NDIS Quality and Safeguards Commission

The Use of Psychotropics in People With Disability

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Director Research and Practice Evidence

Human Rights at our Doorstep, Adelaide 6 March 2024

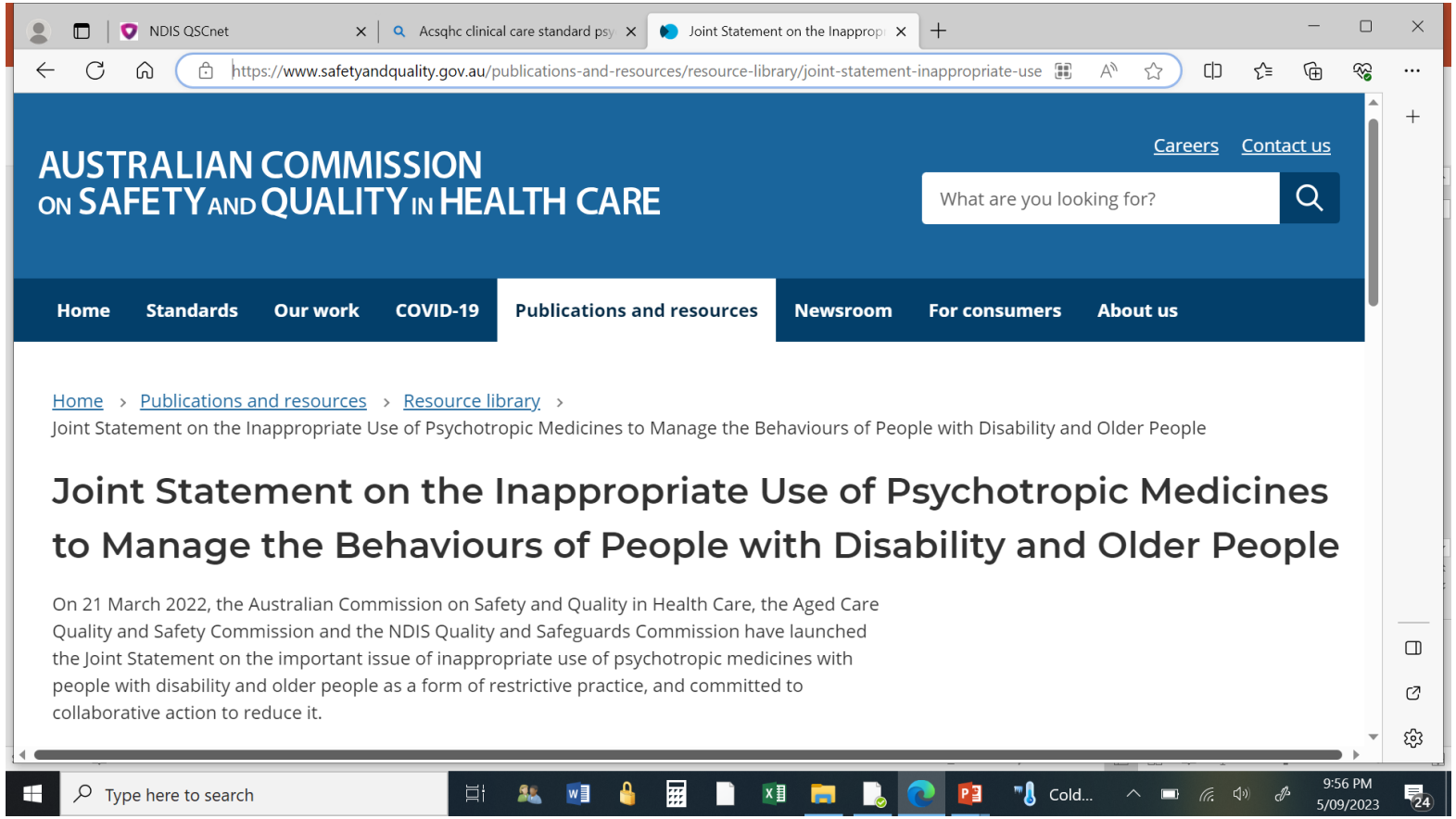
Three Commissions

Joint Statement on the Inappropriate Use of Psychotropics

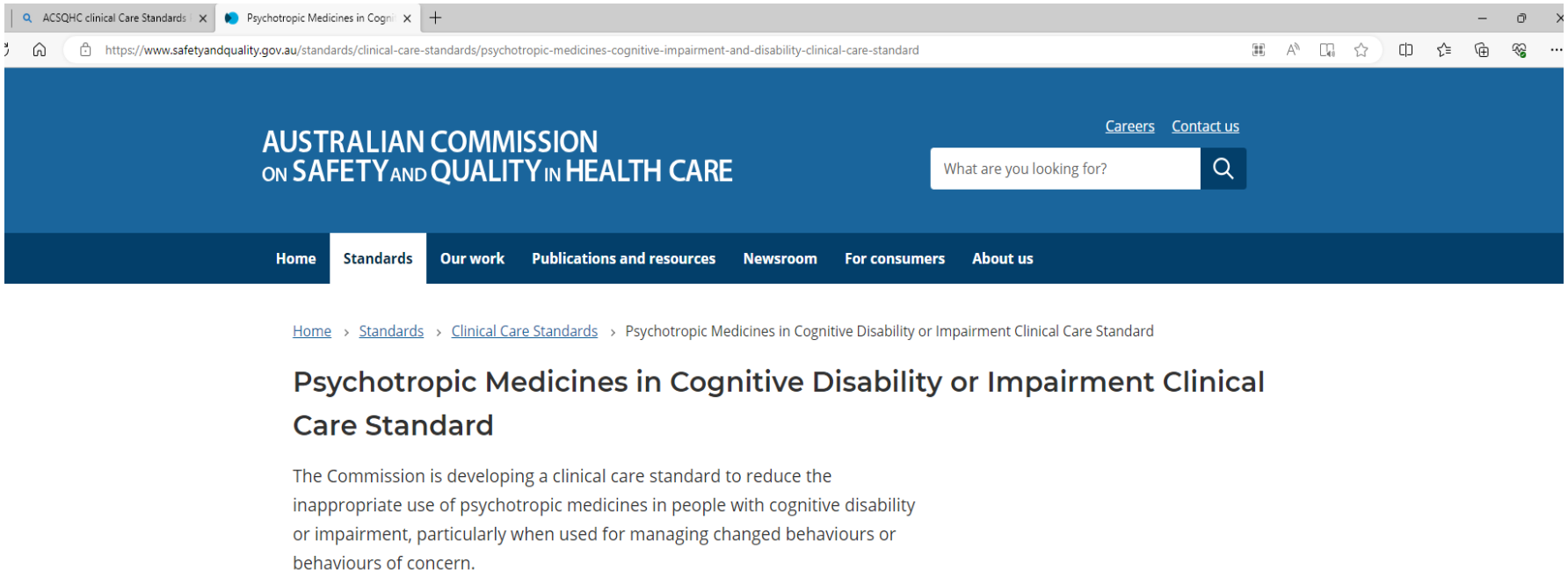
[Joint Statement on the Inappropriate Use of Psychotropic Medicines to Manage the Behaviours of People with Disability and Older People]

Three Commissions:

- The Australian Commission on Safety and Quality in Health Care
- The Aged Care Quality and Safety Commission
- The NDIS Quality and Safeguards Commission



Clinical Care Standards



[Psychotropic Medicines in Cognitive Disability or Impairment Clinical Care Standard | Australian Commission on Safety and Quality in Health Care]

Aims of the ACSQHC Clinical Care Standard

The Psychotropic Medicines in Cognitive Disability or Impairment Clinical Care Standard (the Standard) aims to support the Joint Statement in the following areas:

- Managing the *risks associated with the use* of psychotropic medicines for managing changed behaviours or behaviours of concern
- Supporting *improvements in diagnosis and assessment, behaviour support planning, and preventative and de-escalation strategies* for such behaviours
- Strengthening providers' *understanding and capacity for appropriate informed consent* when psychotropic medicines are used for behavioural reasons
- Addressing the *appropriateness of prescribing, dispensing, administration, monitoring, and discontinuation of psychotropic medicines*.

Project Overview

Using linked, national datasets held by AIHW to investigate *prevalence* and *risk* among a ten-year cohort of >800,000 people using disability services:

- Prescribing and supply of psychotropic medicines
- Physical and mental health outcomes, particularly preventable hospitalisations, ED presentations and potentially avoidable deaths
- Identifying *strategies to address poor outcomes and increased risk*

Australian Data Linkage project
Use of Psychotropics

- To what extent are psychotropic medicines used in Australians with disabilities?
- To what extent is psychotropic polypharmacy used?
- Do people prescribed psychotropic drugs have access to MBS-subsidised mental health services?
- Are Medication Reviews used for people with disabilities?

Psychotropic prescriptions

N different psychotropic medicines* supplied per person in 2016-17

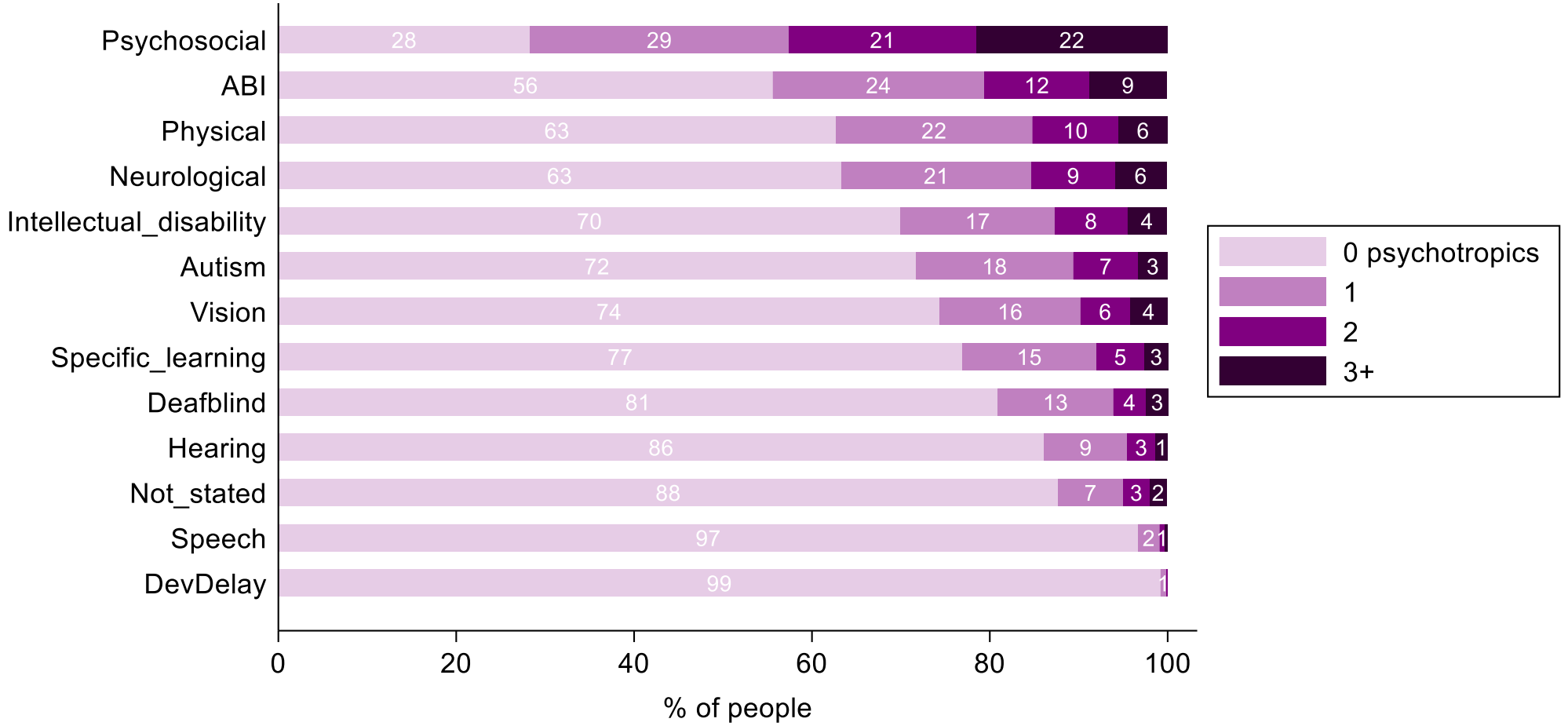
Among 300,000+ people aged <65 years using services under National Disability Agreement in 2016-17 financial year

N psychotropics	% of population
0	62.3
1	19.6
2	10.3
3 or more	7.8
Total	100.0

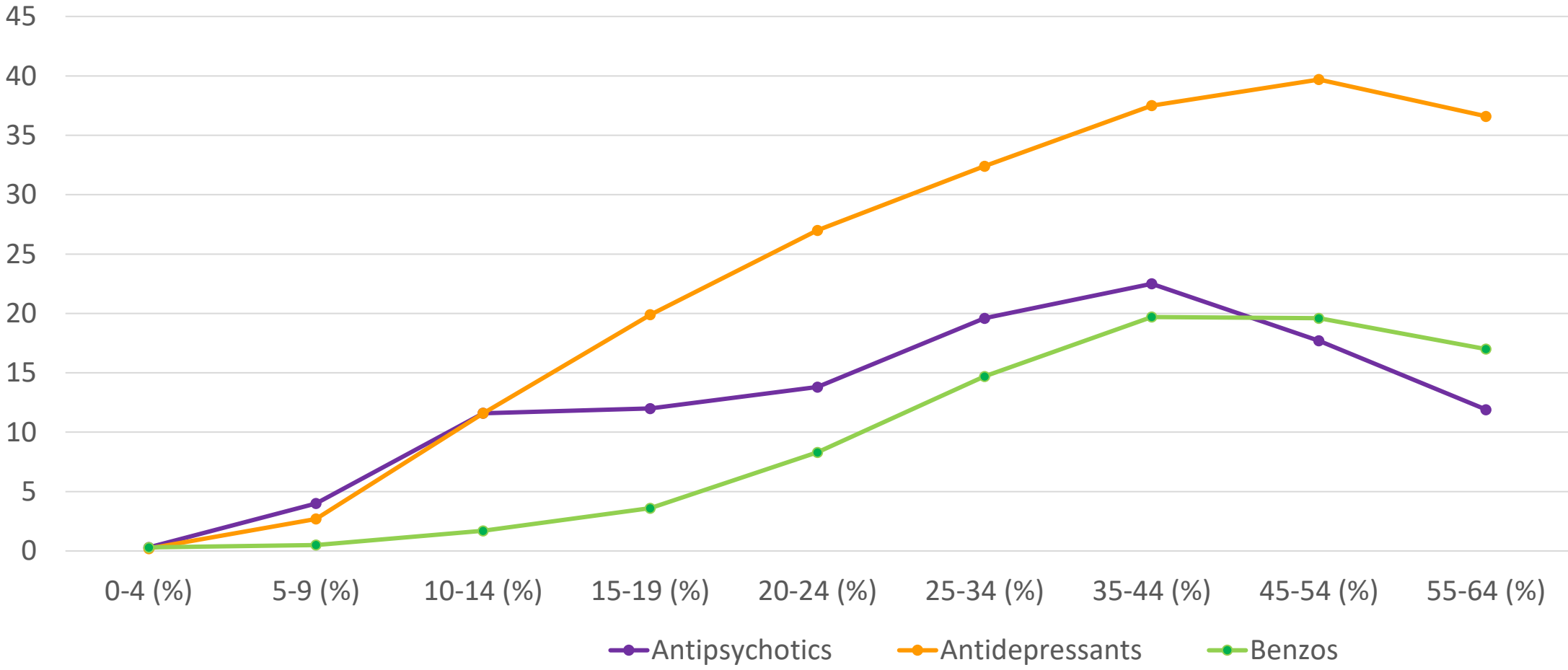
*Psychotropic medicines include antipsychotics, antidepressants, anxiolytics, benzodiazepine derivatives from other drug classes

Psychotropics by disability

N different psychotropics supplied per person in 2016-17, by **primary disability**



Psychotropic prescriptions by age group



Psychotropic prescriptions in people with Intellectual Disability

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Number of psychotropics	0-9 years (%)	10-14 (%)	15-19 (%)	20-24 (%)	25-34 (%)	35-44 (%)	44-54 (%)	55-64 (%)	Total (%)
0	93.1	80	76.8	73.6	67.5	60.5	56.4	52.3	**67.6**
1	5.1	14.2	15.0	16.0	18.4	21.6	23.6	24.8	**18.5**
2	1.8	4.9	5.9	7.0	8.7	11.5	13.2	14.9	**9.1**
3 or more	0	1.0	2.4	3.4	5.4	6.5	6.8	8.0	**4.8**

Psychotropic prescriptions in people with Autism Spectrum Disorders

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Number of psychotropics	0-9 years (%)	10-14 (%)	15-19 (%)	20-24 (%)	25-34 (%)	35-44 (%)	44-54 (%)	55-64 (%)	Total (%)
0	86.8	68.4	65.0	63.7	57.9	48.1	45.4	46.2	**68.9**
1	10.2	21.0	22.3	21.6	23.6	25.8	26.5	23.8	**19.2**
2	2.6	8.7	9.0	9.8	11.8	15.7	17.3	20.2	**8.3**
3 or more	0.4	1.8	3.7	4.9	6.8	10.4	8.2	9.8	**3.5**

Psychotropic prescriptions in people with Psychosocial Disability

Number of psychotropics	0-14 years (%)	15-19 (%)	20-24 (%)	25-34 (%)	35-44 (%)	45-54 (%)	55-64 (%)	Total (%)
0	80.1	41.9	34.1	26.7	23.0	24.0	27.0	**26.8**
1	15.2	30.3	30.4	29.3	28.9	30.9	33.6	**30.4**
2	4.7	15.8	19.0	21.9	22.9	22.9	21.3	**21.7**
3 or more	0	12.0	16.4	22.0	25.2	22.2	18.1	**21.1**

Use of Mental Health Services

Did people supplied psychotropics in 2016-17 access MBS-funded **mental health services*** in that year?

Number different psychotropics	Accessed 1 or more mental health services (%)	Did not access any mental health services (%)
1	42.5	57.5
2	54.8	45.2
3 or more	67.5	32.5
Overall	*48.9*	*51.1*

* Includes GP-related, psychiatry, psychology or other allied health-related mental health services

PBS data - mid 2016 to mid 2017; MBS data - mid 2016 to end 2017

Home Medicines Reviews

Did people supplied psychotropics in 2016-17 access an MBS-funded **Home Medicines Review*** in that year?

Number different psychotropics	Accessed Home Medicines Review (%)	Did not access Home Medicines Review (%)
1	1.4	98.6
2	2.0	98.0
3 or more	2.3	97.7
Overall	*1.7*	*98.3*

* Includes medication review for people with disability who were permanent residents of aged care facilities

Key findings

- 38% of people using disability services in 2016-17 were supplied at least one psychotropic
  - Rates were highest for those with psychosocial disability (72%)
  - People with intellectual disability and autism had rates of 30% and 28% respectively
- Antidepressants were more commonly supplied (28%) than antipsychotics (14%) and benzodiazepines (12%)
- Supply of psychotropics increased with age until ~35-44 years
  - Marked increase in antipsychotics supply from ages 5-9 years (4%) to 10-14 years (12%)
- Only 49% accessed mental health services
- There were VERY low rates of Home Medicines Review (<2%)

Limitations

- PBS data does not include private prescriptions, medicines supplied in NSW/ACT hospitals, or prisoners and young people in detention
- MBS data does not include private mental health services
- No data on mental health diagnoses, however *use of MBS-subsidised mental health items* was available

Implications

These data can help us:

1. Monitor the rates of use of psychotropics in people with disability;
2. Identify strategies that can help reduce the inappropriate use of psychotropics;
3. Evaluate the effectiveness of regulatory, policy and practice activities aimed in reducing inappropriate psychotropic use;
4. Identify potential gaps in the reporting of chemical restraint.

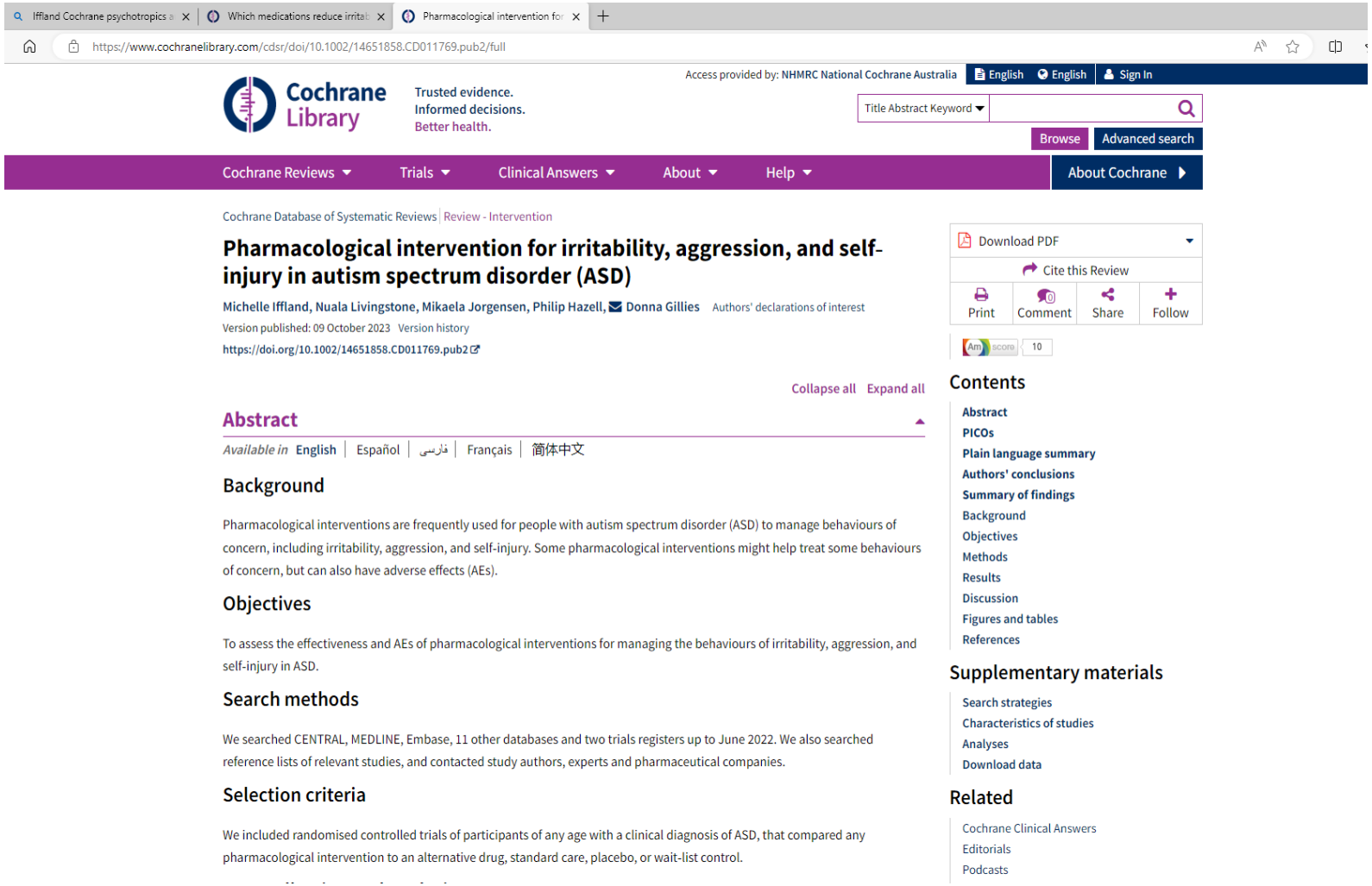
Next steps

- Patterns of prescribing over the entire ten year cohort – is it increasing?
- Identify rates of adverse effects associated with psychotropic use i.e. cardiovascular and diabetes amongst people with disability
- Potentially avoidable hospitalisations

A COCHRANE REVIEW

Pharmacological interventions for irritability, aggression, and self-injury in Autism Spectrum Disorders (ASD)

Which medications reduce irritability, aggression or self-harm in people with ASD?



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Pharmacological intervention for irritability, aggression, and self-injury in autism spectrum disorder (ASD)

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Abstract

Available in English | Español | فارسی | Français | 简体中文

Background

Pharmacological interventions are frequently used for people with autism spectrum disorder (ASD) to manage behaviours of concern, including irritability, aggression, and self-injury. Some pharmacological interventions might help treat some behaviours of concern, but can also have adverse effects (AEs).

Objectives

To assess the effectiveness and AEs of pharmacological interventions for managing the behaviours of irritability, aggression, and self-injury in ASD.

Search methods

We searched CENTRAL, MEDLINE, Embase, 11 other databases and two trials registers up to June 2022. We also searched reference lists of relevant studies, and contacted study authors, experts and pharmaceutical companies.

Selection criteria

We included randomised controlled trials of participants of any age with a clinical diagnosis of ASD, that compared any pharmacological intervention to an alternative drug, standard care, placebo, or wait-list control.

Contents

- Abstract
- PICOs
- Plain language summary
- Authors' conclusions
- Summary of findings
- Background
- Objectives
- Methods
- Results
- Discussion
- Figures and tables
- References

Supplementary materials

- Search strategies
- Characteristics of studies
- Analyses
- Download data

Related

- Cochrane Clinical Answers
- Editorials
- Podcasts

Objective

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To assess the effectiveness and adverse effects of pharmacological interventions for the management of challenging behaviours (i.e. irritability, aggression, and self-injury) in people with ASD.

Inclusion criteria

Studies

- Randomised controlled trials (RCTs) (including crossover studies) that compare pharmacological interventions to an alternative drug, standard care, placebo, or wait-list control.

Participants

- People of any age with a diagnosis of autism spectrum disorder (ASD). People with reported comorbidities were included in the analysis.
- Study participants diagnosed using Diagnostic and Statistical Manual for Mental Disorders (DSM) or International Classification of Diseases (ICD) criteria, or a validated diagnostic instrument.

Types of interventions

- Any pharmacological intervention used to manage behaviours of concern
- Any dosage, duration, or frequency of administration
- Included first generation "typical" antipsychotics such as haloperidol
- second generation "atypical" antipsychotics such as risperidone and aripiprazole
- antidepressants - including selective serotonin re-uptake inhibitors (SSRIs) and tricyclics
- ADHD-related medications – stimulant and non-stimulant
- Also - anticonvulsants, antidementia medications, antiparkinsonian medication, anxiolytics, neurohormones
- Other drugs that did not fall into any of these classes and we grouped as experimental

Outcomes

Primary

- Irritability
- Aggression
- self-injury

Secondary

- Quality of life
- Tolerability/acceptability
- Adverse effects

Follow-up periods

- short term (less than six months);
- medium term (6 to 12 months);
- long term (over 12 months)

Searches

- CENTRAL, MEDLINE, Embase, 11 other databases and two trials registers
- Searched up to June 2022
- Reference lists of relevant studies, and contacted study authors, experts and pharmaceutical companies.

Data extraction and synthesis

- Two authors independently selected and assessed every study to determine whether they meet the inclusion criteria.
- Any disagreements between the authors was resolved through discussion with the full review group.
- Two independently assessed the seven risk of bias domains for each study.

Data synthesis

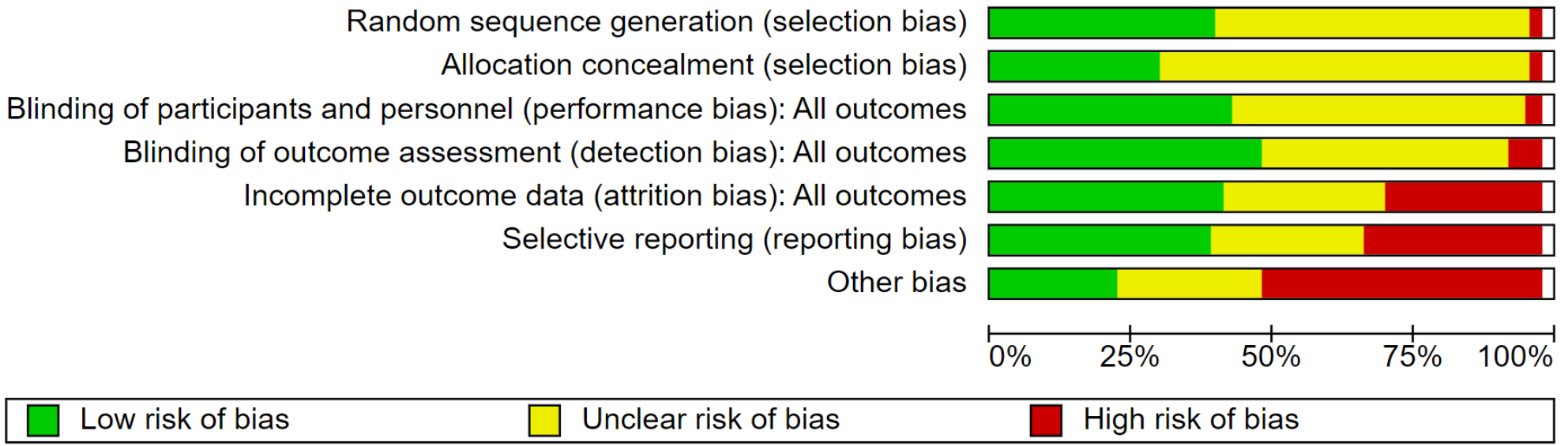
Continuous data

- We calculated standardised mean differences (SMDs) with 95% confidence intervals (CIs) for continuous outcome data (e.g. scores on standardised measures).

Dichotomous data

- Calculated effect sizes as odds ratios (ORs) with 95% CIs for dichotomous outcome data (e.g. adherence).

Risk of Bias Graph



Results

- We included 132 studies (266 reports and 136 datasets) involving 7103 participants.
- Participants were:
  - Children (under 13 years, 52 studies)
  - Children and adolescents (37 studies)
  - Adolescents only (two studies
  - Children and adults (17 studies)
  - Adults (23 studies)

Pharmacological interventions

1. Atypical and typical antipsychotics
2. Antidepressants
3. ADHD-related medications
4. Anticonvulsants
5. Neurohormones
6. Dementia-related medications
7. Antiparkinsonian medications
8. Anxiolytics
9. Experimental drugs

Only two classes of drugs showed any reduction in behaviours of concern i.e.

Antipsychotics and **ADHD-related drugs**

Atypical antipsychotics – meta-analysis

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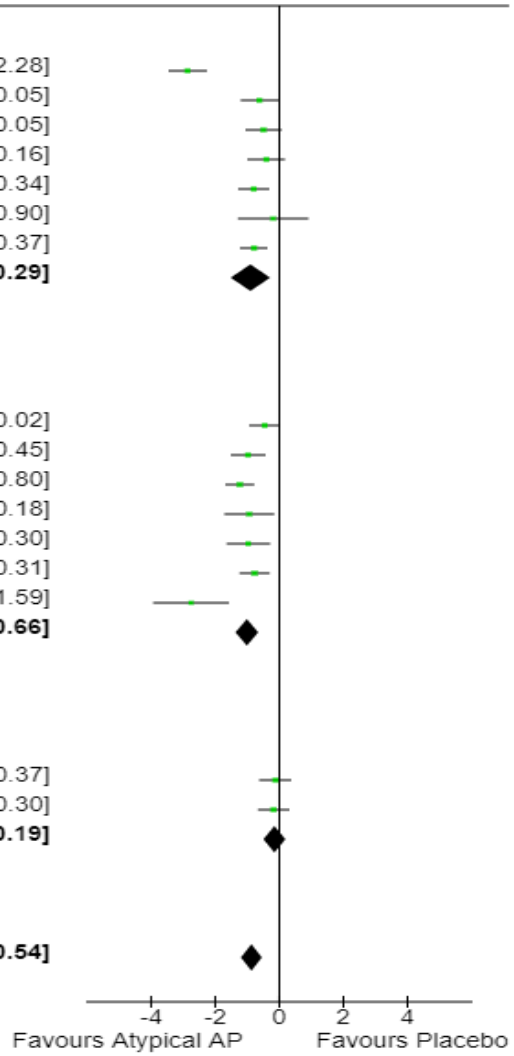
Study or Subgroup	Atypical antipsychotic Mean	SD	Total	Placebo Mean	SD	Total	Weight	Std. mean difference IV, Random, 95% CI
2.1.1 Aripiprazole vs placebo								
Ichikawa 2017	-11.4	1.3	47	-7.5	1.4	45	6.3%	-2.87 [-3.45 , -2.28]
Marcus 2009 (1)	-14.4	9.54	53	-8.4	9.73	16	6.4%	-0.62 [-1.19 , -0.05]
Marcus 2009 (2)	-13.2	9.6	59	-8.4	9.73	17	6.5%	-0.49 [-1.04 , 0.05]
Marcus 2009 (3)	-12.4	9.81	52	-8.4	9.73	16	6.4%	-0.40 [-0.97 , 0.16]
NCT00198107	18.6	8.52	38	25.5	8.6	40	6.9%	-0.80 [-1.26 , -0.34]
NCT00468130	6.83	6.87	7	8.67	10.69	6	4.2%	-0.19 [-1.29 , 0.90]
Owen 2009	-12.9	9.77	46	-5	10.11	50	7.0%	-0.79 [-1.20 , -0.37]
Subtotal (95% CI)			**302**			**190**	**43.8%**	**-0.90 [-1.52 , -0.29]**
Heterogeneity: Tau² = 0.59; Chi² = 50.95, df = 6 (P < 0.00001); I² = 88%								
Test for overall effect: Z = 2.87 (P = 0.004)								
2.1.2 Risperidone vs placebo								
Hellings 2006a	13.31	8.92	36	18.23	12.36	33	6.8%	-0.45 [-0.93 , 0.02]
Kent 2013	-12.4	6.52	29	-3.5	10.67	34	6.6%	-0.98 [-1.50 , -0.45]
McCracken 2002	11.3	7.4	49	21.9	9.5	51	7.0%	-1.23 [-1.66 , -0.80]
McDougle 1998a	0.35	0.37	14	0.82	0.57	16	5.6%	-0.94 [-1.70 , -0.18]
NCT01624675	-9.7	7.29	21	-2.8	6.62	18	6.0%	-0.97 [-1.64 , -0.30]
Shea 2004	-12.1	5.8	39	-6.5	8.4	38	6.9%	-0.77 [-1.23 , -0.31]
Troost 2005	1.5	1.7	12	7.6	2.5	12	3.9%	-2.76 [-3.92 , -1.59]
Subtotal (95% CI)			**200**			**202**	**42.7%**	**-1.01 [-1.37 , -0.66]**
Heterogeneity: Tau² = 0.13; Chi² = 15.52, df = 6 (P = 0.02); I² = 61%								
Test for overall effect: Z = 5.59 (P < 0.00001)								
2.1.3 Lurasidone vs Placebo								
Loebel 2016 (4)	-8.8	10.39	48	-7.5	10.64	24	6.7%	-0.12 [-0.61 , 0.37]
Loebel 2016 (5)	-9.4	10.21	51	-7.5	10.64	25	6.8%	-0.18 [-0.66 , 0.30]
Subtotal (95% CI)			**99**			**49**	**13.5%**	**-0.15 [-0.50 , 0.19]**
Heterogeneity: Tau² = 0.00; Chi² = 0.03, df = 1 (P = 0.87); I² = 0%								
Test for overall effect: Z = 0.87 (P = 0.38)								
Total (95% CI)			**601**			**441**	**100.0%**	**-0.87 [-1.20 , -0.54]**
Heterogeneity: Tau² = 0.35; Chi² = 83.16, df = 15 (P < 0.00001); I² = 82%								
Test for overall effect: Z = 5.23 (P < 0.00001)								
Test for subgroup differences: Chi² = 12.61, df = 2 (P = 0.002), I² = 84.1%								



Atypical antipsychotics – effects on behaviours of concern

OUTCOMES	Risk with antipsychotic	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
Irritability *Short term (up to six months)*	SMD 0.90 lower (95% CI 1.25 lower to 0.55 lower)	973 (12 studies: risperidone 6 studies; aripiprazole 5 studies; lurasidone 1 study)	⨁⨁⨁⨀ Moderate	An SMD of 0.90 may represent a large effect
Aggression *Short term*	SMD 0.44 lower (95% CI 0.89 lower to 0.01 higher)	77 (1 study, risperidone)	⨁⨀⨀⨀ Very low	An SMD of 0.44 may represent a moderate effect
Self-injurious behaviour *Short term*	SMD 1.43 lower (95% CI 2.24 lower to 0.61 lower)	30 (1 study, risperidone)	⨁⨁⨀⨀ Low	An SMD of 1.43 may represent a large effect

Atypical antipsychotics – adverse effects (AEs)

Neurological (974 participants, 11 studies)

Low quality evidence of an increase in the neurological adverse effects (AEs):

- dizziness, fatigue, sedation, somnolence, tremor.

Metabolic (930 participants, 10 studies)

Low quality evidence of an increase in the metabolic adverse effects (AEs):

- increased appetite.

ADHD medicines – effects on behaviours of concern

OUTCOMES	Risk with ADHD-related drugs	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
Irritability *Short term*	SMD 0.20 lower (95% CI 0.40 lower to 0.01 lower)	400 (10 studies: methylphenidate 2 studies; clonidine 2 studies; guanfacine 2 studies; atomoxetine 4 studies)	⨁⊖⊖ Low	An SMD of 0.20 may represent a small effect size
Aggression *Short term*	No data were reported for this outcome			
Self-injurious behaviour *Short term*	No evidence of an effect	16 participants (1 study)		

ADHD medicines - adverse effects

Neurological (511 participants, 9 studies)

Low quality evidence of an increase in the neurological adverse effects:

- drowsiness, emotional responsiveness, fatigue, headache and insomnia.

Psychological (252 participants, 5 studies)

Very low evidence quality evidence of an increase in the psychological adverse effects:

- depression

Metabolic (511 participants, 9 studies)

Very low evidence quality evidence of an increase in the metabolic adverse effects :

- decreased appetite.

Atypical antipsychotics- Summary

Behaviours of Concern

- Moderate level evidence that antipsychotics significantly reduce irritability
- Low level evidence that antipsychotics significantly reduce aggression, and self-injury

Adverse effects

- Sedation, fatigue, tremor, and dizziness
- Increased appetite

in the short-term

ADHD medicines - Summary

Behaviours of Concern

- Low level evidence that ADHD-related medicines decreased irritability.
- This was most likely related to stimulants.
- There was no evidence to make conclusions about aggression or self-injury.

Adverse effects

- Emotion, fatigue and insomnia
- Decreased appetite

in the short-term

Summary

- This large review included 15 major comparisons with data from 121 studies
- Of nine major classes of drugs, only two classes showed any reduction in behaviours of concern: Antipsychotics and ADHD-related drugs
- These were also associated with a number of adverse effects
- Most data were short-term up to 6 months but most commonly 3 months or less
- Most study participants were children, few were adults

Accessible Information on Psychotropic Medication for Australian Disability and Aged Care Settings

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- This project aims to build co-designed accessible information for all people in disability and aged care settings
- It will provide easy-to-read medication leaflets that can support informed decision-making and medication review.
- To ensure it is fit for purpose we will consult with stakeholders in disability and aged care settings, with a particular focus on useability.