benefit to cost ratio in comparison to alternate options.

Relative value is defined as outcomes (e.g., improvement in participation or quality of life) achieved relative to the cost of achieving those outcomes, in comparison to available alternatives. As such, AI-enabled AT products are said to represent 'good value for money' when the cost to achieve an improvement in outcomes is lower than that of available alternatives to achieve the same improvement. Three measures to capture and evaluate relative value are proposed.

Measures	Guiding principles
Cost	The total cost and cost consequences associated with the AI-enabled AT should be considered when assessing relative value.
Outcomes	The AI-enabled AT should benefit the quantity or quality of life experiences of individuals, based on their preferences.
Opportunity cost	The AI-enabled AT should generate greater benefits relative to costs, than the next best alternative.

Costs: Cost-based approaches should avoid the potential for false "savings", or misinterpretation that technologies should be used as a cost reduction measure. Cost requires the consideration of the total costs over the lifetime of the technology or user's condition. This includes the cost of human support needed for setup, training, troubleshooting, or maintenance; the longevity of the product, and costs associated with repair or replacement. Cost may also consider subsequent direct or indirect economic benefits and cost reductions because of the use of assistive products, compared to not having them available. Costs should not be considered in isolation but with respect to outcomes.

Outcomes: Measures that are considered of importance to end-users. That is, benefits that people would choose to achieve and therefore be willing to give up something else in order to achieve them. Examples include life expectancy, quality of life, independence, productivity, dignity, and respect. Adverse outcomes would be a negative in this regard.

Opportunity cost: Represents the potential benefits that are given up when choosing one option over another, including potential missed benefits when choosing available alternatives. We do this by looking at the benefits and costs of a proposed product or service and comparing it with the benefits and costs of the alternatives.

A.6 Human Rights

AI-enabled AT must protect human rights and fundamental freedoms.

International human rights law provides globally accepted principles that uphold the fundamental freedoms and dignity of all people (United Nations, 1948). Preventing and mitigating human rights

risks is fundamental when analysing the potential impact of AI-enabled AT. While AI technologies can be of enormous benefit to persons with disabilities and drive the search for inclusive equality, there are also many well-known discriminatory impacts. There is growing awareness of the broad challenges and risks to the enjoyment of human rights that these new technologies can pose (Quinn, 2021). Adhering to human rights guiding principles is of immense importance to ensure the human rights impacts of AT are positive. Four elements of human rights are proposed.

Measures	Guiding principles
Legal compliance	The AI-enabled AT should comply with all relevant international and domestic obligations, regulations, and laws.
Fairness	The development and use of AI models must not result in unfair bias or discrimination against individuals, communities, or groups.
Transparency	AI-enabled AT should provide sufficient information to users about the workings of the system to afford them the right (or dignity) to take reasonable risks.
Ethical compliance	The AI-enabled AT should comply with national and international ethical principles and obligations.

Legal compliance: Australia is a party to seven core human rights agreements which have shaped Australian laws (Dawson et al., 2019), including The Convention on the Rights of the Child (CRC) and The Convention on the Rights of Persons with Disabilities (CRPD) (United Nations, 2006). In addition, Australia has several anti-discrimination laws, including the Age Discrimination Act 2004, the Disability Discrimination Act of 1992, and the Sex Discrimination Act of 1984.

Fairness: Even if there is perfect data, modelling methods can introduce bias (Trewin et al., 2019). This principle aims to ensure that AI systems are fair and enable inclusion throughout their entire lifecycle of a product or service. A recent survey (Mehrabi et al., 2021) provides a comprehensive view of the types of bias and various pre-processing, in-processing and post-processing techniques that can be employed to address bias and achieve fairness.

Transparency: Transparency, which refers to the understandability of a specific model, can be a mechanism that facilitates accountability (Lepri, 2018). Transparency can be considered at the level of the entire model or within individual components. There are open questions regarding what constitutes transparency, and what level of transparency is sufficient for different stakeholders. According to the Artificial Intelligence: Australia's Ethics Framework (Dawson et al., 2019), people should always be aware when a decision that affects them has been made by an AI system.

Ethical compliance: There is no single ethical framework available to guide all decision making and implementation of AI-enabled AT. Relevant frameworks include the "four pillars of medical ethics" that underpin the moral compass within which medical professionals must work (Beauchamp and Childress, 2001) and Australia's AI Ethics Framework (Australian Government - Department of Industry Science Energy and Resources; Dawson et al., 2019). Elements to consider include beneficence (generates net-benefit); non-maleficence (do no harm); autonomy (freedom of choice), accountability, and justice. Additionally, some of the Australian and international organisations that support a human rights approach to the development and use of emerging technologies, such as AI, include: the CRPD, the United Nations (UN) Guiding Principles on

Business and Human Rights (United Nations, 2019) and the Australian Human Rights Commission, who recently released a report to foster a deeper understanding of the human rights implications of new and emerging technologies (Australian Human Rights Commission, 2021).

3 Next steps: Implementation Roadmap

The co-design of the Framework and initial consultation with industry and key stakeholders is a significant first step in realising the vision of increased innovation in safe and effective AI-enabled AT for the benefit of PWD. Through the development of the Framework, we confirmed the appetite and need for this initiative and the resulting framework articulates stakeholder priorities. Uptake and implementation of the Framework will be challenging without further initiatives, governance, and planning. To this end, CSIRO is developing an implementation roadmap (the Roadmap), which outlines a pathway to the widespread adoption and implementation of the Framework by the key user groups.

Using the key principles outlined by the Framework, the Roadmap will consider the contexts and settings in which AI-enabled AT is currently being used to support PWD. The Roadmap will be driven by the key considerations for implementation identified and agreed upon amongst stakeholders as part of the Framework development process. Ongoing collaboration with end-users, families, carers, disability workforce, and industry stakeholders will be critical in the development of the Roadmap.

Together with the Roadmap, the Framework will guide how the NDIA and other Australian government entities support and regulate the development of a vibrant and innovative market.

4 Conclusion

Emerging technologies, such as AI-enabled AT, are already bringing new opportunities to PWD and will continue to do so in the coming years. These innovations have the potential to promote better functioning, independence, a sense of empowerment and opportunities for inclusivity for PWD. Achieving the right match between an individual and the AT that best supports their needs and goals can be complex.

This document is intended to guide Australia's first steps towards the development of a framework that supports the development and implementation of AI-enabled AT in Australia. The proposed principle-based Framework supports a person-centric approach that acknowledges the unique capabilities, preferences, and goals of people PWD. Its aim is to provide a practical tool to facilitate informed decision making for all stakeholders, while supporting choice and control for people with disability.

Moving into the future, a Roadmap is required to successfully implement and operationalise the Framework. A fully operationalised Framework will require input from all stakeholders, including PWD, government, industry, and research. Ongoing collaboration will be of utmost importance in the creation of an equitable and effective framework to facilitate access to safe, appropriate, and beneficial AT for all.

References

Australian Competition & Consumer Commission. (2018). *Product Safety: A Guide to Testing* www.productsafety.gov.au

Australian Council of Learned Acadamies, A. (2020). *The effective and ethical development of Artificial Intelligence. An opportunity to improve our well being - Summary paper*. https://acola.org/wp-content/uploads/2020/11/hs4_artificial-intelligence_summary-paper.pdf

Australian Digital Health Agency, A. (2021). *National mHealth applications assessment framework - Consultation Paper*. Australian Digital Health Agency

Australian Government - Department of Industry Science Energy and Resources. Australia's Artificial Intelligence Ethics Framework. https://www.industry.gov.au/data-and-publications/australias-artificial-intelligence-ethics-framework/australias-ai-ethics-principles

Privacy Act 1988, (1988). https://www.legislation.gov.au/Details/C2022C00135

Competition and Consumer Act 2010, (2010).

Australian Human Rights Commission. (2021). *Human Rights and Technology*. https://humanrights.gov.au/our-work/rights-and-freedoms/projects/human-rights-and-technology

Australian Signals Directorate. (2021). *Cyber Security Principals*. https://www.cyber.gov.au/acsc/view-all-content/advice/cyber-security-principles

Beauchamp and Childress. (2001). *Principles of Biomedical Ethics* Oxford University Press. https://books.google.com.au/books?hl=en&lr=&id=_14H7MOw1o4C&oi=fnd&pg=PR9&ots=1xWg4HEkXw&sig=Evj4RgpFH3nxjj-7koncvhpXYg8&redir_esc=y#v=onepage&q&f=false

Bernd, T., Van Der Pijl, D., & De Witte, L. P. (2009). Existing models and instruments for the selection of assistive technology in rehabilitation practice. *Scandinavian Journal of Occupational Therapy*, *16*(3), 146-158. https://doi.org/10.1080/11038120802449362

Boger, J., Jackson, P., Mulvenna, M., Sixsmith, J., Sixsmith, A., Mihailidis, A., Kontos, P., Miller Polgar, J., Grigorovich, A., & Martin, S. (2017). Principles for fostering the transdisciplinary development of assistive technologies. *Disability and Rehabilitation: Assistive Technology*, *12*(5), 480-490. https://doi.org/10.3109/17483107.2016.1151953

Candelon, F., Carlo, R. C. d., Bondt, M. D., & Evgeniou, T. (2021). *AI Regulation Is Coming*. https://hbr-org.cdn.ampproject.org/c/s/hbr.org/amp/2021/09/ai-regulation-is-coming

Chen, K. (2020). Why do older people love and hate assistive technology? – an emotional experience perspective. *Ergonomics*, *63*(12), 1463-1474. https://doi.org/10.1080/00140139.2020.1808714

Commonwealth of Australia. (2016). *Consumer Product Safety: A guide for Businesses and Legal Practitioners* (Australian Consumer Law Issue.

Consumer Data Right. (2020). Your Rights. https://www.cdr.gov.au/your-rights

Dawson, D., Schleiger, E., Horton, J., & et al. (2019). *Artificial Intelligence: Australia's ethics framework* [Discussion paper]. https://www.csiro.au/en/research/technology-space/ai/ai-ethics-framework

de Witte, L., Steel, E., Gupta, S., Ramos, V. D., & Roentgen, U. (2018). Assistive technology provision: towards an international framework for assuring availability and accessibility of

affordable high-quality assistive technology. *Disability and Rehabilitation: Assistive Technology*, *13*(5), 467-472. https://doi.org/10.1080/17483107.2018.1470264

Department of Health - TGA. (2019a). *Australian Register of Therapeutic Goods*. https://www.tga.gov.au/australian-register-therapeutic-goods

Department of Health - TGA. (2019b). *Cyber security for medical devices and IVDs*. https://www.tga.gov.au/cyber-security-medical-devices-and-ivds

Department of Health - TGA. (2021). *Medical devices Essential Principles checklist*. https://www.tga.gov.au/sites/default/files/essential-principles-checklist-medical-devices.pdf

Department of Health. (2019). *About Health Technology Assessment*. Australian Government. https://www1.health.gov.au/internet/hta/publishing.nsf/Content/about-1

Department of Health & Social Care. (2021). *A guide to good practice for digital and data-driven health technologies*. https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology#usability-and-accessibility

Dermody, G., & Fritz, R. (2019). A conceptual framework for clinicians working with artificial intelligence and health-assistive Smart Homes. *Nursing Inquiry*, *26*(1), e12267. https://doi.org/https://doi.org/10.1111/nin.12267

Digital Curation Centre, Trilateral Research, & The School of Informatics: University of Edinburgh. (2020). *The Role of Data in AI*. https://gpai.ai/projects/data-governance/role-of-data-in-ai.pdf

Digital Transformation Agency. (2021). *9. Make it accessible.* Commonwealth of Australia. https://www.dta.gov.au/help-and-advice/digital-service-standard/digital-service-standard-criteria/9-make-it-accessible

Drummond, M. F., Sculpher, M. J., Torrance, G. W., O'Brien, B. J., & Stoddart, G. L. (2005). *Methods for the economic evaluation of health care programme. Third edition*: Oxford: Oxford University Press.

Eisenberg, J., Dye, B., Jones, S., Lyons, T., Pruett, M., Wiegle, C., & Yancey, D. (2008). *Assistive Technology: A Framework for Consideration and Assessment* https://www.doe.virginia.gov/special_ed/iep_instruct_svcs/assistive_technology/framework_assistive_technology.pdf

European Commission. (2020). *White Paper: On Artificial Intelligence - A European approach to excellence and trust*. https://ec.europa.eu/info/sites/default/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf

The European Data Protection Regulation. (2016). https://gdpr-info.eu/

Felzmann, H., Murphy, K., Casey, D., & Beynan, O. (2015). *Robot-assisted care for elderly with dementia: is there a potential for genuine end-user empowerment?* The Emerging Policy and Ethics in Human Robot Interaction, Portland, OR. http://www.openroboethics.org/hri15/wp-content/uploads/2015/02/Hf-Felzmann.pdf

Global Disability Innovation Hub. (2021). Powering Inclusion: Artificial Intelligence and Assistive Technology.https://cdn.disabilityinnovation.com/uploads/images/AIATPolicyBrief_ToPublish.pdf?v=1619774523

Hajkowicz SA, Karimi S, Wark T, Chen C, Evans M, Rens N, Dawson D, Charlton A, Brennan T, Moffatt C, Srikumar S, & Tong KJ. (2019). *Artificial intelligence: Solving problems, growing the economy and improving our quality of life.* CSIRO. https://data61.csiro.au/en/Our-Research/Our-Work/AI-Roadmap

Henson, P., David, G., Albright, K., & Torous, J. (2019). Deriving a practical framework for the evaluation of health apps. *The Lancet Digital Health*, *1*(2), e52-e54. https://doi.org/10.1016/S2589-7500(19)30013-5

How, T.-V., Wang, R. H., & Mihailidis, A. (2013). Evaluation of an intelligent wheelchair system for older adults with cognitive impairments. *Journal of NeuroEngineering and Rehabilitation*, *10*(1), 90. https://doi.org/10.1186/1743-0003-10-90

Hussain, M. S., Silvera-Tawil, D., & Farr-Wharton, G. (2021). Technology assessment framework for precision health applications. *International Journal of Technology Assessment in Health Care*, *37*(1), e67, Article e67. https://doi.org/10.1017/S0266462321000350

Ienca, M., Wangmo, T., Jotterand, F., Kressig, R. W., & Elger, B. (2018). Ethical Design of Intelligent Assistive Technologies for Dementia: A Descriptive Review. *Science and Engineering Ethics*, *24*(4), 1035-1055. https://doi.org/10.1007/s11948-017-9976-1

International Organisation for Standards. (2014). *Guide for addressing accessibility in standards*. (2nd edition). ISO/IEC GUIDE 71:2014(E): Reviewed and confirmed 2021. https://www.iso.org/standard/57385.html

International Organisation for Standards. (2021). *International Standards*. https://www.iso.org/

ISO/IEC JTC/SC42 -Artifical Intellegence. (2022). *International Standards Organisation, ISO /IEC JTC 1/SC 42 Artificial intelligence*. https://www.iso.org/committee/6794475.html

ISO/TC173 - Assistive Products. (2022). *International Standards Organisation ISO/TC173 Assistive Products.* https://committee.iso.org/home/tc173

Kintsch, A., & DePaula, R. (2002). A Framework for the Adoption of Assistive Technology.

Klaassen, B., van Beijnum, B. J. F., & Hermens, H. J. (2016). Usability in telemedicine systems—A literature survey. *International Journal of Medical Informatics*, *93*, 57-69. https://doi.org/https://doi.org/10.1016/j.ijmedinf.2016.06.004

Layton, N., & Callaway, L. (2020). *Person-centered approaches to evaluation of assistive technology products and outcomes: An Australian policy and practice perspective* RESNA Annual Conference, Virtual. https://www.resna.org/sites/default/files/conference/2020/GAATO/144Layton.html

Lepri, B., Oliver, N., Letouze,E., Pentland,A., and Vinck, P. (2018). Fair, Transparent, and Accountable Algorithmic Decision-making Processes: The Premise, the Proposed Solutions, and the Open Challenges. *Philosophy & Technology volume*, *31*, 611–627. https://link.springer.com/content/pdf/10.1007/s13347-017-0279-x.pdf

Mathews, S. C., McShea, M. J., Hanley, C. L., Ravitz, A., Labrique, A. B., & Cohen, A. B. (2019). Digital health: a path to validation. *Npj Digital Medicine*, *2*.

Mehrabi, N., Morstatter, F., Saxena, N., Lerman, K., & Galstyan, A. (2021). A Survey on Bias and Fairness in Machine Learning. *ACM Comput. Surv.*, *54*(6), Article 115. https://doi.org/10.1145/3457607

Myllyaho, L., Raatikainen, M., Mannisto, T., Mikkonen, T., & Nurminen, J. K. (2021). Systematic literature review of validation methods for AI systems. *Journal of Systems and Software*, *181*.

National Disability Insurance Agency. (2014). *NDIA. Towards Solutions for Assistive Technology - Discussion Paper*. https://apo.org.au/sites/default/files/resource-files/2014-12/apo-nid53419.pdf

National Disability Insurance Agency. (2021). *Corporate Plan 2021-25. Building a better NDIS.* https://www.ndis.gov.au/about-us/publications/corporate-plan#corporate-plan-2021-2025

National Disability Insurance Scheme Act 2013, (2013). https://www.legislation.gov.au/Details/C2013A00020

National Institute for Health and Care Excellence. (2013). *National Institute for Health and Care Excellence (NICE): Guide to the methods of technology appraisal 2013*. https://www.nice.org.uk/process/pmg9

National Institute for Health and Care Excellence. (2018). *National Institute for Health and Care Excellence (NICE): Evidence standards framework for digital health technologies* https://www.nice.org.uk/corporate/ecd7

Newell, S. J., & Goldsmith, R. E. (2001). The development of a scale to measure perceived corporate credibility. *Journal of Business Research*, *52*(3), 235-247. https://doi.org/Doi 10.1016/S0148-2963(99)00104-6

Nielsen, J. (2012). *Usability 101: Introduction to Usability*. Nielsen Norman Group,. https://www.nngroup.com/articles/usability-101-introduction-to-usability/

NSW Health. (2018). *NSW Framework for New Health Technologies and Specialised Services*. https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2018_023.pdf

O'Rourke, B., Oortwijn, W., & Schuller, T. (2020). The new definition of health technology assessment: A milestone in international collaboration. *International Journal of Technology Assessment in Health Care*, *36*(3), 187-190. https://doi.org/10.1017/S0266462320000215

Office of the Australian Information Commissioner. (2014). *Australian Privacy Principles*. https://www.oaic.gov.au/__data/assets/pdf_file/0006/2004/the-australian-privacy-principles.pdf

Qian, Z. J., Nuyen, B. A., Kandathil, C. K., Truong, M.-T., Tribble, M. S., Most, S. P., & Chang, K. W. (2021). Social Perceptions of Pediatric Hearing Aids. *The Laryngoscope*, *131*(7), E2387-E2392. https://doi.org/https://doi.org/10.1002/lary.29369

Quinn, G. (2021). *Artificial intelligence and the rights of persons with disabilities - Report of the Special Rapporteur on the rights of persons with disabilities*. https://www.ohchr.org/en/documents/thematic-reports/ahrc4952-artificial-intelligence-and-rights-persons-disabilities-report

Ran, M., Banes, D., & Scherer, M. J. (2020). Basic principles for the development of an AI-based tool for assistive technology decision making. *Disability and Rehabilitation: Assistive Technology*, 1-4. https://doi.org/10.1080/17483107.2020.1817163

Scherer, M., Jutai, J., Fuhrer, M., Demers, L., & Deruyter, F. (2007). A framework for modelling the selection of assistive technology devices (ATDs). *Disability and Rehabilitation: Assistive Technology*, *2*(1), 1-8. https://doi.org/10.1080/17483100600845414

Scherer, M. J. (2017). Technology adoption, acceptance, satisfaction and benefit: integrating various assistive technology outcomes. *Disability and Rehabilitation: Assistive Technology*, *12*(1), 1-2. https://doi.org/10.1080/17483107.2016.1253939

Schnall, R., Cho, H., & Liu, J. (2018). Health Information Technology Usability Evaluation Scale (Health-ITUES) for Usability Assessment of Mobile Health Technology: Validation Study. *JMIR Mhealth Uhealth*, *6*(1), e4. https://doi.org/10.2196/mhealth.8851

Sheehan, B., Lee, Y., Rodriguez, M., Tiase, V., & Schnall, R. (2012). A comparison of usability factors of four mobile devices for accessing healthcare information by adolescents. *Applied clinical informatics*, *3*(4), 356-366. https://doi.org/10.4338/ACI-2012-06-RA-0021

Shore, L., de Eyto, A., & O'Sullivan, L. (2020). Technology acceptance and perceptions of robotic assistive devices by older adults – implications for exoskeleton design. *Disability and Rehabilitation: Assistive Technology*, 1-9. https://doi.org/10.1080/17483107.2020.1817988

Standards Australia. (2020). *An Artificial Intelligence Standards Roadmap: Making Australia's Voice Heard - Final Report*. https://www.standards.org.au/getmedia/ede81912-55a2-4d8e-849f-9844993c3b9d/R_1515-An-Artificial-Intelligence-Standards-Roadmap-soft.pdf.aspx

The Office of Best Practice Regualtion. (2020). Guidance Note: Cost-Benefit Analysis. https://obpr.pmc.gov.au/resources/guidance-assessing-impacts/cost-benefit-analysis

Trewin, S., Basson, S., Muller, M., Branham, S., Treviranus, J., Gruen, D., Hebert, D., Lyckowski, N., & Manser, E. (2019). Considerations for AI fairness for people with disabilities. *AI Matters*, *5*(3), 40–63. https://doi.org/10.1145/3362077.3362086

Tsopra, R., Fernandez, X., Luchinat, C., Alberghina, L., Lehrach, H., Vanoni, M., Dreher, F., Sezerman, O. U., Cuggia, M., de Tayrac, M., Miklasevics, E., Itu, L. M., Geanta, M., Ogilvie, L., Godey, F., Boldisor, C. N., Campillo-Gimenez, B., Cioroboiu, C., Ciusdel, C. F., . . . Burgun, A. (2021). A framework for validating AI in precision medicine: considerations from the European ITFoC consortium. *BMC Medical Informatics and Decision Making*, *21*(1), 274. https://doi.org/10.1186/s12911-021-01634-3

Tuazon, J. R., & Jutai, J. W. (2021). Toward guidelines for reporting assistive technology device outcomes. *Disability and Rehabilitation: Assistive Technology*, *16*(7), 702-711. https://doi.org/10.1080/17483107.2019.1697384

United Nations. (1948). *Universal Declaration of Human Rights (UDHR)*.

United Nations. (2006). *Convention on the Rights of Persons with Disabilities and Optional Protocol*. https://www.un.org/disabilities/documents/convention/convoptprot-e.pdf

United Nations. (2019). *United Nations Human Rights Business and Human Rights in Technology Project (B-Tech), Applying the United Nations Guiding Principles on Business and Human Rights to digital technologies*. https://www.ohchr.org/sites/default/files/Documents/Issues/Business/B-Tech/B_Tech_Project_revised_scoping_final.pdf

usability.gov. (2021a). *Accessibility Basics*. https://www.usability.gov/what-and-why/accessibility.html

usability.gov. (2021b). *User Experience Basics*. U.S. General Services Administration. https://www.usability.gov/what-and-why/user-experience.html

Venkatesh, V., & Davis, F. D. (2000). A Theoretical Extension of the Technology Acceptance Model: Four Longitudinal Field Studies. *Management Science*, *46*(2), 186-204. https://doi.org/10.1287/mnsc.46.2.186.11926

Wangmo, T., Lipps, M., Kressig, R. W., & Ienca, M. (2019). Ethical concerns with the use of intelligent assistive technology: findings from a qualitative study with professional stakeholders. *BMC Medical Ethics*, *20*(1), 98. https://doi.org/10.1186/s12910-019-0437-z

WIPO, W. I. P. O. (2021). *WIPO Technology Trends 2021: Assistive Technology*. https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1055_2021.pdf

World Health Organisation. (2002). *Towards a common language for Functioning, Disability and Health. ICF. The International Classification of Functioning, Disability and Health.* https://www.who.int/standards/classifications/international-classification-of-functioning-disability-and-health

World Wide Web Consortium. (2008). *Web Content Accessibility Guidelines (WCAG) 2.0.* https://www.w3.org/TR/2008/REC-WCAG20-20081211/

World Wide Web Consortium. (2021). *Making Content Usable for People with Cognitive and Learning Disabilities.* https://www.w3.org/TR/2021/NOTE-coga-usable-20210429/

Zabala, J., Bowser, G., & Korsten, J. (2005). SETT and ReSETT: Concepts for AT implementation *Closing The Gap*, *23*(5). https://educationtechpoints.org/wp-content/uploads/SETT_Implementation_CTG.pdf

Zapata, B. C., Fernández-Alemán, J. L., Idri, A., & Toval, A. (2015). Empirical Studies on Usability of mHealth Apps: A Systematic Literature Review. *Journal of Medical Systems*, *39*(2), 1. https://doi.org/10.1007/s10916-014-0182-2

Appendix

A.1 AI and Assistive Technology Frameworks

The desktop analysis focussed on reviewing a range of existing and proposed guidelines and frameworks relevant to the health, disability, and AI domains. A summary of these findings is presented here. A general review of Assistive technology Frameworks is presented first. Then, Health Technology Assessment (HTA) frameworks are reviewed due to their focus on the digital landscape. This is followed by a section that focus on regulatory assessment to reflect key safety and quality considerations. Finally, this section will conclude with a close look at AI frameworks.

A.1.1 Assistive Technology Frameworks

Many technologies exist with the potential to support individuals with disabilities (National Disability Insurance Agency, 2014; WIPO, 2021). However, there is a selection and integration process that must be navigated before successful adoption of an AT can take place. Because so much is involved in the development, evaluation, implementation and adoption process, several assessment and implementation frameworks have been developed to support the effective assessment and implementation of ATs. Most of these frameworks consider all stakeholders (the person with a disability, caregivers, AT specialists and developers) at the centre of the assessment and implementation (Boger et al., 2017; Eisenberg et al., 2008; Kintsch & DePaula, 2002; Layton & Callaway, 2020).

The AT assessment process involves a person-centred approach that considers the user needs and abilities, their goals or activities, and the context in which the AT will be used (Boger et al., 2017). AT Assessment frameworks also consider aspects such as informed evidence (e.g., effectiveness and reliability), social significance, sustainability, privacy, security, risk relative to the level of consequence, and value for money (Boger et al., 2017; Layton & Callaway, 2020; Tuazon & Jutai, 2021). AT implementation frameworks draw particular attention to aspects around affordability, customization/personalisation, training, and the use of ATs in daily life including follow-up and maintenance (de Witte et al., 2018; Global Disability Innovation Hub, 2021; Kintsch & DePaula, 2002).

A variety of frameworks have been developed to assist people in selecting AT, including factors that support the provision of AT and its application in education and daily living (Bernd et al., 2009; Eisenberg et al., 2008; Ran et al., 2020; Scherer et al., 2007; Zabala et al., 2005). The aim of these frameworks is to identify an optimal fit between the person with a disability, the environment, the tasks, goals, and a concrete device which users could benefit from and reduce the likelihood of AT abandonment. These frameworks also consider technical (e.g., effectiveness), individual and environmental factors.

The availability of frameworks to evaluate AI-enabled ATs is limited. In this vein, the ethical considerations of AI-enabled AT were explored by Ienca et al. (2018) who highlight that due to the pervasive and ubiquitous character of intelligent ATs, this technology has the potential to affect

not only the clinical dimension of users, but also their emotional, psychosocial, and relational dimensions. As such, they identified six key ethical categories that should be considered during the design of intelligent AT: autonomy and independence, preventing harm (non-maleficence), promoting overall good (beneficence), justice, interdependence, and privacy.

Other concerns discussed in the literature include stigma, self-determination, social isolation, deception, and whether AI-enabled ATs would and should replace human care (Dermody & Fritz, 2019; Felzmann et al., 2015; Global Disability Innovation Hub, 2021; Wangmo et al., 2019).

A.1.2 Health Technology Assessment Frameworks

Health Technology Assessment (HTA) frameworks are an effective tool to systematically evaluate a wide range of technologies in health care including medical devices, equipment, and care delivery. HTA is formally defined as *"…a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making to promote an equitable, efficient, and high-quality health system*" (O'Rourke et al., 2020). At its core, HTA is the consideration of processes and mechanisms that use scientific evidence to assess the quality, safety, efficacy, effectiveness, and cost effectiveness of health services (Department of Health, 2019).

General HTA frameworks and guidelines address principals focused on national or local systemwide services targeting available evidence, cost implications, and requirements for high quality service provision (Department of Health - TGA, 2021; Department of Health, 2019; National Institute for Health and Care Excellence, 2013; NSW Health, 2018). The majority of the HTA frameworks reviewed included the following assessment areas: safety (evaluating harms, benefits, and risks), health outcome improvements (adequate evidence of benefits), and economic evidence (cost effectiveness of technology).

The accelerating development of digital health technology has seen an additional body of work looking at criteria specific to digital technologies, such as mobile and precision health applications, with new HTA frameworks developed to address the specific requirements of these technologies (Australian Digital Health Agency, 2021; Department of Health & Social Care, 2021; Henson et al., 2019; Hussain et al., 2021; National Institute for Health and Care Excellence, 2018). In addition to general HTA frameworks, these digital health frameworks consider assessment areas such as: usability, accessibility, cybersecurity, data protection and transparency, quality, accuracy, performance of the technology, and credibility of producers.

The construct of HTAs are variable, with some opting for a hierarchical approach indicating differing priority and importance levels of evaluation criteria (Henson et al., 2019), whilst other proposed frameworks use flow chart approaches and risk assessment indicating direction of steps (Australian Digital Health Agency, 2021).

Typically, HTA considers evidence appraisal of safety and effectiveness in the first instance. This is swiftly followed by an economic evaluation where the value or cost effectiveness of a proposed technology is assessed to guide reimbursement and access decisions. Generally, there are eight main steps which comprise a typical economic evaluation: define alternatives, define the

perspective of the decision maker and time horizon of analysis, identify impacts, predict the impacts over the life of the proposed technology or consumer, value the costs and consequences, discount future costs and benefits if appropriate, assess the uncertainty and test for robustness, and interpret results and reach a conclusion (Drummond, Sculpher, Torrance, O'Brien, & Stoddart, 2005; The Office of Best Practice Regualtion, 2020).

A.1.3 Regulatory Assessments

In Australia, many assistive products meet the definition of a medical device, and so require regulatory oversight, including safety and quality assessments. Due to regulatory changes introduced in February 2021 software-based AT and accessories that make specific claims in relation to being able to diagnose, screen, or monitor a serious condition may also be classed as Software as a Medical Device (SaMD) and require regulatory approvals and oversight.

The complimentary nature of HTAs and regulatory pathways is important for harmonisation of assessment procedures across the AT product landscape. As AT spans a risk spectrum, it is appropriate that an AT framework compliments and operates in conjunction with TGA regulatory policies and management approaches.

Regulatory frameworks focus on the quality, safety, and performance of medical devices. TGA operates a risk-based approach to regulating therapeutic goods. The distinction between non-regulated software and SaMD is based on the potential risk of the product causing harm to consumers.

A.1.4 Artificial Intelligence Frameworks

A variety of literature has emerged pertaining to AI guidance, roadmaps and strategies, all confirming the need for AI to be scrutinised and examined to ensure safety, ethics and ongoing performance (Australian Council of Learned Acadamies, 2020; Candelon et al., 2021; Dawson et al., 2019; European Commission, 2020; Hajkowicz SA et al., 2019; Standards Australia, 2020; Tsopra et al., 2021).

The most advanced and comprehensive guidance is an article from colleagues at the Boston Consulting Group, which discussed the potential future regulatory and legal issues that are essential to the development of AI-enabled products that can be trusted (Candelon et al., 2021). The three main challenges for businesses and leaders considering integration of AI were identified as the avoidance of bias or discrimination, transparency of AI, and the performance or accuracy of the AI over time.

In the Australian context, CSIRO has developed a roadmap to provide guidance on pathways for utilising the full potential of AI, encompassing national consultation and earlier work on aligning the design and application of AI with ethical and inclusive values (Dawson et al., 2019; Hajkowicz SA et al., 2019).

Building on this work, and through consultation with a broad cross-section of stakeholders, Standards Australia have also developed a roadmap to provide a framework for Australians to intervene and shape the development of standards for AI internationally (Standards Australia, 2020). Privacy, inclusion and fairness, safety and security, and proportionate policy and regulatory

response were the requirements for building and sustaining trust in AI. Complementary to this, the Australian Council of Learned Academies' (ACOLA) focus on key considerations for effective and ethical development of AI (Australian Council of Learned Acadamies, 2020):

- human-centered deployment (human rights principles, inclusivity)
- data (trustworthy, non-discriminative, not biased, privacy, storage, and security)
- changing nature of work (adoption of AI, training in AI, human rights, and ethical principles)
- community trust and engagement (increase understanding of AI technologies, effective and responsible use of AI, securing community trust).

Across the AI guidelines and discussion papers included, there was a consensus of the need for a clear national strategy or framework for safe, responsible, and strategic implementation of AI. While AI frameworks and standards have been proposed, and there is harmonisation between agencies of the key principals and issues for assessment, the level of maturity, acceptance and adoption is low. It remains unclear as to the extent that AI frameworks and standards are being adopted by producers and manufacturers.

These frameworks collectively provide similar themes and considerations that are fundamental to the development of an evaluation framework for AI-enabled AT for use in the disability sector.

A.2 Stakeholder Consultations: Procedure, participants, and outcomes

A.2.1 Consultations with people with disability and careers

i. Procedure

NDIS participants were recruited through the NDIA Participant First initiative. Participants were offered the choice to participate in semi-structured interviews via videoconference, phone, or an emailed list of interview questions. Allowances were provided to support any participants who may have required this.

All interviews (~60 minutes in length) were conducted via videoconference between 24 January 2022 and 4 February 2022 by two researchers. Sessions were audio recorded (with participant permission), professionally transcribed, coded and analysed by themes (using NVivo) by two researchers.

ii. Participants

A total of 20 participants (12 Female, 8 Male) were recruited via a e-newsletter to members of the NDIS Participant First Engagement Initiative (PFEI). Participants were randomly selected from a sample of 100 who expressed their interest in participating. Of those, 15 (75%) participants identified as living with a disability (PWD), three (15%) as carers, and two (10%) as both a PWD and a carer. The age range of those who took part in the interviews, including carers and people with a disability, was:

Age range	Number of Participants
18 - 34 years	3
35 - 44 years	4
45 - 54 years	5
55 - 64 years	7
65 years and above	1

The age range of NDIS participants represented by a carer was:

Age range	Number of Participants
1-17	1
18 - 34 years	3
55 - 64 years	1

A wide range of disability types were represented amongst the 20 participants, with the most common including physical (N = 6), psychosocial (N = 5), vision loss (N = 5), and neurological disorders (N = 4). The next most reported disability types included autism (N = 3); multiple sclerosis (N = 3); acquired brain injury (N = 2); genetic conditions (N = 2); intellectual (N = 2); speech / sensory (N = 2); and spinal cord injury (N = 2). Less frequent disability types included

cerebral palsy, developmental delay, and hearing loss with one participant for each type.[1] Thirteen participants reported living with two or more disabilities.

The most common impairment types reported were mobility (N = 12) and self-care (N = 9). The impairment types are listed below:

Impairment Type	Number of Participants
Mobility	12
Self-care	9
Social Interaction	8
Learning	8
Self-management	8
Communication	7
Other	5

iii. Summary of outcomes

Participants reported using a range of assistive products, including hearing and vision aids, mobility aids, smart in-home devices, and computer hardware and software. Products were used for assistance with cognition, personal organisation and reminders, verbal and written communication, a range of household tasks, mobility, news and entertainment, safety and reassurance, continence, vision impairment, general data collection and tracking. Participants described numerous benefits from using AI-enabled AT, including being able to live independently, maintain a personal routine and an overall improved quality of life.

It was acknowledged that without the NDIS funding many participants would not have access to AT that have made a significant impact to their quality of life.

Discoverability of AT

Participants discussed gaining knowledge of what AT is available to them from health professionals and experts in the field including occupational therapists, support workers, and medical specialists. Numerous disability groups and non-government organisations (NGO) were also mentioned, as well as internet searches, social media, peers, family, and friends.

When asked to describe how the provision of AT information could be improved, participants described a desire for having access to consistent information about AT in one location, such as a website, but highlighted the importance of the information being updated regularly. Some participants discussed the need to provide information in a variety of formats, to ensure it could cater to different user needs, abilities, and preferences. They voiced a desire for unbiased and independent information sources.

There were some concerns raised around the transparency of information provided by manufacturers and suppliers. Dissemination of results from research studies was considered a

[1] The total number of participants are greater than 20 because participants were allowed to select more than one disability and impairment type.

credible source of information, however, it was noted that information from these sources would need to be provided in a more accessible and easier to understand format than current peer-reviewed journal manuscripts.

Selection of AT

When considering AI-enabled AT, there were several characteristics that were important for participants to make their product/service choice. The characteristics aligned to user experience, value, quality, safety, privacy, and security. Overall, whether participants considered an AI-enabled AT as fit for purpose, depended on how each of these factors aligned to their individual needs, goals and preferences.

Participants expressed a desire for quality products that would last over time. They described a preference for mainstream companies and products that everyone else has. Participants mentioned that whether the product is made in Australia or overseas often has implications for accessibility, repairs, privacy laws, the ability to trial the product before purchase, and the overall product quality.

Personal safety is of particular concern for users, and something that carries significant weight in participant's decision-making processes. Adequate training in the use of a new AI-enabled AT is considered important to ensure products are used to their fullest potential, safely and as intended.

A.2.2 Consultations with representatives from industry, peak bodies, government departments and other relevant organisations

i. Procedure

Two focus groups, each lasting ~60-90 mins, were completed on the 8th and 9th of December 2021. Both focus groups were conducted online via videoconference with MIRO (an online whiteboarding platform) used to enable individuals to collaborate and brainstorm ideas. Individual interviews with NDIA executives (~30 minutes in length) were conducted via videoconference between 23 November 2021 and 25 January 2022.

During all sessions, participants were asked to focus on their experience and thoughts about AI-enabled AT, and on how the NDIS may safely and effectively incorporate it to support PLWD. A draft framework was shared with participants to collect their feedback, as well as their views in potential barriers and opportunities for implementation. Sessions were audio recorded (with participant permission) and analysed by content by two researchers.

ii. Contributors

A total of 18 contributors were recruited to participate in the focus groups and semi-structured interviews. Contributors were recruited from a purposive sample of those who had been invited to the Roundtable that the NDIA convened in 2021 to explore the potential role of AI in NDIS funded supports.

The focus groups (n=14) included representatives from government departments and regulatory agencies (n = 4), peak bodies and peer organisations (n = 6), industry, research organisations and

an Allied Health professional (n = 4). Semi-structured interviews were also conducted with NDIA leaders (n=4). Four of the participants representing the above stakeholder groups also identified as people with a disability.

iii. Summary of outcomes

Contributors reported that AI has been helpful in delivering better quality and more streamlined services in other industries, and that this is needed in the disability sector to ensure the sustainability of the NDIS. Contributors expressed their desire for AI-enabled AT to assist human services rather than to replace human service provision.

Contributors acknowledged the need for the Framework to complement other regulatory agencies (e.g., the Therapeutic Goods Administrations) and improve clarity about what AT is supported by the NDIS. They noted the importance of the Framework to provide a balance between evidence required (regulation) and innovation. Contributors also highlighted that the TGA does not assess cost/benefit, value, and alternative options, which, as an insurer, the NDIS needs to consider.

Contributors mentioned that the Framework could empower end-users to be better informed, providing them with an increased understanding of what impactful AI-enabled AT looks like, and giving them the opportunity to choose what works for them. It could support industry during their development and discoverability of products, fostering innovation in the sector, improving choices for end-users, and enabling positive market segments to flourish. Contributors also noted that the Framework could be used more broadly by all people with disability, not just those who are current NDIS participants.

Feedback from the preliminary framework

Most contributors mentioned that the domains covered in the preliminary framework were appropriate, but that more detail was needed as to what sits under each domain, what the rulesets/guidelines are, and what is expected from them. There was significant debate regarding what should be at the centre of the Framework, with all areas being considered important. Contributors believe the Framework should focus on end-users and the community around them.

Feedback was also provided that **Human Rights** risks and ethical considerations, while mentioned implicitly in some sections, should be highlighted, and identified more explicitly. The importance of AI-enabled AT being “fitted for a particular person” was highlighted.

There were differing views amongst contributors about the inclusion of **value** as a core element. Some individuals felt that “Value” should be replaced by “Outcome” or “Benefit”. Others noted that value for money comparisons were important to ensure sustainability of the scheme and to allow comparisons between products.

Contributors also discussed considerations for how to ensure that **quality** outcomes are maintained over time, particularly if AI-enabled AT includes machine learning, which changes the system overtime. The amount of evidence that is required for an AI-enabled AT to be approved was also discussed with various stakeholders mentioning the tension between “choice and control” and the “level of evidence required”.

Contributors also highlighted that **safety** is of particular importance for AI-enabled AT and should be heavily scrutinised to protect end-users, and highlighted the importance of reliability, transparency, explainability and accountability in ensuring the safety of systems. Contributors discussed "trade-offs" around the level of risk an individual may be willing to accept (the dignity of risk) versus the risks the NDIA/NDIS are willing to accept.

Additionally, contributors agreed that individuals should have the right to manage their data. They noted that awareness, clarity, and improving user understanding around who owns any data that is collected and used is important to allow end users to make informed decisions.

Finally, a number of challenges to the implementation of the Framework were identified, including distrust from individuals in the use of technology, distrust in government, and the change journey.

As Australia's national science agency and innovation catalyst, CSIRO is solving the greatest challenges through innovative science and technology.

CSIRO. Unlocking a better future for everyone.

Contact us

1300 363 400
+61 3 9545 2176
csiro.au/contact
csiro.au

For further information

Health and Biosecurity
Dr David Silvera
+61 2 9372 4282
david.silvera@csiro.au
aehrc.csiro.au